

**Header Text:** C4591001

**Visit:** COHORT\_SELECTION

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

**Site No:** 1231

**Subject No:** 12312125

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

**Form:** COHORT\_SELECTION

**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](#)

**Cohort Selection**

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

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

**Header Text:** C4591001

**Visit:** COHORT\_SELECTION

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

**Site No:** 1231

**Subject No:** 12312125

**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

[eCRF Audit Trail History](#)

**Informed Consent**

1.	Consent Was:	OBTAINED Date Written Consent Obtained Aug/18/2020
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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:** 12312125

**Subject Initials:** ---

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

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

[eCRF Audit Trail History](#)

**Demography**

1.	Subject ID	[12312125]
2.	Birth Date:	(b) (6)/1971
3.	Sex:	MALE
4.	Ethnicity:	HISPANIC OR LATINO(A) OR OF SPANISH ORIGIN
5.	Race: (Check X all that apply):	WHITE
6.	Racial Designation:	

090177e196ae2e5a\Final\Final On: 01-Apr-2021 03:10 (GMT)

**Header Text:** C4591001

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

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

**Site No:** 1231

**Subject No:** 12312125

**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/18/2020
2.	Erroneous Visit	

**Header Text:** C4591001

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

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

**Site No:** 1231

**Subject No:** 12312125

**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
1.c	Inclusion Number:	3
	Criterion Description:	Healthy participants who are determined by medical history, physical examination, and clinical judgment of the investigator to be eligible for inclusion in the study
	Criterion met?	YES
	Criterion ID: (For Pfizer use only)	IN03A00
1.d	Inclusion Number:	4
	Criterion Description:	Capable of giving personal signed informed consent, which includes compliance with the requirements and restrictions listed in the ICD and in this protocol
	Criterion met?	YES
	Criterion ID: (For Pfizer use only)	IN04A00

**Exclusion Criteria**

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

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**Header Text:** C4591001

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

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

**Site No:** 1231

**Subject No:** 12312125

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

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**Header Text:** C4591001

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

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

**Site No:** 1231

**Subject No:** 12312125

**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 h	Exclusion Number:	12
	Criterion Description:	Previous vaccination with any coronavirus vaccine
	Criterion met?	NO
	Criterion ID: (For Pfizer use only)	EX12A00
2.i	Exclusion Number:	13
	Criterion Description:	Subjects who receive immunosuppressive therapy, such as cytotoxic agents or systemic corticosteroids
	Criterion met?	NO
	Criterion ID: (For Pfizer use only)	EX13A01
2.j	Exclusion Number:	15
	Criterion Description:	Receipt of blood/plasma products or immunoglobulin, from 60 days before study intervention administration or planned receipt throughout the study
	Criterion met?	NO
	Criterion ID: (For Pfizer use only)	EX14A01
2 k	Exclusion Number:	16
	Criterion Description:	Participation in other studies involving study intervention within 28 days prior to study entry and/or during study participation
	Criterion met?	NO
	Criterion ID: (For Pfizer use only)	EX15A01
2.l	Exclusion Number:	17
	Criterion Description:	Previous participation in other studies involving study intervention containing lipid nanoparticles
	Criterion met?	NO
	Criterion ID: (For Pfizer use only)	EX16A01
2 m	Exclusion Number:	22
	Criterion Description:	Investigator site staff or Pfizer employees directly involved in the conduct of the study, site staff otherwise supervised by the investigator, and their respective family members
	Criterion met?	NO
	Criterion ID: (For Pfizer use only)	EX21A01

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**Header Text:** C4591001

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

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

**Site No:** 1231

**Subject No:** 12312125

**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/18/2020
2.	Phase of Disposition:	SCREENING
3.	Status:	COMPLETED
4.	Specify Status:	[ ]



**Header Text:** C4591001

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

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

**Site No:** 1231

**Subject No:** 12312125

**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

[Form Comments](#)

**Medical History Details**

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

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**Header Text:** C4591001

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

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

**Site No:** 1231

**Subject No:** 12312125

**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/18/2020
2.	Weight:	[98.0]
3.	Unit:	kg
4.	Height:	[190.0]
5.	Unit:	cm
6.	Body Mass Index:	[27.1]

**Vital Signs Details**

7.a	Record Identifier:	1
	Temperature:	[36.5]
	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:** 12312125

**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/18/2020
2.	Randomization Number:	[55410]
3.	Randomization Group:	[ ]

**Header Text:** C4591001

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

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

**Site No:** 1231

**Subject No:** 12312125

**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/18/2020
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	[BHWTTV]
5.b	Sample ID	[BHWTTW]
5.c	Sample ID	[BHWTTX]
5.d	Sample ID	[BLCV9N]
5.e	Sample ID	[BLCV9P]
5.f	Sample ID	[BLCV9R]

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**Header Text:** C4591001

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

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

**Site No:** 1231

**Subject No:** 12312125

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

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

**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	NASAL_SWAB
3.	Sample Collected?	YES Date of Collection: Aug/18/2020
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	[BHWTRK]
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090177e196ae2e5a\Final\Final On: 01-Apr-2021 03:10 (GMT)

**Header Text:** C4591001

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

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

**Site No:** 1231

**Subject No:** 12312125

**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/18/2020 19:42
5.	Anatomical Location:	DELTOID MUSCLE
6.	Body Side:	LEFT
7.	Route:	INTRAMUSCULAR
8.	Actual Dose:	[ ]
9.	Unit:	
10.	Timeframe Subject Was Observed	THE PROTOCOL SPECIFIED OBSERVATION PERIOD
11.	Was the subject observed for at least the protocol specified observation period after investigational product administration?	YES

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**Header Text:** C4591001

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

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

**Site No:** 1231

**Subject No:** 12312125

**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	NO - REACTOGENICITY E-DIARY NOT COLLECTED FOR THIS SUBJECT
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**Header Text:** C4591001

**Visit:** V2\_VAX2\_L

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

**Site No:** 1231

**Subject No:** 12312125

**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	Sep/7/2020
2.	Erroneous Visit	



**Header Text:** C4591001

**Visit:** V2\_VAX2\_L

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

**Site No:** 1231

**Subject No:** 12312125

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

**Form:** VITAL SIGNS - TEMP

**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:	Sep/7/2020
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**Vital Signs Details**

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

**Header Text:** C4591001

**Visit:** V2\_VAX2\_L

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

**Site No:** 1231

**Subject No:** 12312125

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

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

**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	NASAL_SWAB
3.	Sample Collected?	YES Date of Collection: Sep/7/2020
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	[BP1TG4]
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**Header Text:** C4591001

**Visit:** V2\_VAX2\_L

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

**Site No:** 1231

**Subject No:** 12312125

**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/7/2020 10:50
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:** 12312125

**Subject Initials:** ---

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

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

[eCRF Audit Trail History](#)

**Date of Visit**

1.	Date of Visit	Oct/7/2020
2.	Erroneous Visit	

**Header Text:** C4591001

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

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

**Site No:** 1231

**Subject No:** 12312125

**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: Oct/7/2020
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	[BLDZ7D]
5.b	Sample ID	[BLDZ6H]
5.c	Sample ID	[BPW7GV]

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**Header Text:** C4591001

**Visit:** V4\_MONTH6\_L

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

**Site No:** 1231

**Subject No:** 12312125

**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/1/2021
2.	Erroneous Visit	

**Header Text:** C4591001

**Visit:** V4\_MONTH6\_L

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

**Site No:** 1231

**Subject No:** 12312125

**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: Mar/1/2021
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	[BLBWVF]
5.b	Sample ID	[BLBWT3]
5.c	Sample ID	[BR2007]

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**Header Text:** C4591001

**Visit:** V5\_MONTH12\_L

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

**Site No:** 1231

**Subject No:** 12312125

**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:** 12312125

**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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090177e196ae2e5a\Final\Final On: 01-Apr-2021 03:10 (GMT)

**Header Text:** C4591001

**Visit:** V6\_MONTH24\_L

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

**Site No:** 1231

**Subject No:** 12312125

**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:** 12312125

**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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090177e196ae2e5a\Final\Final On: 01-Apr-2021 03:10 (GMT)

**Header Text:** C4591001

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

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

**Form Status:** Not Started

**Site No:** 1231

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

**Subject No:** 12312125

**Subject Initials:** ---

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

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

**Date of Visit**

1.	Date of Visit	//
2.	Erroneous Visit	

**COVID-19 Illness Visit**

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

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

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

**Form Status:** Not Started

**Site No:** 1231

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

**Subject No:** 12312125

**Subject Initials:** ---

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

**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:	[ ]
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090177e196ae2e5a\Final\Final On: 01-Apr-2021 03:10 (GMT)

**Header Text:** C4591001

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

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

**Form Status:** Not Started

**Site No:** 1231

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

**Subject No:** 12312125

**Subject Initials:** ---

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

**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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090177e196ae2e5a\Final\Final On: 01-Apr-2021 03:10 (GMT)

**Header Text:** C4591001

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

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

**Form Status:** Not Started

**Site No:** 1231

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

**Subject No:** 12312125

**Subject Initials:** ---

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

**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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090177e196ae2e5a\Final\Final On: 01-Apr-2021 03:10 (GMT)

**Header Text:** C4591001

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

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

**Form Status:** Not Started

**Site No:** 1231

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

**Subject No:** 12312125

**Subject Initials:** ---

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

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

**Health Care Utilization**

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

**Health Care Utilization Other**

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

**Health Care Utilization**

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



**Header Text:** C4591001

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

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

**Form Status:** Not Started

**Site No:** 1231

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

**Subject No:** 12312125

**Subject Initials:** ---

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

**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:	

090177e196ae2e5a\Final\Final On: 01-Apr-2021 03:10 (GMT)

**Header Text:** C4591001

**Visit:** POT\_COVID\_CONVA - New Unscheduled Visit      **Form:** DATE OF VISIT - ILLNESS CONVALESCENT

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

**Form Status:** Not Started

**Site No:** 1231

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

**Subject No:** 12312125

**Subject Initials:** ---

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

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

**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:** 12312125

**Subject Initials:** ---

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

**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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090177e196ae2e5a\Final\Final On: 01-Apr-2021 03:10 (GMT)

**Header Text:** C4591001

**Visit:** Unplanned - New Unscheduled Visit

**Form:** DATE OF VISIT

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

**Form Status:** Not Started

**Site No:** 1231

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

**Subject No:** 12312125

**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:** 12312125

**Subject Initials:** ---

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

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

**Unplanned Assessments**

1.	Assessments	
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**Header Text:** C4591001

**Visit:** End of Treatment - Unscheduled

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

**Site No:** 1231

**Subject No:** 12312125

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

**Form:** DISPOSITION - TREATMENT

**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 - Treatment**

1.	Date of Completion/Discontinuation /Death :	Oct/7/2020
2.	Phase of Disposition:	VACCINATION
3.	Status:	COMPLETED
4.	Specify Status:	[ ]

**Header Text:** C4591001

**Visit:** Follow-Up - Unscheduled

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

**Site No:** 1231

**Subject No:** 12312125

**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 - New  
Unscheduled Visit

**Form:** DATE OF VISIT - 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:** 12312125

**Subject Initials:** ---

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

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

**Date of Visit**

1.	Date of Visit	//
2.	Erroneous Visit	

**COVID-19 Repeat Swab**

3.	COVID-19 Repeat Swab:	
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**Header Text:** C4591001

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

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

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

**Form Status:** Not Started

**Site No:** 1231

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

**Subject No:** 12312125

**Subject Initials:** ---

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

**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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090177e196ae2e5a\Final\Final On: 01-Apr-2021 03:10 (GMT)

**Header Text:** C4591001

**Visit:** Unplanned Vaccination - Unscheduled

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

**Site No:** 1231

**Subject No:** 12312125

**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:** 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:** 12312125

**Subject Initials:** ---

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

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

**Vital Signs**

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

**Vital Signs Details**

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

090177e196ae2e5a\Final\Final On: 01-Apr-2021 03:10 (GMT)

**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:** 12312125

**Subject Initials:** ---

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

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

**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?	

090177e196ae2e5a\Final\Final On: 01-Apr-2021 03:10 (GMT)

**Header Text:** C4591001

**Visit:** Unplanned Vaccination - Unscheduled

**Form:** CONTACT OUTCOME - MONTH 1

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

**Form Status:** Not Started

**Site No:** 1231

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

**Subject No:** 12312125

**Subject Initials:** ---

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

**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:** CONTACT OUTCOME - MONTH 6

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

**Form Status:** Not Started

**Site No:** 1231

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

**Subject No:** 12312125

**Subject Initials:** ---

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

**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 - 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:** 12312125

**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:** 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:** 12312125

**Subject Initials:** ---

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

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

**Informed Consent - Asymptomatic Surveillance**

1.	Consent Was:	
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**Header Text:** C4591001

**Visit:** V201\_SURVEIL\_CONSENT - Unscheduled **Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

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

**Form Status:** Not Started

**Site No:** 1231

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

**Subject No:** 12312125

**Subject Initials:** ---

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

**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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090177e196ae2e5a\Final\Final On: 01-Apr-2021 03:10 (GMT)

**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:** 12312125

**Subject Initials:** ---

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

**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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090177e196ae2e5a\Final\Final On: 01-Apr-2021 03:10 (GMT)

**Header Text:** C4591001

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

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

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

**Site No:** 1231

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

**Subject No:** 12312125

**Subject Initials:** ---

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

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

[eCRF Audit Trail History](#)

**Date of Visit**

1.	Date of Visit	Feb/24/2021
2.	Erroneous Visit	

**Header Text:** C4591001

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

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

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

**Site No:** 1231

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

**Subject No:** 12312125

**Subject Initials:** ---

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

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

[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: 12312125

Subject Initials: ---

Generated By: (b) (4)

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

#	Category	AE Identifier	Adverse Event	Start Date	Is the Adverse Event Still Ongoing	Form Instance
1.	ADVERSE EVENT	1	Peritonitis	Jan/6/2021 22:00	NO End Date Time: Feb/11/2021 19:00	<a href="#">Repeating Pages</a>
2.	ADVERSE EVENT	2	Acute appendicitis	Jan/6/2021 22:00	NO End Date Time: Feb/11/2021 19:00	<a href="#">Repeating Pages</a>
3.	ADVERSE EVENT	3	Acute Paroxysmal Atrial Fibrillation with High Ventricular Response.	Jan/11/2021 12:00	NO End Date Time: Jan/15/2021 10:00	<a href="#">Repeating Pages</a>

090177e196ae2e5a\Final\Final On: 01-Apr-2021 03:10 (GMT)

Header Text: C4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1231

Subject No: 12312125

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

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[Form Audit Trail](#)

**Adverse Event Report**

1.	Category:	ADVERSE EVENT
2.	AE ID:	[1]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[Peritonitis]
4.	Start Date Time:	Jan/6/2021 22:00
5.	Is the adverse event still ongoing?	NO End Date Time: Feb/11/2021 19:00
6.	Toxicity Grade:	3
7.	Is the adverse event serious?  If Yes, NOTIFY PFIZER IMMEDIATELY.  Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).	YES  Is this serious event associated with congenital anomaly or birth defect? NO  Did this serious event result in death? NO  Did this serious event require or prolong hospitalization? YES  Did this serious event result in persistent or significant disability/incapacity? NO  Is this serious event life threatening? NO  Other medically important serious event YES
8.	Is this adverse event the result of a study Medication Error? If Yes, record the type of medication error on the Medication Error Log.	NO
9.	Is this event related to study treatment:	NOT RELATED If Not Related to study treatment(s), this event is due to: OTHER If Other, specify: [unknown]

090177e196ae2e5a\Final\Final On: 01-Apr-2021 03:10 (GMT)

**Header Text:** C4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1231

**Subject No:** 12312125

**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

10.	Latest Action Taken with Study Treatment:	NOT APPLICABLE
11.	Was a Concomitant Medication given?	YES
12.	Was a Non-Drug Treatment given?	YES
13.	What was the outcome of this adverse event?:	RECOVERED/RESOLVED
14.	Did the adverse event cause the subject to be discontinued from the study?	NO
15.	Serious Adverse Event Number: For Pfizer Use Only	[2021024519]

090177e196ae2e5a\Final\Final On: 01-Apr-2021 03:10 (GMT)

**Header Text:** C4591001**Visit:** Logs - Unscheduled**Form Version:** 22-Apr-2020 21:02**Site No:** 1231**Subject No:** 12312125**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

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**Adverse Event Report**

1.	Category:	ADVERSE EVENT
2.	AE ID:	[2]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[Acute appendicitis]
4.	Start Date Time:	Jan/6/2021 22:00
5.	Is the adverse event still ongoing?	NO End Date Time: Feb/11/2021 19:00
6.	Toxicity Grade:	3
7.	Is the adverse event serious?  If Yes, NOTIFY PFIZER IMMEDIATELY.  Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).	YES  Is this serious event associated with congenital anomaly or birth defect? NO  Did this serious event result in death? NO  Did this serious event require or prolong hospitalization? YES  Did this serious event result in persistent or significant disability/incapacity? NO  Is this serious event life threatening? NO  Other medically important serious event YES
8.	Is this adverse event the result of a study Medication Error? If Yes, record the type of medication error on the Medication Error Log.	NO
9.	Is this event related to study treatment:	NOT RELATED If Not Related to study treatment(s), this event is due to: OTHER If Other, specify: [unknown]



**Header Text:** C4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1231

**Subject No:** 12312125

**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

10.	Latest Action Taken with Study Treatment:	NOT APPLICABLE
11.	Was a Concomitant Medication given?	YES
12.	Was a Non-Drug Treatment given?	YES
13.	What was the outcome of this adverse event?:	RECOVERED/RESOLVED
14.	Did the adverse event cause the subject to be discontinued from the study?	NO
15.	Serious Adverse Event Number: For Pfizer Use Only	[2021024519]

090177e196ae2e5a\Final\Final On: 01-Apr-2021 03:10 (GMT)

**Header Text:** C4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1231

**Subject No:** 12312125

**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

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[Form Audit Trail](#)

**Adverse Event Report**

1.	Category:	ADVERSE EVENT
2.	AE ID:	[3]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[Acute Paroxysmal Atrial Fibrillation with High Ventricular Response.]
4.	Start Date Time:	Jan/11/2021 12:00
5.	Is the adverse event still ongoing?	NO End Date Time: Jan/15/2021 10:00
6.	Toxicity Grade:	1
7.	Is the adverse event serious?  If Yes, NOTIFY PFIZER IMMEDIATELY.  Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).	NO
8.	Is this adverse event the result of a study Medication Error? If Yes, record the type of medication error on the Medication Error Log.	NO
9.	Is this event related to study treatment:	NOT RELATED If Not Related to study treatment(s), this event is due to: OTHER If Other, specify: [Unknown]
10.	Latest Action Taken with Study Treatment:	NOT APPLICABLE
11.	Was a Concomitant Medication given?	YES

090177e196ae2e5a\Final\Final On: 01-Apr-2021 03:10 (GMT)

**Header Text:** C4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1231

**Subject No:** 12312125

**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

12.	Was a Non-Drug Treatment given?	NO
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	[ ]

090177e196ae2e5a\Final\Final On: 01-Apr-2021 03:10 (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:** 12312125

**Subject Initials:** ---

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

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

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

**Header Text:** C4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1231

**Subject No:** 12312125

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

**Form:** MEDICATION ERROR

**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

[Back to Form](#)

**Medication Error**

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

090177e196ae2e5a\Final\Final On: 01-Apr-2021 03:10 (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:** 12312125

**Subject Initials:** ---

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

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

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

**Header Text:** C4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1231

**Subject No:** 12312125

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

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

**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

[Back to Form](#)

**Concomitant Medications**

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

090177e196ae2e5a\Final\Final On: 01-Apr-2021 03:10 (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:** 12312125

**Subject Initials:** ---

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

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

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



**Header Text:** C4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1231

**Subject No:** 12312125

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

**Form:** CONCOMITANT MEDICATIONS - PROHIBITED

**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

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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?	

090177e196ae2e5a\Final\Final On: 01-Apr-2021 03:10 (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:** 12312125

**Subject Initials:** ---

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

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

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

**Header Text:** C4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1231

**Subject No:** 12312125

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

**Form:** RADIATION TREATMENT

**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

[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?	

090177e196ae2e5a\Final\Final On: 01-Apr-2021 03:10 (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:** 12312125

**Subject Initials:** ---

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

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

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

**Header Text:** C4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1231

**Subject No:** 12312125

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

**Form:** TRANSFUSIONS

**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

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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:** 12312125

**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:** 12312125

**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:** 12312125

**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/24/2021
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:** 12312125

**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 :	//
----	------------------------------	----

090177e196ae2e5a\Final\Final On: 01-Apr-2021 03:10 (GMT)

**Header Text:** C4591001

**Visit:** Disposition - Unscheduled

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

**Site No:** 1231

**Subject No:** 12312125

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

**Site No:** 1231

**Subject No:** 12312125

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

**Form:** SUBJECT STATUS

**Form Status:** Data Complete, 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](#)

**Subject Status**

1.	Subject Status	FOLLOW-UP
2.	Subject Status Date	Oct/7/2020

**Header Text:** C4591001

**Visit:** Investigator Signature - Unscheduled

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

**Site No:** 1231

**Subject No:** 12312125

**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:** 12312125

**Subject Initials:** ---

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

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

[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-22-2021 20:31:25 (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.

090177e196ae2e5a\Final\Final On: 01-Apr-2021 03:10 (GMT)

**Header Text:** C4591001

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

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

**Site No:** 1231

**Subject No:** 12312125

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

**Form:** GENERAL MEDICAL HISTORY - Comments

**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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Item	Date	User	Comment
Form	Aug-19-2020 09:19:44 (UTC-03:00) City of Buenos Aires	(b) (4), (b) (6)	Not Applicable

**Header Text:** C4591001

**Visit:** Investigator Signature - Unscheduled

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

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

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

**Site No:** 1231

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

**Subject No:** 12312125

**Subject Initials:** ---

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

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

[Back to Form](#)

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

- CRF\_Sign

Name	Signature Meaning	Date	Type	Action
(b) (6)	Approved	Mar-22-2021 20:31:25 (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.

(b) (6)	N/A	Mar-22-2021 05:18:57 (UTC-03:00) City of Buenos Aires		Edit - All signatures invalidated
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**Affidavit:**

N/A

Yanina Rivera	Approved	Mar-19-2021 19:21:36 (UTC-03:00) City of Buenos Aires	BOOK	Signed
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**Affidavit:**

By my dated signature below, I, YaninaRivera, 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-19-2021 11:56:58 (UTC-03:00) City of Buenos Aires		Edit - All signatures invalidated
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**Affidavit:**

N/A

Fernando Polack	Approved	Mar-19-2021 11:11:19 (UTC-03:00) City of Buenos Aires	BOOK	Signed
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090177e196ae2e5a\Final\Final On: 01-Apr-2021 03:10 (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:** 12312125

**Subject Initials:** ---

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

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

**Affidavit:**

By my dated signature below, I, FernandoPolack, 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-18-2021 17:31:11 (UTC-03:00) City of Buenos Aires		Edit - All signatures invalidated
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**Affidavit:**

N/A

(b) (6)	Approved	Mar-16-2021 15:54:27 (UTC-03:00) City of Buenos Aires	BOOK	Signed
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**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	Feb-10-2021 19:17:59 (UTC-03:00) City of Buenos Aires		Edit - All signatures invalidated
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**Affidavit:**

N/A

Tatiana Estrada	Approved	Feb-04-2021 21:41:11 (UTC-03:00) City of Buenos Aires	BOOK	Signed
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**Affidavit:**

By my dated signature below, I, TatianaEstrada, 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.

090177e196ae2e5a\Final\Final On: 01-Apr-2021 03:10 (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:** 12312125

**Subject Initials:** ---

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

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

(b) (6)	N/A	Jan-27-2021 10:30:09 (UTC-03:00) City of Buenos Aires		Edit - All signatures invalidated
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**Affidavit:**

N/A

(b) (6)	Approved	Jan-21-2021 23:58:41 (UTC-03:00) City of Buenos Aires	BOOK	Signed
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**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-13-2021 10:38:35 (UTC-03:00) City of Buenos Aires		Edit - All signatures invalidated
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**Affidavit:**

N/A

(b) (6)	Approved	Oct-21-2020 19:23:22 (UTC-03:00) City of Buenos Aires	BOOK	Signed
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**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.

090177e196ae2e5a\Final\Final On: 01-Apr-2021 03:10 (GMT)

**Header Text:** C4591001

**Visit:** COHORT\_SELECTION

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

**Site No:** 1231

**Subject No:** 12312125

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

**Form:** COHORT\_SELECTION - 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. Select appropriate response - Protocol version*

Date	Location	User	Value	Reason
Aug-19-2020 09:17:20 (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-19-2020 09:17:20 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> STAGE 3 COHORTS	Initial Entry

**Header Text:** C4591001

**Visit:** COHORT\_SELECTION

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

**Site No:** 1231

**Subject No:** 12312125

**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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*I. Consent Was:*

Date	Location	User	Value	Reason
Aug-19-2020 09:17:35 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> OBTAINED Date Written Consent Obtained  Aug/18/2020	Initial Entry

Header Text: C4591001

Visit: COHORT\_SELECTION

Form Version: 06-Jul-2020 21:55

Site No: 1231

Subject No: 12312125

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

[Back to Form](#)

**1. Subject ID**

Date	Location	User	Value	Reason
Aug-18-2020 17:47:55 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 12312125	Item copied from previous form

**2. Birth Date:**

Date	Location	User	Value	Reason
Aug-18-2020 17:47:50 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> (b) (6)/1971	Enrollment Entry

**3. Sex:**

Date	Location	User	Value	Reason
Aug-19-2020 09:17:44 (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-19-2020 09:17:44 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> HISPANIC OR LATINO(A) OR OF SPANISH ORIGIN	Initial Entry

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

Date	Location	User	Value	Reason
Aug-19-2020 09:17:44 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> WHITE	Initial Entry

090177e196ae2e5a\Final\Final On: 01-Apr-2021 03:10 (GMT)

**Header Text:** C4591001

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

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

**Site No:** 1231

**Subject No:** 12312125

**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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*I. Date of Visit*

Date	Location	User	Value	Reason
Aug-19-2020 09:18:13 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Aug/18/2020	Initial Entry

Header Text: C4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 30-Jul-2020 21:27

Site No: 1231

Subject No: 12312125

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

[Back to Form](#)

*I.a*

Date	Location	User	Value	Reason
Aug-19-2020 09:18:38 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Inclusion Number:</b> <b>Criteria</b> Male or female participants between the ages of 18 and 55 years, inclusive, 65 and 85 years, inclusive, or 18 and 85 years, inclusive, at randomization (dependent upon study stage) <b>Criteria met?:</b> <b>Criteria ID:</b> (For Pfizer use only):	Initial Entry

*I.a Inclusion Number:*

Date	Location	User	Value	Reason
Aug-19-2020 09:18:38 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 1	Initial Entry

*I.a Criterion Description:*

Date	Location	User	Value	Reason
Aug-19-2020 09:18:38 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Male or female participants between the ages of 18 and 55 years, inclusive, 65 and 85 years, inclusive, or 18 and 85 years, inclusive, at randomization (dependent upon study stage)	Initial Entry

*I.a Criterion met?*

Date	Location	User	Value	Reason
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090177e196ae2e5a\Final\Final On: 01-Apr-2021 03:10 (GMT)

Header Text: C4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 30-Jul-2020 21:27

Site No: 1231

Subject No: 12312125

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

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Aug-19-2020 09:18:38 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry
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*I.a Criterion ID: (For Pfizer use only)*

Date	Location	User	Value	Reason
Aug-19-2020 09:18:38 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> IN01A00	Initial Entry

*I.b*

Date	Location	User	Value	Reason
Aug-19-2020 09:18:38 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Inclusion Number:</b> 2 <b>Criteria on Description:</b> Participants who are willing and able to comply with all scheduled visits, vaccination plan, laboratory tests, lifestyle considerations, and other study procedures <b>Criteria met?:</b> YES <b>Criterion ID: (For Pfizer use only):</b> IN02A00	Initial Entry

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Header Text: C4591001

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Site No: 1231

Subject No: 12312125

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

**I.b Inclusion Number:**

Date	Location	User	Value	Reason
Aug-19-2020 09:18:38 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 2	Initial Entry

**I.b Criterion Description:**

Date	Location	User	Value	Reason
Aug-19-2020 09:18:38 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Participants who are willing and able to comply with all scheduled visits, vaccination plan, laboratory tests, lifestyle considerations, and other study procedures	Initial Entry

**I.b Criterion met?**

Date	Location	User	Value	Reason
Aug-19-2020 09:18:38 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

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

Date	Location	User	Value	Reason
Aug-19-2020 09:18:38 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> IN02A00	Initial Entry

**I.c**

Date	Location	User	Value	Reason
Aug-19-2020 09:18:38 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Inclusion Number: Criteria: Healthy participants who are determined by medical history, physical examination, and clinical judgment of the investigator to be eligible for inclusion in the study	Initial Entry

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Header Text: C4591001

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Site No: 1231

Subject No: 12312125

Generated By: (b) (4)

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Subject Initials: ---

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			Criteri on met ?: Criteri on ID: (For Pf izer use only):	
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**I.c Inclusion Number:**

Date	Location	User	Value	Reason
Aug-19-2020 09:18:38 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> 3	Initial Entry

**I.c Criterion Description:**

Date	Location	User	Value	Reason
Aug-19-2020 09:18:38 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Healthy participants who are determin ed by medical history, physical examin ation, and clinical judgment of the inv estigator to be eligible for inclusion in the study	Initial Entry

**I.c Criterion met?**

Date	Location	User	Value	Reason
Aug-19-2020 09:18:38 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> YES	Initial Entry

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

Date	Location	User	Value	Reason
Aug-19-2020 09:18:38 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> IN03A00	Initial Entry

**I.d**

Date	Location	User	Value	Reason
Aug-19-2020 09:18:38 (UTC-03:00) City of	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Inclusi 4	Initial Entry

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**Header Text:** C4591001

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

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**Site No:** 1231

**Subject No:** 12312125

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

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Buenos Aires		(b) (4), (b) (6)	<p><b>on Number:</b></p> <p><b>Criterion Description:</b> Capable of giving personal signed informed consent, which includes compliance with the requirements and restrictions listed in the ICD and in this protocol</p> <p><b>Criterion met?:</b> YES</p> <p><b>Criterion ID:</b> IN04A00</p> <p><b>For Pfizer use only):</b></p>	
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Header Text: C4591001

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Site No: 1231

Subject No: 12312125

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: ---

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

**1.d Inclusion Number:**

Date	Location	User	Value	Reason
Aug-19-2020 09:18:38 (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-19-2020 09:18:38 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Capable of giving personal signed informed consent, which includes compliance with the requirements and restrictions listed in the ICD and in this protocol	Initial Entry

**1.d Criterion met?**

Date	Location	User	Value	Reason
Aug-19-2020 09:18:38 (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)**

Date	Location	User	Value	Reason
Aug-19-2020 09:18:38 (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-19-2020 09:18:38 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Exclusion Number:</b> <b>Criteria Description:</b> Other medical or psychiatric condition incl. recent (within past year) or active suicidal ideation/behavior/lab abnormality that may increase the risk of study participation	Initial Entry

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Site No: 1231

Subject No: 12312125

Generated By: (b) (4)

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

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

Date	Location	User	Value	Reason
Aug-19-2020 09:18:38 (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-19-2020 09:18:38 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Other medical or psychiatric condition incl. recent (within past year) or active suicidal ideation/behavior/lab abnormality that may increase the risk of study participation	Initial Entry

2.a Criterion met?

Date	Location	User	Value	Reason
Aug-19-2020 09:18:38 (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-19-2020 09:18:38 (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-19-2020 09:18:38	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>	Initial Entry

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Site No: 1231

Subject No: 12312125

Generated By: (b) (4)

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

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(UTC-03:00) City of Buenos Aires		(b) (4), (b) (6)	<b>Exclusion Number:</b> <b>Criterion Description:</b> Known infection with human immunodeficiency virus (HIV), hepatitis C virus (HCV), or hepatitis B virus (HBV) <b>Criterion met?:</b> <b>Criterion ID: (For Pfizer use only):</b> EX02A00	
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2.b Exclusion Number:

Date	Location	User	Value	Reason
Aug-19-2020 09:18:38 (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-19-2020 09:18:38 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Known infection with human immunodeficiency virus (HIV), hepatitis C virus (HCV), or hepatitis B virus (HBV)	Initial Entry

2.b Criterion met?

Date	Location	User	Value	Reason
Aug-19-2020 09:18:38 (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
Aug-19-2020 09:18:38 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> EX02A00	Initial Entry

2.c

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**Header Text:** C4591001

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**Site No:** 1231

**Subject No:** 12312125

**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

Date	Location	User	Value	Reason
Aug-19-2020 09:18:38 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Exclusi 3 on Nu mber: Criteri History of severe adverse rea on Desc ction associated with a vacci ription: ne and/or severe allergic rea ction (eg, anaphylaxis) to an y component of the study int ervention(s) Criteri NO on met ?: Criteri EX03A00 on ID: ( For Pfi zer use only):	Initial Entry

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Site No: 1231

Subject No: 12312125

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

2.c Exclusion Number:

Date	Location	User	Value	Reason
Aug-19-2020 09:18:38 (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-19-2020 09:18:38 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> History of severe adverse reaction associated with a vaccine and/or severe allergic reaction (eg, anaphylaxis) to any component of the study intervention(s)	Initial Entry

2.c Criterion met?

Date	Location	User	Value	Reason
Aug-19-2020 09:18:38 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

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

Date	Location	User	Value	Reason
Aug-19-2020 09:18:38 (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-19-2020 09:18:38 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Exclusion Number: 4 <b>Criterion Description:</b> Receipt of medications 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 No: 1231

Subject No: 12312125

Generated By: (b) (4)

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

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2.d Exclusion Number:

Date	Location	User	Value	Reason
Aug-19-2020 09:18:38 (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-19-2020 09:18:38 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Receipt of medications intended to prevent COVID-19	Initial Entry

2.d Criterion met?

Date	Location	User	Value	Reason
Aug-19-2020 09:18:38 (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-19-2020 09:18:38 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> EX04A00	Initial Entry

2.e

Date	Location	User	Value	Reason
Aug-19-2020 09:18:38 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Exclusion Number: <b>Criterion Description:</b> Immunocompromised individuals with known or suspected immunodeficiency, as determined by history and/or laboratory/physical examination <b>Criterion met?:</b> NO	Initial Entry

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Header Text: C4591001

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Site No: 1231

Subject No: 12312125

Generated By: (b) (4)

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Subject Initials: ---

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			<b>Criterion ID: (For Pfizer use only):</b> EX08A00	
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**2.e Exclusion Number:**

Date	Location	User	Value	Reason
Aug-19-2020 09:18:38 (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-19-2020 09:18:38 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Immunocompromised individuals with known or suspected immunodeficiency, as determined by history and/or laboratory/physical examination	Initial Entry

**2.e Criterion met?**

Date	Location	User	Value	Reason
Aug-19-2020 09:18:38 (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
Aug-19-2020 09:18:38 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> EX08A00	Initial Entry

**2.f**

Date	Location	User	Value	Reason
Aug-19-2020 09:18:38 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Exclusion Number:	Initial Entry

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Site No: 1231

Subject No: 12312125

Generated By: (b) (4)

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

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

			<p><b>Criterion Description:</b> Bleeding diathesis or condition associated with prolonged bleeding that would, in the opinion of the investigator, contraindicate intramuscular injection</p> <p><b>Criterion met?:</b> NO</p> <p><b>Criterion ID: (For Pfizer use only):</b> EX10A00</p>
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2.f Exclusion Number:

Date	Location	User	Value	Reason
Aug-19-2020 09:18:38 (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-19-2020 09:18:38 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Bleeding diathesis or condition associated with prolonged bleeding that would, in the opinion of the investigator, contraindicate intramuscular injection	Initial Entry

2.f Criterion met?

Date	Location	User	Value	Reason
Aug-19-2020 09:18:38 (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
Aug-19-2020 09:18:38 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> EX10A00	Initial Entry

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Header Text: C4591001

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Subject No: 12312125

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Subject Initials: ---

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

Date	Location	User	Value	Reason
Aug-19-2020 09:18:38 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Exclusion Num 11 ber: Criterion Descri Women who are pr ption: egnant or breastfee ding Criterion met?: NO Criterion ID: (F EX11A00 or Pfizer use onl y):	Initial Entry

2.g Exclusion Number:

Date	Location	User	Value	Reason
Aug-19-2020 09:18:38 (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-19-2020 09:18:38 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Women who are pregnant or breastfee ding	Initial Entry

2.g Criterion met?

Date	Location	User	Value	Reason
Aug-19-2020 09:18:38 (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-19-2020 09:18:38 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> EX11A00	Initial Entry

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Date	Location	User	Value	Reason
Aug-19-2020 09:18:38	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>	Initial Entry

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Site No: 1231

Subject No: 12312125

Generated By: (b) (4)

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Subject Initials: ---

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(UTC-03:00) City of Buenos Aires	(b) (4), (b) (6)	Exclusion Number: 12	Criterion Description: Previous vaccination with any coronavirus vaccine	Criterion met? NO	Criterion ID: ( EX12A00 For Pfizer use only):
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2.h Exclusion Number:

Date	Location	User	Value	Reason
Aug-19-2020 09:18:38 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 12	Initial Entry

2.h Criterion Description:

Date	Location	User	Value	Reason
Aug-19-2020 09:18:38 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Previous vaccination with any coronavirus vaccine	Initial Entry

2.h Criterion met?

Date	Location	User	Value	Reason
Aug-19-2020 09:18:38 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

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

Date	Location	User	Value	Reason
Aug-19-2020 09:18:38 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: EX12A00	Initial Entry

2.i

Date	Location	User	Value	Reason
Aug-19-2020 09:18:38 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Exclusion Number: 13	Initial Entry

090177e196ae2e5a\Final\Final On: 01-Apr-2021 03:10 (GMT)

Header Text: C4591001

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Form Version: 30-Jul-2020 21:27

Site No: 1231

Subject No: 12312125

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>Criterion Description:</b> Subjects who receive immunosuppressive therapy, such as cytotoxic agents or systemic corticosteroids  <b>Criterion met?:</b> NO  <b>Criterion ID: (For Pfizer use only):</b> EX13A01	
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**2.i Exclusion Number:**

Date	Location	User	Value	Reason
Aug-19-2020 09:18:38 (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-19-2020 09:18:38 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Subjects who receive immunosuppressive therapy, such as cytotoxic agents or systemic corticosteroids	Initial Entry

**2.i Criterion met?**

Date	Location	User	Value	Reason
Aug-19-2020 09:18:38 (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
Aug-19-2020 09:18:38 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> EX13A01	Initial Entry

**2.j**

Date	Location	User	Value	Reason
Aug-19-2020 09:18:38 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Exclusion 15	Initial Entry

090177e196ae2e5a\Final\Final On: 01-Apr-2021 03:10 (GMT)

Header Text: C4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 30-Jul-2020 21:27

Site No: 1231

Subject No: 12312125

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

Buenos Aires	(b) (4), (b) (6)	on Number: Criterion Description: Receipt of blood/plasma products or immunoglobulin, from 60 days before study intervention administration or planned receipt throughout the study Criterion met?: NO Criterion ID: (EX14A01) For Pfizer use only):
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2.j Exclusion Number:

Date	Location	User	Value	Reason
Aug-19-2020 09:18:38 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 15	Initial Entry

2.j Criterion Description:

Date	Location	User	Value	Reason
Aug-19-2020 09:18:38 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Receipt of blood/plasma products or immunoglobulin, from 60 days before study intervention administration or planned receipt throughout the study	Initial Entry

2.j Criterion met?

Date	Location	User	Value	Reason
Aug-19-2020 09:18:38 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

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

Date	Location	User	Value	Reason
Aug-19-2020 09:18:38 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: EX14A01	Initial Entry

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**Header Text:** C4591001

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

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

**Site No:** 1231

**Subject No:** 12312125

**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

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2.k				
Date	Location	User	Value	Reason
Aug-19-2020 09:18:38 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Exclusion Number:</b> 16 <b>Criterion Description:</b> Participation in other studies involving study intervention within 28 days prior to study entry and/or during study participation <b>Criterion met?:</b> NO <b>Criterion ID: (For Pfizer use only):</b> EX15A01	Initial Entry

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Header Text: C4591001

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Form Version: 30-Jul-2020 21:27

Site No: 1231

Subject No: 12312125

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

2.k Exclusion Number:

Date	Location	User	Value	Reason
Aug-19-2020 09:18:38 (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-19-2020 09:18:38 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Participation in other studies involving study intervention within 28 days prior to study entry and/or during study participation	Initial Entry

2.k Criterion met?

Date	Location	User	Value	Reason
Aug-19-2020 09:18:38 (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
Aug-19-2020 09:18:38 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> EX15A01	Initial Entry

2.l

Date	Location	User	Value	Reason
Aug-19-2020 09:18:38 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Exclusion Number:</b> 17 <b>Criterion Description:</b> Previous participation in other studies involving study intervention containing lipid nanoparticles <b>Criterion met?:</b> NO	Initial Entry

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Header Text: C4591001

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Subject No: 12312125

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: ---

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			<b>Criterion ID: (For Pfizer use only):</b> EX16A01	
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**2.1 Exclusion Number:**

Date	Location	User	Value	Reason
Aug-19-2020 09:18:38 (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-19-2020 09:18:38 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Previous participation in other studies involving study intervention containing lipid nanoparticles	Initial Entry

**2.1 Criterion met?**

Date	Location	User	Value	Reason
Aug-19-2020 09:18:38 (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
Aug-19-2020 09:18:38 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> EX16A01	Initial Entry

**2.m**

Date	Location	User	Value	Reason
Aug-19-2020 09:18:38 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Exclusion Number: 22	Initial Entry

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**Header Text:** C4591001

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**Site No:** 1231

**Subject No:** 12312125

**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>Criteria Description:</b> Investigator site staff or Pfizer employees directly involved in the conduct of the study, site staff otherwise supervised by the investigator, and their respective family members</p> <p><b>Criteria Met?:</b> NO</p> <p><b>Criteria ID:</b> EX21A01 (For Pfizer users only)</p>	
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Header Text: C4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 30-Jul-2020 21:27

Site No: 1231

Subject No: 12312125

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: ---

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2.m Exclusion Number:

Date	Location	User	Value	Reason
Aug-19-2020 09:18:38 (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-19-2020 09:18:38 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Investigator site staff or Pfizer employees directly involved in the conduct of the study, site staff otherwise supervised by the investigator, and their respective family members	Initial Entry

2.m Criterion met?

Date	Location	User	Value	Reason
Aug-19-2020 09:18:38 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

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

Date	Location	User	Value	Reason
Aug-19-2020 09:18:38 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> EX21A01	Initial Entry

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**Header Text:** C4591001

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

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

**Site No:** 1231

**Subject No:** 12312125

**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-19-2020 09:18:51 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Aug/18/2020	Initial Entry

**2. Phase of Disposition:**

Date	Location	User	Value	Reason
Aug-19-2020 09:18:51 (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-19-2020 09:19:33 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> COMPLETED	Initial Entry

090177e196ae2e5a\Final\Final On: 01-Apr-2021 03:10 (GMT)

Header Text: C4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 30-Jul-2020 21:28

Site No: 1231

Subject No: 12312125

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-19-2020 09:21:21 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Aug/18/2020	Initial Entry

**2. Weight:**

Date	Location	User	Value	Reason
Aug-19-2020 09:21:21 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 98.0	Initial Entry

**3. Unit:**

Date	Location	User	Value	Reason
Aug-19-2020 09:21:21 (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
Aug-19-2020 09:21:21 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 190.0	Initial Entry

**5. Unit:**

Date	Location	User	Value	Reason
Aug-19-2020 09:21:21 (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-19-2020 09:21:21 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 27.1	Initial Entry

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Header Text: C4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 30-Jul-2020 21:28

Site No: 1231

Subject No: 12312125

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

7.a

Date	Location	User	Value	Reason
Aug-19-2020 09:21:21 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Record Identifier::</b> 1 <b>Temperature:</b> 36.5 <b>Temperature Unit:</b> C <b>Temperature Location:</b> ORAL CAVITY <b>n::</b> Y	Initial Entry

7.a Record Identifier:

Date	Location	User	Value	Reason
Aug-19-2020 09:21:21 (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-19-2020 09:21:21 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 36.5	Initial Entry

7.a Unit:

Date	Location	User	Value	Reason
Aug-19-2020 09:21:21 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> C	Initial Entry

7.a Temperature Location:

Date	Location	User	Value	Reason
Aug-19-2020 09:21:21 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> ORAL CAVITY	Initial Entry

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**Header Text:** C4591001

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

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

**Site No:** 1231

**Subject No:** 12312125

**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-19-2020 09:21:41 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Aug/18/2020	Initial Entry

**2. Randomization Number:**

Date	Location	User	Value	Reason
Aug-19-2020 09:21:41 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 55410	Initial Entry

090177e196ae2e5a\Final\Final On: 01-Apr-2021 03:10 (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: 12312125

Subject Initials: ---

Generated By: (b) (4)

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

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**1. Data Origin**

Date	Location	User	Value	Reason
Aug-19-2020 09:21:54 (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-19-2020 09:21:54 (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-22-2020 12:13:56 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Aug-19-2020 15:48:22 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Aug-19-2020 09:21:54 (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.
Aug-19-2020 09:21:54 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES Date of Collection:  Aug/18/2020	Initial Entry

**5.a**

Date	Location	User	Value	Reason
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090177e196ae2e5a\Final\Final On: 01-Apr-2021 03:10 (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: 12312125

Subject Initials: ---

Generated By: (b) (4)

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

Aug-22-2020 12:13:56 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample ID:</b> BHWTTV	Initial Entry
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5.a Sample ID

Date	Location	User	Value	Reason
Aug-22-2020 12:13:56 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BHWTTV	Initial Entry

5.b

Date	Location	User	Value	Reason
Aug-22-2020 12:14:06 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample ID:</b> BHWTTW	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Aug-22-2020 12:14:06 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BHWTTW	Initial Entry

5.c

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

5.c Sample ID

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

5.d

Date	Location	User	Value	Reason
Aug-22-2020 12:48:33 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	Romina Barrera	<b>Data Entry:</b> <b>Sample ID:</b> BLCV9N	Initial Entry

090177e196ae2e5a\Final\Final On: 01-Apr-2021 03:10 (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: 12312125

Subject Initials: ---

Generated By: (b) (4)

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

Buenos Aires		(b) (4)		
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5.d Sample ID

Date	Location	User	Value	Reason
Aug-22-2020 12:48:33 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	Romina Barrera (b) (4)	<u>Data Entry:</u> BLCV9N	Initial Entry

5.e

Date	Location	User	Value	Reason
Aug-22-2020 12:48:54 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	Romina Barrera (b) (4)	<u>Data Entry:</u> Sample ID: BLCV9P	Initial Entry

5.e Sample ID

Date	Location	User	Value	Reason
Aug-22-2020 12:48:54 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	Romina Barrera (b) (4)	<u>Data Entry:</u> BLCV9P	Initial Entry

5.f

Date	Location	User	Value	Reason
Aug-22-2020 12:49:05 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	Romina Barrera (b) (4)	<u>Data Entry:</u> Sample ID: BLCV9R	Initial Entry

5.f Sample ID

Date	Location	User	Value	Reason
Aug-22-2020 12:49:05 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	Romina Barrera (b) (4)	<u>Data Entry:</u> BLCV9R	Initial Entry

090177e196ae2e5a\Final\Final On: 01-Apr-2021 03:10 (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: 12312125

Subject Initials: ---

Generated By: (b) (4)

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

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**1. Data Origin**

Date	Location	User	Value	Reason
Aug-19-2020 09:22:06 (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-19-2020 09:22:06 (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-22-2020 10:24:59 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Aug-19-2020 15:48:22 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Aug-19-2020 09:22:06 (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.
Aug-19-2020 09:22:06 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES Date of Collection:  Aug/18/2020	Initial Entry

**5.a**

Date	Location	User	Value	Reason
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090177e196ae2e5a\Final\Final On: 01-Apr-2021 03:10 (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:** 12312125

**Subject Initials:** ---

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

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

Aug-22-2020 10:24:59 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample ID:</b> BHWTRK	Initial Entry
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**5.a Sample ID**

Date	Location	User	Value	Reason
Aug-22-2020 10:24:59 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BHWTRK	Initial Entry

Header Text: C4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 22-Apr-2020 21:04

Site No: 1231

Subject No: 12312125

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-19-2020 09:22:47 (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-19-2020 09:22:47 (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-19-2020 09:22:47 (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-19-2020 09:22:47 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Aug/18/2020 19:42	Initial Entry

**5. Anatomical Location:**

Date	Location	User	Value	Reason
Aug-19-2020 09:22:47 (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-19-2020 09:22:47 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> LEFT	Initial Entry

090177e196ae2e5a\Final\Final On: 01-Apr-2021 03:10 (GMT)

**Header Text:** C4591001

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

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

**Site No:** 1231

**Subject No:** 12312125

**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

**7. Route:**

Date	Location	User	Value	Reason
Aug-19-2020 09:22:47 (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
Aug-19-2020 09:22:47 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> THE PROTOCOL SPECIFIED OBSE RVATION PERIOD	Initial Entry

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

Date	Location	User	Value	Reason
Aug-19-2020 09:22:47 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

090177e196ae2e5a\Final\Final On: 01-Apr-2021 03:10 (GMT)

**Header Text:** C4591001

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

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

**Site No:** 1231

**Subject No:** 12312125

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

**Form:** REACTOGENICITY DIARY - 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. Select appropriate response - Reactogenicity diary collection*

Date	Location	User	Value	Reason
Aug-19-2020 09:22:53 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO - REACTOGENICITY E-DIARY NOT COLLECTED FOR THIS SUBJ ECT	Initial Entry

**Header Text:** C4591001

**Visit:** V2\_VAX2\_L

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

**Site No:** 1231

**Subject No:** 12312125

**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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*I. Date of Visit*

Date	Location	User	Value	Reason
Sep-07-2020 12:10:46 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	<u>Data Entry:</u> Sep/7/2020	Initial Entry



Header Text: C4591001

Visit: V2\_VAX2\_L

Form Version: 21-Aug-2020 02:51

Site No: 1231

Subject No: 12312125

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-07-2020 12:11:05 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	<b>Data Entry:</b> Sep/7/2020	Initial Entry

**2.a**

Date	Location	User	Value	Reason
Sep-07-2020 12:11:05 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	<b>Data Entry:</b> <b>Record Identifier::</b> 1 <b>Temperature:</b> 36.5 <b>Temperature Unit:</b> C <b>Temperature Location::</b> ORAL CAVITY	Initial Entry

**2.a Record Identifier:**

Date	Location	User	Value	Reason
Sep-07-2020 12:11:05 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	<b>Data Entry:</b> 1	Initial Entry

**2.a Temperature:**

Date	Location	User	Value	Reason
Sep-07-2020 12:11:05 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	<b>Data Entry:</b> 36.5	Initial Entry

**2.a Unit:**

Date	Location	User	Value	Reason
Sep-07-2020 12:11:05 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	<b>Data Entry:</b> C	Initial Entry

**2.a Temperature Location:**

Date	Location	User	Value	Reason
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090177e196ae2e5a\Final\Final On: 01-Apr-2021 03:10 (GMT)

**Header Text:** C4591001

**Visit:** V2\_VAX2\_L

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

**Site No:** 1231

**Subject No:** 12312125

**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

Sep-07-2020 12:11:05 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	<b>Data Entry:</b> ORAL CAVITY	Initial Entry
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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: 12312125

Subject Initials: ---

Generated By: (b) (4)

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

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**1. Data Origin**

Date	Location	User	Value	Reason
Sep-07-2020 12:11:14 (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-07-2020 12:11:14 (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-08-2020 10:07:42 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Sep-08-2020 03:00:49 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Sep-07-2020 12:11:14 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Sep-07-2020 12:11:14 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	<b>Data Entry:</b> YES Date of Collection:  Sep/7/2020	Initial Entry

**5.a**

Date	Location	User	Value	Reason
Sep-08-2020 10:07:42 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sample ID: BP1TG4	Initial Entry

090177e196ae2e5a\Final\Final On: 01-Apr-2021 03:10 (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:** 12312125

**Subject Initials:** ---

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

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

Buenos Aires

**5.a Sample ID**

Date	Location	User	Value	Reason
Sep-08-2020 10:07:42 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BP1TG4	Initial Entry

Header Text: C4591001

Visit: V2\_VAX2\_L

Form Version: 22-Apr-2020 21:04

Site No: 1231

Subject No: 12312125

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-07-2020 12:11:43 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**2. Treatment Name**

Date	Location	User	Value	Reason
Sep-07-2020 12:11:43 (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-07-2020 12:11:43 (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-07-2020 12:11:43 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	<b>Data Entry:</b> Sep/7/2020 10:50	Initial Entry

**5. Anatomical Location:**

Date	Location	User	Value	Reason
Sep-07-2020 12:11:43 (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-07-2020 12:11:43 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	<b>Data Entry:</b> RIGHT	Initial Entry

090177e196ae2e5a\Final\Final On: 01-Apr-2021 03:10 (GMT)

**Header Text:** C4591001

**Visit:** V2\_VAX2\_L

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

**Site No:** 1231

**Subject No:** 12312125

**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

**7. Route:**

Date	Location	User	Value	Reason
Sep-07-2020 12:11:43 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> INTRAMUSCULAR	Initial Entry

**10. Timeframe Subject Was Observed**

Date	Location	User	Value	Reason
Sep-07-2020 12:11:43 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> THE PROTOCOL SPECIFIED OBSE RVATION PERIOD	Initial Entry

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

Date	Location	User	Value	Reason
Sep-07-2020 12:11:43 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

090177e196ae2e5a\Final\Final On: 01-Apr-2021 03:10 (GMT)

**Header Text:** C4591001

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

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

**Site No:** 1231

**Subject No:** 12312125

**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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**I. Date of Visit**

Date	Location	User	Value	Reason
Oct-15-2020 02:26:25 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Oct-14-2020 10:50:43 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Query 1: Answered	EOT form completed
Oct-13-2020 07:44:12 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	DM: Patient completed the treatment phase and reached at Visit 3. Kindly consider to update EOT form with matching V3 date or else clarify. Thank you.
Oct-07-2020 18:55:58 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Oct/7/2020	Initial Entry

090177e196ae2e5a\Final\Final On: 01-Apr-2021 03:10 (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: 12312125

Subject Initials: ---

Generated By: (b) (4)

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

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**1. Data Origin**

Date	Location	User	Value	Reason
Oct-07-2020 18:56:05 (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-07-2020 18:56:05 (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-08-2020 10:40:35 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Oct-08-2020 04:29:05 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Oct-07-2020 18:56:05 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Oct-07-2020 18:56:05 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES Date of Collection:  Oct/7/2020	Initial Entry

**5.a**

Date	Location	User	Value	Reason
Oct-08-2020 10:40:35 (UTC-03:00) City of	ACV0PFEINFP6000	Agustin Morato	<b>Data Entry:</b> <b>Sample ID: BLDZ7D</b>	Initial Entry

090177e196ae2e5a\Final\Final On: 01-Apr-2021 03:10 (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:** 12312125

**Subject Initials:** ---

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

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

Buenos Aires		Cabral (b) (4)		
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**5.a Sample ID**

Date	Location	User	Value	Reason
Oct-08-2020 10:40:35 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	Agustin Morato Cabral (b) (4)	<b>Data Entry:</b> BLDZ7D	Initial Entry

**5.b**

Date	Location	User	Value	Reason
Oct-08-2020 11:56:06 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample ID:</b> BLDZ6H	Initial Entry

**5.b Sample ID**

Date	Location	User	Value	Reason
Oct-08-2020 11:56:06 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BLDZ6H	Initial Entry

**5.c**

Date	Location	User	Value	Reason
Oct-08-2020 12:42:44 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	Agustin Morato Cabral (b) (4)	<b>Data Entry:</b> <b>Sample ID:</b> BPW7GV	Initial Entry

**5.c Sample ID**

Date	Location	User	Value	Reason
Oct-08-2020 12:42:44 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	Agustin Morato Cabral (b) (4)	<b>Data Entry:</b> BPW7GV	Initial Entry

090177e196ae2e5a\Final\Final On: 01-Apr-2021 03:10 (GMT)

**Header Text:** C4591001

**Visit:** V4\_MONTH6\_L

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

**Site No:** 1231

**Subject No:** 12312125

**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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*I. Date of Visit*

Date	Location	User	Value	Reason
Mar-01-2021 13:16:53 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	Martina Davalli (b) (4)	<b>Data Entry:</b> Mar/1/2021	Initial Entry

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: 12312125

Subject Initials: ---

Generated By: (b) (4)

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

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**1. Data Origin**

Date	Location	User	Value	Reason
Mar-01-2021 13:17:06 (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-01-2021 13:17:06 (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-01-2021 15:19:57 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Mar-01-2021 13:17:06 (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.
Mar-01-2021 13:17:06 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	Martina Davalli (b) (4)	<b>Data Entry:</b> YES Date of Collection: Mar/1/2021	Initial Entry

**5.a**

Date	Location	User	Value	Reason
Mar-01-2021 15:19:57 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample ID:</b> BLBWVF	Initial Entry

**5.a Sample ID**

Date	Location	User	Value	Reason
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090177e196ae2e5a\Final\Final On: 01-Apr-2021 03:10 (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: 12312125

Subject Initials: ---

Generated By: (b) (4)

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

Mar-01-2021 15:19:57 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BLBWVF	Initial Entry
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5.b

Date	Location	User	Value	Reason
Mar-02-2021 10:03:34 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample ID:</b> BLBWT3	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Mar-02-2021 10:03:34 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BLBWT3	Initial Entry

5.c

Date	Location	User	Value	Reason
Mar-02-2021 10:17:44 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample ID:</b> BR2007	Initial Entry

5.c Sample ID

Date	Location	User	Value	Reason
Mar-02-2021 10:17:44 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BR2007	Initial Entry

090177e196ae2e5a\Final\Final On: 01-Apr-2021 03:10 (GMT)

**Header Text:** C4591001

**Visit:** End of Treatment - Unscheduled

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

**Site No:** 1231

**Subject No:** 12312125

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

**Form:** DISPOSITION - TREATMENT - 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
Oct-14-2020 10:50:26 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	<b>Data Entry:</b> Oct/7/2020	Initial Entry

**2. Phase of Disposition:**

Date	Location	User	Value	Reason
Oct-14-2020 10:50:26 (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-14-2020 10:50:26 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	<b>Data Entry:</b> COMPLETED	Initial Entry

090177e196ae2e5a\Final\Final On: 01-Apr-2021 03:10 (GMT)

**Header Text:** C4591001

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

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

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

**Site No:** 1231

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

**Subject No:** 12312125

**Subject Initials:** ---

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

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

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*I. Date of Visit*

Date	Location	User	Value	Reason
Feb-24-2021 14:51:31 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Feb/24/2021	Initial Entry

**Header Text:** C4591001

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

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

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

**Site No:** 1231

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

**Subject No:** 12312125

**Subject Initials:** ---

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

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

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

Date	Location	User	Value	Reason
Feb-24-2021 14:52:02 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Feb-24-2021 14:51:41 (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-24-2021 14:51:41 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Participant is willing to return for Vaccination 3 Participant is:  eligible and NOT confirmed to have received only placebo at Vaccination 1/2	Initial Entry

090177e196ae2e5a\Final\Final On: 01-Apr-2021 03:10 (GMT)

**Header Text:** C4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1231

**Subject No:** 12312125

**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:** ---

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

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Date	Location	User	Value	Reason
Jan-13-2021 10:38:35 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Form Created	



**Header Text:** C4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1231

**Subject No:** 12312125

**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
Mar-19-2021 11:56:58 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Undeleted	At the request for Safety is undeleted
Mar-18-2021 17:31:11 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Deleted	At the request of the Sponsor, the serious adverse events Peritonitis (1) and Appendicitis (2) are merged under the serious adverse event Peritonitis (1).
Feb-17-2021 11:46:42 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Created	

090177e196ae2e5a\Final\Final On: 01-Apr-2021 03:10 (GMT)

**Header Text:** C4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1231

**Subject No:** 12312125

**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:** ---

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

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Date	Location	User	Value	Reason
Mar-01-2021 11:15:56 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Created	

Header Text: C4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1231

Subject No: 12312125

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

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

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**1. Category:**

Date	Location	User	Value	Reason
Jan-13-2021 10:38:35 (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
Jan-13-2021 10:38:35 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 1	Initial Entry

**3. Adverse Event:**

*(If possible specify diagnosis, not individual symptoms)*

Date	Location	User	Value	Reason
Feb-17-2021 11:41:55 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Peritonitis	Transcription Error
Feb-16-2021 22:12:46 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Query 4: Closed	Response satisfies query
Feb-10-2021 19:17:59 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 4: Answered	At the request of DM, a new SAE Form report is sent under the name of Acute Appendicitis, associated with the case Peritonitis num 2021024519 Peritonitis was previously reported as SAE
Feb-10-2021 19:17:59 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Acute Appendicitis	At the request of DM, a new SAE Form report is sent under the name of Acute Appendicitis, associated with the case Peritonitis num 2021024519 Peritonitis was

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**Header Text:** C4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1231

**Subject No:** 12312125

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

**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History

**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

				previously reported as SAE
Feb-01-2021 19:52:48 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Query 4: Reissued:Opened	Clinical Thank you. Please finalize whether the subject had appendicitis (per wife report) or not (if not in discharge summary); this 2nd event needs to be clearly reported either way.
Jan-30-2021 10:58:50 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 4: Answered	Discharge summary was provided. Follow up SAE form was sent on 29JAN2021
Jan-27-2021 14:56:30 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Query 5: Closed	Query closed; please submit any documentation for sepsis in subsequent medical records received
Jan-27-2021 14:55:34 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Query 4: Reissued:Opened	Clinical Thank you; however no details concerning the original surgery (& accompanying path) on 09Jan21 are reported. Please submit this information when med Records received.
Jan-27-2021 10:33:13 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 5: Answered	Sepsis was mentioned by a cardiologist as a cause of atrial fibrillation. Blood culture is not available at this moment. SAE follow up form was sent.
Jan-27-2021 10:31:10 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 4: Answered	SAE safety update was sent

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**Header Text:** C4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1231

**Subject No:** 12312125

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

**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History

**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

Jan-26-2021 14:37:37 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Query 5: Opened	Clinical - SAE report reports the event 'Sepsis'; however, no blood cultures are reported. Please submit information for 'Sepsis' and review this event for potential serious criteria; report only if SAE (to AE log/SAE report)
Jan-26-2021 14:34:30 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Query 4: Opened	Clinical Please submit a SAE safety update with the 09Jan21 surgical report (including resected tissue) and surgical path report for resected tissue
Jan-25-2021 11:56:50 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	Marjorie Buonanno (b) (4)	Query 3: Closed	Will discuss with medical monitor
Jan-23-2021 10:18:43 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Query 3: Answered	We have nothing confirmatory for appendicitis. It is a retrospective diagnosis, since at the time it was not diagnosed and that is why it led to peritonitis.
Jan-22-2021 14:43:51 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	Marjorie Buonanno (b) (4)	Query 3: Opened	GPD Clin: The SAE narrative for event of peritonitis confirms it was due to appendicitis. Please add appendicitis as SAE, update SAE report and submit to Pfizer Safety. Thank you.
Jan-22-2021 12:03:49 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	Marjorie Buonanno (b) (4)	Query 2: Closed	Response satisfies query

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**Header Text:** C4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1231

**Subject No:** 12312125

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

**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History

**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

Jan-21-2021 10:42:40 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Answered	On 19JAN, SAE follow up form was sent with the available information
Jan-20-2021 11:44:05 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	Marjorie Buonanno (b) (4)	Query 2: Opened	GPD Clin: Please confirm when information regarding surgical details, hospitalization course,(i.e. is subject still in ICU?) and confirmation of etiology for peritonitis.
Jan-18-2021 09:13:09 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	Marjorie Buonanno (b) (4)	Query 1: Closed	Response satisfies query
Jan-16-2021 19:35:00 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Communication was made with the volunteer's wife, she referred to an improvement in laboratory parameters. Volunteer continues hospitalized in ICU. No further information is available so far. Continuous in follow-up.
Jan-15-2021 17:04:42 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	Marjorie Buonanno (b) (4)	Query 1: Opened	GPD Clin: Please provide further detail regarding etiology and surgery performed for peritonitis. Ensure all details are added to SAE report through standard SAE reporting process.
Jan-13-2021 10:38:35 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Peritonitis	Initial Entry

**4. Start Date Time:**

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Header Text: C4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1231

Subject No: 12312125

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

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

Date	Location	User	Value	Reason
Jan-13-2021 10:38:35 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Jan/6/2021 22:00	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Mar-06-2021 00:17:12 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Mar-05-2021 10:46:26 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Peritonitis stop date was sent in a FU on 17Feb2021. Also in the FU sent on 26Feb2021 is clarified that both stop dates peritonitis/appendicitis are the same. Please double check records with Pfizer Safety Argentina.
Mar-04-2021 10:58:10 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reissued:Opened	Clinical - Unfortunately, no Safety followup on 26Feb21 was received; please send the stop date for peritonitis as a new safety followup submission
Mar-03-2021 10:37:48 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	On FU on 26FEB2021 says "I clarify that the event acute appendicitis stop date is 11 Feb 2021 19.00hrs. Please note that as this event is related to peritonitis they have the same stopdate."
Mar-02-2021 15:58:08 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reissued:Opened	Clinical thank you; however 25Feb21 SAAE (#2021024519) did not report an end date for event peritonitis

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Header Text: C4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1231

Subject No: 12312125

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

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

Feb-26-2021 12:24:32 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	SAE followup was sent.
Feb-25-2021 22:40:50 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	Clinical - End date is 11Feb21; however, SAE report (#2021024519) has no end date. Please submit end date in a SAE followup
Feb-18-2021 13:41:22 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO End Date Time: Feb/11/2021 19:00	New Information
Jan-13-2021 10:38:35 (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
Jan-13-2021 10:38:35 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 3	Initial Entry

7. Is the adverse event serious?

If Yes, NOTIFY PFIZER IMMEDIATELY.

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

Date	Location	User	Value	Reason
Feb-25-2021 22:38:12 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Closed	Response satisfies query
Feb-18-2021 13:38:44 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Answered	It was clarify on FU on 02FEB.
Feb-16-2021 23:11:35 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Reissued:Opened	Clinical – Thank you. If NO hospital COVID test was

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Header Text: C4591001

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Subject No: 12312125

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen

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

Subject Initials: ---

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				performed is known, please submit this information on a follow-up SAE form to this SAE as well (#2021148906), as pertinent information for this trial.
Feb-03-2021 11:13:03 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Answered	Covid testing was not performed because the AE is not related to COVID illness.
Feb-01-2021 19:53:38 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Opened	Clinical Followup Clinical COVID test status (yes/no) during Hosp was not reported in the SAE. Please submit a follow-up SAE form to document if COVID testing was performed (YES/NO or info not available) and if yes, the date and results.
Jan-21-2021 00:51:51 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Closed	Query closed; will follow for SAE update with the requested COVID test info
Jan-18-2021 12:30:26 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Answered	Information about COVID testing is not available at this moment. Further follow up will be provided as soon as possible.
Jan-18-2021 06:56:18 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Jan-13-2021 19:37:05 (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 [#2021024519] to

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Header Text: C4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1231

Subject No: 12312125

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

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

				document if COVID testing was performed (YES/NO or info not available) and if yes, the date and results.
Jan-13-2021 10:38:35 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	For AE Peritonitis: Response to "Is the adverse event serious?" is 'Yes' but "Serious Adverse Event Number" is blank.
Jan-13-2021 10:38:35 (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> <p>NO</p> <p>Is this serious event life threatening?</p> <p>NO</p> <p>Other medically important serious event</p> <p>YES</p>	Initial Entry

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

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**Header Text:** C4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1231

**Subject No:** 12312125

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

**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History

**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

Date	Location	User	Value	Reason
Jan-13-2021 10:38:35 (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
Jan-27-2021 14:46:27 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Jan-27-2021 10:28:59 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Peritonitis secondary to appendicitis was informed by the subject's wife however the surgeon consulted did not confirm nor rule out this information.
Jan-26-2021 14:21:23 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	Clinical 'Other' cause for event Peritonitis is unknown; however, SAE reports 'peritonitis secondary to appendicitis'. Please review event causality, harmonize reporting, & update where applicable

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Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

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9. Is this event related to study treatment:

Date	Location	User	Value	Reason
Jan-13-2021 10:38:35 (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:  OTHER  If Other, specify:  unknown	Initial Entry

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Jan-13-2021 10:38:35 (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
Jan-27-2021 14:46:11 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Jan-27-2021 10:30:09 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	New Information
Jan-27-2021 10:30:09 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	New Information
Jan-26-2021 14:22:38 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	Clinical Con Med for SAE is NO; however, SAE reports use of antibiotics. Please review Con Meds, and update if appropriate
Jan-13-2021 10:38:35 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

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Generated By: (b) (4)

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Buenos Aires				
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12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Jan-13-2021 10:38:35 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> YES	Initial Entry

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

Date	Location	User	Value	Reason
Mar-08-2021 05:27:38 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Closed	SDDDB outcome updated
Mar-01-2021 06:47:53 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Reissued:Candidate	Pending PSSR review
Feb-26-2021 12:29:55 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Answered	According to the DM and ICON guidance provided above, when SAE includes more than one event, all events are reported as initial, but FU is performed on the main severe event. FU was sent on 17FEB2021; SAE end date 11FEB2021, Subject's status is RECOVERED.
Feb-24-2021 01:19:12 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Reissued:Opened	SAE RECON: Per latest SAE listing last update on Feb 17 for the other AER for the subject. For peritonitis event (AER#2021024519),if correct outcome is RECOVERED/RESOLVED' please submit follow up AEM to update safety database.
Feb-22-2021 19:44:18 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Reissued:Candidate	Pending SDB Update

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Generated By: (b) (4)

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Feb-22-2021 10:21:18 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Answered	On 17FEB2021 SAE FU was sent with this information
Feb-21-2021 09:40:31 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Opened	SAE RECON:AER#2021024519 ,outcome was reported as Recovering/Resolving to Safety DB however, recorded as RECOVERED/RESOLVED on AE CRF. Please confirm correct outcome. If safety update is required, please submit a follow-up form.
Feb-18-2021 13:41:40 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Feb-18-2021 13:41:40 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> RECOVERED/RESOLVED	New Information
Feb-18-2021 13:41:22 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	For AE Peritonitis: Response to "What was the outcome of this adverse event?" is 'Recovering/Resolving' but AE End Date/Time is present.
Feb-03-2021 11:17:27 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> RECOVERING/RESOLVING	New Information
Jan-13-2021 10:38:35 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NOT RECOVERED/NOT RESOLVED	Initial Entry

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

Date	Location	User	Value	Reason
Jan-13-2021 10:38:35 (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
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Feb-18-2021 06:17:50 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 2021024519	updated AER
Feb-15-2021 04:41:27 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 2021148906	new aer number for appendicitis
Jan-18-2021 06:56:18 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 2021024519	Initial Entry

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**1. Category:**

Date	Location	User	Value	Reason
Feb-17-2021 11:46:42 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> ADVERSE EVENT	Initial Entry

**2. AE ID:**

Date	Location	User	Value	Reason
Feb-17-2021 11:46:42 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 2	Initial Entry

**3. Adverse Event:**

*(If possible specify diagnosis, not individual symptoms)*

Date	Location	User	Value	Reason
Feb-18-2021 16:22:51 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000.InFormAdapter.Discrepancy	PFETMS Oracle (b) (4)	Query 1: Closed	Discrepancy has been closed.
Feb-18-2021 13:40:50 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Acute appendicitis	Transcription Error
Feb-18-2021 13:39:54 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Transcription Error
Feb-18-2021 13:39:54 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Acute apPendicitis	Transcription Error
Feb-17-2021 14:14:00 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000.InFormAdapter.Discrepancy	PFETMS Oracle (b) (4)	Query 1: Opened	Clarify ACUTE APENDICITIS as follows. Please confirm if spelling should be ACUTE APPENDICITIS and edit term. Or further clarify and

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Subject No: 12312125

Generated By: (b) (4)

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Form Status: Data Complete, Locked, Frozen

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				edit. Thank you.
Feb-17-2021 11:46:42 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Acute apendicitis	Initial Entry

4. Start Date Time:

Date	Location	User	Value	Reason
Feb-17-2021 11:46:42 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Jan/6/2021 22:00	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Mar-02-2021 16:03:14 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Feb-26-2021 12:22:42 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	New Information
Feb-26-2021 12:22:42 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO End Date Time: Feb/11/2021 19:00	New Information
Feb-25-2021 22:44:52 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	Clinical End date is NONE; however, SAE report (#2021148906) reports End date of 22Feb21. Please review, harmonize reporting, and update where applicable
Feb-17-2021 11:46:42 (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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Generated By: (b) (4)

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Form Status: Data Complete, Locked, Frozen

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Feb-17-2021 11:46:42 (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
Mar-06-2021 00:14:35 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Closed	Response satisfies query
Mar-03-2021 10:33:46 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Answered	This information was sent on FU on 02FEB2021. Covid testing was not performed because the AE is not related to COVID illness.
Mar-02-2021 16:05:36 (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 [#2021148906] to document if COVID testing was performed (YES/NO or info not available) and if yes, the date and results.
Feb-19-2021 07:22:18 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Feb-18-2021 13:39:54 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	For AE Acute apPendicitis: Response to "Is the adverse event serious?" is 'Yes' but "Serious Adverse Event Number" is blank.

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Feb-17-2021 11:46:42 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	For AE Acute apendicitis: Response to "Is the adverse event serious?" is 'Yes' but "Serious Adverse Event Number" is blank.
Feb-17-2021 11:46:42 (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> <p>NO</p> <p>Is this serious event life threatening?</p> <p>NO</p> <p>Other medically important serious event</p> <p>YES</p>	Initial Entry

**8. Is this adverse event the result of a study Medication Error?**

*If Yes, record the type of medication error on the Medication Error Log.*

Date	Location	User	Value	Reason
Feb-17-2021 11:46:42 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<p><b>Data Entry:</b></p> <p>NO</p>	Initial Entry

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9. Is this event related to study treatment:

Date	Location	User	Value	Reason
Feb-17-2021 11:46:42 (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:  OTHER  If Other, specify:  unknown	Initial Entry

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Feb-17-2021 11:46:42 (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
Feb-17-2021 11:46:42 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Feb-17-2021 11:46:42 (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
Feb-26-2021 18:35:38 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (b) (4)	Query 2: Closed	Auto closed by Validation Check: VC_AE001_35
Feb-26-2021	ACV0PFEINFP6000	(b) (4), (b) (6)	Query	End Date/Time was uploaded.

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12:23:24 (UTC-03:00) City of Buenos Aires		(b) (4), (b) (6)	2: Answered	
Feb-24-2021 04:53:38 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (b) (4)	Query 2: Opened	DMW7387203;Response to "What was the outcome of this adverse event?" is 'Recovered/Resolved' or 'Recovered/Resolved with Sequelae' but End Date/Time is missing. Please review and update as appropriate.
Feb-22-2021 19:45:29 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Feb-22-2021 12:33:13 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	New Information
Feb-22-2021 12:33:13 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry</b> : RECOVERED/RESOLVED	New Information
Feb-21-2021 09:42:54 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	SAE RECON:AER#2021148906 ,outcome was reported as Recovered/Resolved to Safety DB however, recorded as RECOVERING/RESOLVING on AE CRF. Please confirm correct outcome. If safety update is required, please submit a follow-up form.
Feb-17-2021 11:46:42	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry</b>	Initial Entry

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(UTC-03:00) City of Buenos Aires			:	REC OVE RING /RES OLVI NG
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**14. Did the adverse event cause the subject to be discontinued from the study?**

Date	Location	User	Value	Reason
Feb-17-2021 11:46:42 (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
Mar-22-2021 05:18:57 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 2021024519	AER merged in SDB
Feb-19-2021 07:22:18 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 2021148906	Initial Entry

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**1. Category:**

Date	Location	User	Value	Reason
Mar-01-2021 11:15:56 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> ADVERSE EVENT	Initial Entry

**2. AE ID:**

Date	Location	User	Value	Reason
Mar-01-2021 11:15:56 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 3	Initial Entry

**3. Adverse Event:**

*(If possible specify diagnosis, not individual symptoms)*

Date	Location	User	Value	Reason
Mar-04-2021 17:21:07 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Mar-04-2021 16:47:10 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Changed Information
Mar-04-2021 16:47:10 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Acute Paroxysmal Atrial Fibrillation with High Ventricular Response.	Changed Information
Mar-03-2021 12:22:57 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	clinical: How was arrhythmia diagnosed eg EKG, heart monitor, and provide more specific diagnosis eg SVT, atrial fibrillation etc.
Mar-01-2021 11:15:56 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> arrhythmia	Initial Entry

**4. Start Date Time:**

Date	Location	User	Value	Reason
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090177e196ae2e5a\Final\Final On: 01-Apr-2021 03:10 (GMT)

Header Text: C4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1231

Subject No: 12312125

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

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

Mar-01-2021 11:15:56 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Jan/11/2021 12:00	Initial Entry
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5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Mar-08-2021 16:17:40 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO End Date Time:  Jan/15/2021 10:00	New Information
Mar-08-2021 10:01:05 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	clinical: sent to ICON
Mar-08-2021 09:55:35 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Query is ambiguous
Mar-07-2021 14:20:24 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reissued:Opened	clinical: sent to ICON to clarify choice of end date.
Mar-06-2021 10:46:00 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	New Information
Mar-06-2021 10:46:00 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	Martina Davalli (b) (4)	<b>Data Entry:</b> NO End Date Time:  Mar/6/2021 10:29	New Information
Mar-05-2021 13:35:49 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reissued:Opened	clinical: per protocol the end date for AE should be when the AE resolved or became stable regardless if still under observation or care. Please update end date on CRF based on these guidelines. Thanks
Mar-04-2021 16:51:34 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Arrhythmia was triggered in the context of abdominal

090177e196ae2e5a\Final\Final On: 01-Apr-2021 03:10 (GMT)



Header Text: C4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1231

Subject No: 12312125

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen

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

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				sepsis. It had a complete reversion to sinus rhythm under treatment (Jan 15th) and did not repeat an episode. Yet subject is still under specialist observation. Therefore AE is still ongoing.
Mar-03-2021 12:24:57 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	clinical: pls confirm ongoing or update end date in CRF. If ongoing, has arrhythmia been continuous or intermittent. Thanks
Mar-01-2021 11:15:56 (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
Mar-01-2021 11:15:56 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 1	Initial Entry

7. Is the adverse event serious?

If Yes, NOTIFY PFIZER IMMEDIATELY.

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

Date	Location	User	Value	Reason
Mar-01-2021 11:15:56 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

8. Is this adverse event the result of a study Medication Error?

If Yes, record the type of medication error on the Medication Error Log.

Date	Location	User	Value	Reason
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090177e196ae2e5a\Final\Final On: 01-Apr-2021 03:10 (GMT)

Header Text: C4591001

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Form Version: 22-Apr-2020 21:02

Site No: 1231

Subject No: 12312125

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

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

Mar-01-2021 11:15:56 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry
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9. Is this event related to study treatment:

Date	Location	User	Value	Reason
Mar-01-2021 11:15:56 (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:  OTHER  If Other, specify:  Unknown	Initial Entry

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Mar-01-2021 11:15:56 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NOT APPLICABLE	Initial Entry

11. Was a Concomitant Medication given?

Date	Location	User	Value	Reason
Mar-01-2021 11:15:56 (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
Mar-01-2021 11:15:56 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

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

Date	Location	User	Value	Reason
Mar-08-2021 11:20:39 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> RECOVERED/RESOLVED WITH SEQUELAE	New Information

090177e196ae2e5a\Final\Final On: 01-Apr-2021 03:10 (GMT)

**Header Text:** C4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1231

**Subject No:** 12312125

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

**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History

**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

Mar-06-2021 10:46:18 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Mar-06-2021 10:46:18 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	Martina Davalli (b) (4)	<b>Data Entry:</b> RECOVERED/RESOLVED	New Information
Mar-06-2021 10:46:00 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	For AE Acute Paroxysmal Atrial Fibrillation with High Ventricular Response.: Response to "What was the outcome of this adverse event?" is 'Not Recovered/Not Resolved' but AE End Date/Time is present.
Mar-01-2021 11:15:56 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NOT RECOVERED/NOT RESOLVED	Initial Entry

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

Date	Location	User	Value	Reason
Mar-01-2021 11:15:56 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

090177e196ae2e5a\Final\Final On: 01-Apr-2021 03:10 (GMT)

**Header Text:** C4591001

**Visit:** Disposition - Unscheduled

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

**Site No:** 1231

**Subject No:** 12312125

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

**Form:** TREATMENT UNBLINDED - eCRF Audit Trail History

**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

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**1. Date Treatment Unblinded :**

Date	Location	User	Value	Reason
Feb-24-2021 14:52:02 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Feb/24/2021	Initial Entry

**2. Primary Reason for Unblinding:**

Date	Location	User	Value	Reason
Feb-24-2021 14:52:02 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> ASSESS ELIGIBILITY FOR ADDI TIONAL VACCINATION	Initial Entry

Header Text: C4591001

Visit: Subject Status - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1231

Subject No: 12312125

Generated By: (b) (4)

Form: SUBJECT STATUS - eCRF Audit Trail History

Form Status: Data Complete, 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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**I. Subject Status**

Date	Location	User	Value	Reason
Oct-14-2020 10:50:26 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> FOLLOW-UP	Initial Entry
Aug-19-2020 09:21:41 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> ENROLLED/RANDOMIZED	Initial Entry
Aug-19-2020 09:19:33 (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
Feb-21-2021 10:05:37 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	event entered in AE CRF
Feb-19-2021 13:19:21 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Please clarify. Reported onset date was 06JAN2021 and was charged in AE CRF.
Feb-15-2021 07:43:26 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	SAE RECON:AER#2021024519 peritonitis(onset date:26Jan2021)was reported as serious in Safety database but missing in AE CRF. Please confirm and update CRF. If safety update is required, submit a follow-up SAE Form.
Oct-14-2020 10:50:26 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> Oct/7/2020	Initial Entry
Aug-19-2020 09:21:41 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> Aug/18/2020	Initial Entry
Aug-19-2020 09:19:33	ACV0PFEINFP6000	auto calc	<b>Data Entry:</b>	Initial Entry

090177e196ae2e5a\Final\Final On: 01-Apr-2021 03:10 (GMT)

**Header Text:** C4591001

**Visit:** Subject Status - Unscheduled

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

**Site No:** 1231

**Subject No:** 12312125

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

**Form:** SUBJECT STATUS - eCRF Audit Trail History

**Form Status:** Data Complete, Verified

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

**Subject Initials:** ---

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

(UTC-03:00) City of Buenos Aires		(autocalc)	Aug/18/2020	
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**Header Text:** C4591001

**Visit:** Investigator Signature - Unscheduled

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

**Site No:** 1231

**Subject No:** 12312125

**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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*I. Casebook Signature*

Date	Location	User	Value	Reason
Oct-21-2020 19:23:13 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Click Here to Enable	Initial Entry