

**Header Text:** C4591001

**Visit:** COHORT\_SELECTION

**Form:** COHORT\_SELECTION

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

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

**Site No:** 1231

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

**Subject No:** 12311862

**Subject Initials:** ---

**Generated By:**

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

(b) (4)

[eCRF Audit Trail History](#)

**Cohort Selection**

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

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

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**Header Text:** C4591001

**Visit:** COHORT\_SELECTION

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

**Site No:** 1231

**Subject No:** 12311862

**Generated By:**

(b) (4)

**Form:** MAIN INFORMED CONSENT

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

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

**Subject Initials:** ---

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

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**Informed Consent**

1.	Consent Was:	OBTAINED Date Written Consent Obtained Aug/17/2020
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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:** 12311862

**Subject Initials:** ---

**Generated By:**

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

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**Demography**

1.	Subject ID	[12311862]
2.	Birth Date:	(b) (6) /1989
3.	Sex:	MALE
4.	Ethnicity:	HISPANIC OR LATINO(A) OR OF SPANISH ORIGIN
5.	Race: (Check X all that apply):	WHITE
6.	Racial Designation:	

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**Header Text:** C4591001

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

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

**Site No:** 1231

**Subject No:** 12311862

**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/17/2020
2.	Erroneous Visit	

**Header Text:** C4591001

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

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

**Site No:** 1231

**Subject No:** 12311862

**Generated By:**

(b) (4)

**Form:** INCLUSION/EXCLUSION CRITERIA

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

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

**Subject Initials:** ---

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

[eCRF Audit Trail History](#)

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

**Inclusion Criteria**

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

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

**Site No:** 1231

**Subject No:** 12311862

**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

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

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

**Exclusion Criteria**

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

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

**Site No:** 1231

**Subject No:** 12311862

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(b) (4)

**Form:** INCLUSION/EXCLUSION CRITERIA

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

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

**Subject Initials:** ---

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

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

**Site No:** 1231

**Subject No:** 12311862

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**Form:** INCLUSION/EXCLUSION CRITERIA

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

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

**Subject Initials:** ---

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

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

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

**Site No:** 1231

**Subject No:** 12311862

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**Form:** INCLUSION/EXCLUSION CRITERIA

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

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

**Subject Initials:** ---

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

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**Header Text:** C4591001

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

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

**Site No:** 1231

**Subject No:** 12311862

**Generated By:**

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**Form:** INCLUSION/EXCLUSION CRITERIA

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

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

**Subject Initials:** ---

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

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

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**Header Text:** C4591001

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

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

**Site No:** 1231

**Subject No:** 12311862

**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/17/2020
2.	Phase of Disposition:	SCREENING
3.	Status:	COMPLETED
4.	Specify Status:	[ ]

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**Header Text:** C4591001

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

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

**Site No:** 1231

**Subject No:** 12311862

**Generated By:**

(b) (4)

**Form:** GENERAL MEDICAL HISTORY

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

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

**Subject Initials:** ---

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

[eCRF Audit Trail History](#)

**Medical History Details**

1.a	Line/MH Number:	[1]
	Disease/Syndrome /Surgery/Non-Drug Allergies/Drug Allergies:	[Bicuspid aortic valve]
	Start Date:	Jun/1/2004
	Ongoing:	NO
		End Date: Mar/2/2021

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**Header Text:** C4591001

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

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

**Site No:** 1231

**Subject No:** 12311862

**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/17/2020
2.	Weight:	[61.0]
3.	Unit:	kg
4.	Height:	[171.0]
5.	Unit:	cm
6.	Body Mass Index:	[20.9]

**Vital Signs Details**

7.a	Record Identifier:	1
	Temperature:	[36.2]
	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:** 12311862

**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/17/2020
2.	Randomization Number:	[53495]
3.	Randomization Group:	[ ]

**Header Text:** C4591001

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

**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

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

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

**Site No:** 1231

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

**Subject No:** 12311862

**Subject Initials:** ---

**Generated By:**

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

(b) (4)

[eCRF Audit Trail History](#)

**Electronic Sample Tracking**

1.	Data Origin	SITE
2.	Sample Type	SERUM
3.	Sample Collected?	YES Date of Collection: Aug/17/2020
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	[BPHZ7Y]
5.b	Sample ID	[BPHZ7Z]
5.c	Sample ID	[BHWSTT]
5.d	Sample ID	[BHWSTV]
5.e	Sample ID	[BHWSTW]

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**Header Text:** C4591001

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

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

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

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

**Site No:** 1231

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

**Subject No:** 12311862

**Subject Initials:** ---

**Generated By:**

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

(b) (4)

[eCRF Audit Trail History](#)

**Electronic Sample Tracking**

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB
3.	Sample Collected?	YES Date of Collection: Aug/17/2020
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	[BHWSRJ]
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**Header Text:** C4591001

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

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

**Site No:** 1231

**Subject No:** 12311862

**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/17/2020 18:36
5.	Anatomical Location:	DELTOID MUSCLE
6.	Body Side:	LEFT
7.	Route:	INTRAMUSCULAR
8.	Actual Dose:	[ ]
9.	Unit:	
10.	Timeframe Subject Was Observed	THE PROTOCOL SPECIFIED OBSERVATION PERIOD
11.	Was the subject observed for at least the protocol specified observation period after investigational product administration?	YES

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**Header Text:** C4591001

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

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

**Site No:** 1231

**Subject No:** 12311862

**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:** 12311862

**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/9/2020
2.	Erroneous Visit	

**Header Text:** C4591001

**Visit:** V2\_VAX2\_L

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

**Site No:** 1231

**Subject No:** 12311862

**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/9/2020
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**Vital Signs Details**

2.a	Record Identifier:	1
	Temperature:	[36.9]
	Unit:	C
	Temperature Location:	ORAL CAVITY

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**Header Text:** C4591001

**Visit:** V2\_VAX2\_L

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

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

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

**Site No:** 1231

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

**Subject No:** 12311862

**Subject Initials:** ---

**Generated By:**

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

(b) (4)

[eCRF Audit Trail History](#)

**Electronic Sample Tracking**

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB
3.	Sample Collected?	YES Date of Collection: Sep/9/2020
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	[BP1YX4]
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**Header Text:** C4591001

**Visit:** V2\_VAX2\_L

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

**Site No:** 1231

**Subject No:** 12311862

**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/9/2020 16:16
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:** 12311862 **Subject Initials:** ---

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

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**Date of Visit**

1.	Date of Visit	Oct/13/2020
2.	Erroneous Visit	

**Header Text:** C4591001**Visit:** V3\_MONTH1\_POSTVAX2\_L **Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY**Form Version:** 22-Apr-2020 21:03 **Form Status:** Data Complete, Locked, Frozen, Verified**Site No:** 1231 **Site Name:** (1231) Hospital Militar Central Cirujano Mayor Dr. Cosme Argerich**Subject No:** 12311862 **Subject Initials:** ---**Generated By:** (b) (4) **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/13/2020
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	[BRXPZL]
5.b	Sample ID	[BRXR01]
5.c	Sample ID	[BPT7TP]



**Header Text:** C4591001

**Visit:** V4\_MONTH6\_L

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

**Site No:** 1231

**Subject No:** 12311862

**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:** V4\_MONTH6\_L

**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:** 12311862

**Subject Initials:** ---

**Generated By:**

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

(b) (4)

**Electronic Sample Tracking**

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

**Aliquot**

Please enter barcode for each aliquot.

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

**Visit:** V5\_MONTH12\_L

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

**Site No:** 1231

**Subject No:** 12311862

**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:** 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:** 12311862

**Subject Initials:** ---

**Generated By:**

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

(b) (4)

**Electronic Sample Tracking**

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

**Aliquot**

Please enter barcode for each aliquot.

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

**Visit:** V6\_MONTH24\_L

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

**Site No:** 1231

**Subject No:** 12311862

**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:** 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:** 12311862

**Subject Initials:** ---

**Generated By:**

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

(b) (4)

**Electronic Sample Tracking**

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

**Aliquot**

Please enter barcode for each aliquot.

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

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Oct/21/2020

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

**Site No:** 1231

**Subject No:** 12311862

**Generated By:**

(b) (4)

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

**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](#)

**Date of Visit**

1.	Date of Visit	Oct/21/2020
2.	Erroneous Visit	

**COVID-19 Illness Visit**

3.	COVID-19 Illness Visit:	COVID_A
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090177e196ae2ea4\Final\Final On: 01-Apr-2021 03:19 (GMT)

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Oct/21/2020

**Form Version:** 10-Oct-2020 16:02

**Site No:** 1231

**Subject No:** 12311862

**Generated By:**

(b) (4)

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

**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](#)

**Signs and Symptoms**

1.	Date of Assessment:	Oct/21/2020
2.	Date of First Symptom Started:	Oct/13/2020
3.	Symptoms Ongoing?	NO Date of Last Symptom Resolved: Nov/2/2020

**Symptoms**

4.a	Symptoms:	FEVER
	Was symptom present?	NO
4.b	Symptoms:	NEW OR INCREASED COUGH
	Was symptom present?	NO
4.c	Symptoms:	NEW OR INCREASED SHORTNESS OF BREATH
	Was symptom present?	YES
4.d	Symptoms:	CHILLS
	Was symptom present?	NO
4.e	Symptoms:	NEW OR INCREASED MUSCLE PAIN
	Was symptom present?	NO

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**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Oct/21/2020

**Form Version:** 10-Oct-2020 16:02

**Site No:** 1231

**Subject No:** 12311862

**Generated By:**

(b) (4)

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

**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

4.f	Symptoms:	NEW LOSS OF TASTE OR SMELL
	Was symptom present?	NO
4.g	Symptoms:	NEW OR INCREASED SORE THROAT
	Was symptom present?	NO
4.h	Symptoms:	DIARRHEA
	Was symptom present?	NO
4.i	Symptoms:	VOMITING
	Was symptom present?	NO
<b>Symptoms - Other</b>		
5.	Symptoms - Other Text:	[ ]

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**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1

**Form:** MICROBIOLOGY SPECIMEN

**Form Version:** 06-Jul-2020 21:54

**Site No:** 1231

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

**Subject No:** 12311862

**Subject Initials:** ---

**Generated By:**

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

(b) (4)

#	Date of Collection	Specimen Type	Specimen Collection Location	Assay Code and Description	Device Type	Form Instance
1.	Oct/21/2020	SWABBED MATERIAL	NASOPHARYNX	SEVERE ACUTE RESPIRATORY SYNDROME CORONAVIRUS 2	SARS-COV-2 DIAGNOSTIC TEST	<a href="#">Repeating Pages</a>

090177e196ae2ea4\Final\Final On: 01-Apr-2021 03:19 (GMT)

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Oct/21/2020

**Form:** MICROBIOLOGY SPECIMEN

**Form Version:** 06-Jul-2020 21:54

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

**Site No:** 1231

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

**Subject No:** 12311862

**Subject Initials:** ---

**Generated By:**

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

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[Form Audit Trail](#)

**Microbiology Specimen**

1.	Actual Date of Collection:	Oct/21/2020
2.	Specimen Type:	SWABBED MATERIAL
3.	Specimen Collection Location:	NASOPHARYNX
4.	Assay Code and Description:	SEVERE ACUTE RESP SYNDROME CORONAVIRUS 2
5.	Device Type:	SARS-COV-2 DIAGNOSTIC TEST
6.	Trade Name:	ATILA BIOSYSTEMS IAMP COVID-19 DETECTION KIT
7.	Test Result:	NEGATIVE
8.	Comments/Findings/Details:	[ ]
9.	Trade Name Other, Specify:	[ ]

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**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Oct/21/2020

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

**Site No:** 1231

**Subject No:** 12311862

**Generated By:**

(b) (4)

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

**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](#)

**Electronic Sample Tracking**

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

**Aliquot**

Please enter barcode for each aliquot.

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

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Oct/21/2020

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

**Site No:** 1231

**Subject No:** 12311862

**Generated By:**

(b) (4)

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

**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](#)

**Electronic Sample Tracking**

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB
3.	Sample Collected?	YES Date of Collection: Oct/21/2020
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	[BPT7X4]
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**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Oct/21/2020

**Form:** HEALTH CARE UTILIZATION

**Form Version:** 10-Oct-2020 15:59

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

**Site No:** 1231

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

**Subject No:** 12311862

**Subject Initials:** ---

**Generated By:**

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

(b) (4)

[eCRF Audit Trail History](#)

**Health Care Utilization**

1.a	Physician or Healthcare Professional:	SPECIALIST
	Occurrence of Visits or Contacts:	NO
1.b	Physician or Healthcare Professional:	EMERGENCY ROOM
	Occurrence of Visits or Contacts:	NO
1.c	Physician or Healthcare Professional:	PRIMARY CARE PHYSICIAN
	Occurrence of Visits or Contacts:	NO
1.d	Physician or Healthcare Professional:	URGENT CARE
	Occurrence of Visits or Contacts:	NO
1.e	Physician or Healthcare Professional:	TELEPHONE CONSULTATION
	Occurrence of Visits or Contacts:	NO

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**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Oct/21/2020

**Form:** HEALTH CARE UTILIZATION

**Form Version:** 10-Oct-2020 15:59

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

**Site No:** 1231

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

**Subject No:** 12311862

**Subject Initials:** ---

**Generated By:**

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

(b) (4)

1.f	Physician or Healthcare Professional:	OTHER
	Occurrence of Visits or Contacts:	NO

**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?	NO
----	--	----

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**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1

**Form:** RESPIRATORY TREATMENT

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

**Site No:** 1231

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

**Subject No:** 12311862

**Subject Initials:** ---

**Generated By:**

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

(b) (4)

#	Treatment Identifier	Con Non-Drug Treatments Pre-specified	Treatm ent	Treatm ent	Start D ate	Form Instanc e
1.						<a href="#">Repeating Pages</a>



**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Oct/21/2020

**Form:** RESPIRATORY TREATMENT

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

**Form Status:** Not Started

**Site No:** 1231

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

**Subject No:** 12311862

**Subject Initials:** ---

**Generated By:**

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

(b) (4)

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**Respiratory Treatment**

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

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**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Oct/21/2020

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

**Site No:** 1231

**Subject No:** 12311862

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

**Form:** ILLNESS DETAILS

**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](#)

**Illness Details**

1.	Category of Clinical Event:	POTENTIAL COVID-19 ILLNESS
2.	Was a diagnosis obtained for Potential COVID-19 Illness?	NO
3.	Toxicity Grade:	2

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**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1

**Form:** ILLNESS DETAILS - SEVERE

**Form Version:** 17-Jul-2020 21:55

**Site No:** 1231

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

**Subject No:** 12311862

**Subject Initials:** ---

**Generated By:**

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

(b) (4)

#	Category of Clinical Event:	Subcategory of Clinical Event	Diagnosis Obtained	Toxicity Grade	Form Instance
1.					<a href="#">Repeating Pages</a>

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Oct/21/2020

**Form Version:** 17-Jul-2020 21:55

**Site No:** 1231

**Subject No:** 12311862

**Generated By:**

(b) (4)

**Form:** ILLNESS DETAILS - SEVERE

**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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**Illness Details**

1.	Category of Clinical Event:	
2.	Subcategory of Clinical Event:	
3.	Was a diagnosis obtained?	
4.	Toxicity Grade:	

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**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1

**Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY

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

**Site No:** 1231

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

**Subject No:** 12311862

**Subject Initials:** ---

**Generated By:**

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

(b) (4)

#	Category for Lab Test	Vendor Name	Collection Date:	Specimen Type	Lab Result			Form Instance
1.					Sponsor-Defined Identifier	Test:	Result:	<a href="#">Repeating Pages</a>

090177e196ae2ea4\Final\Final On: 01-Apr-2021 03:19 (GMT)

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Oct/21/2020

**Form:** LOCAL LABORATORY DATA - REPEATING  
CHEMISTRY

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

**Form Status:** Not Started

**Site No:** 1231

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

**Subject No:** 12311862

**Subject Initials:** ---

**Generated By:**

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

(b) (4)

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**Lab Chemistry Details**

1.	Lab Panel:	
2.	Laboratory Name and Address	[ ]
3.	Collection Date:	//
4.	Specimen Type:	

**Lab Result**

5.	Sponsor ID:	[ ]
	Test:	
	Result:	[ ]
	Not Done:	
	LNMT	Low [ ] High [ ] Unit

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**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1

**Form:** LOCAL LABORATORY DATA - REPEATING Hematology

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

**Site No:** 1231

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

**Subject No:** 12311862

**Subject Initials:** ---

**Generated By:**

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

(b) (4)

#	Category for Lab Test	Vendor Name (DERIVED)	Collection Date:	Specimen Type	Lab Result			Form Instance
1.					Sponsor-Defined Identifier	Test:	Result:	<a href="#">Repeating Pages</a>

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**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Oct/21/2020

**Form:** LOCAL LABORATORY DATA - REPEATING  
Hematology

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

**Form Status:** Not Started

**Site No:** 1231

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

**Subject No:** 12311862

**Subject Initials:** ---

**Generated By:**

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

(b) (4)

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**Laboratory Data Hematology**

1.	Lab Panel:	
2.	Laboratory Name and Address	[ ]
3.	Collection Date:	//
4.	Specimen Type:	

**Lab Result**

5.	Sponsor ID:	[ ]
	Test:	
	Result:	[ ]
	Not Done:	
	LNMT	Low [ ] High [ ] Unit

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**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1

**Form:** VITAL SIGNS - COVID

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

**Site No:** 1231

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

**Subject No:** 12311862

**Subject Initials:** ---

**Generated By:**

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

(b) (4)

#	Date:	Vital Signs Details			Form Instance
1.		<b>Record Identifier:</b>	<b>Systolic:</b>	<b>Diastolic:</b>	<a href="#">Repeating Pages</a>

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Oct/21/2020

**Form:** VITAL SIGNS - COVID

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

**Form Status:** Not Started

**Site No:** 1231

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

**Subject No:** 12311862

**Subject Initials:** ---

**Generated By:**

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

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**Vital Signs**

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

**Vital Signs Details**

2.	Record Identifier:	
	Systolic:	[ ]
	Diastolic:	[ ]
	Respiratory Rate in respirations/minute:	[ ]
	Heart Rate in beats/minute:	[ ]

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**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1

**Form:** VITAL SIGNS - PULSE OX ROOM AIR

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

**Site No:** 1231

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

**Subject No:** 12311862

**Subject Initials:** ---

**Generated By:**

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

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#	Date:	Vital Signs Details		Form Instance
1.		<b>Record Identifier:</b>	<b>Oxygen Saturation</b>	<a href="#">Repeating Pages</a>

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Oct/21/2020

**Form:** VITAL SIGNS - PULSE OX ROOM AIR

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

**Form Status:** Not Started

**Site No:** 1231

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

**Subject No:** 12311862

**Subject Initials:** ---

**Generated By:**

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

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**Vital Signs**

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

**Vital Signs Details**

2.	Record Identifier:	
	SPO2 Pulse Oximetry %	[ ]

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1

**Form:** OXYGENATION PARAMETERS

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

**Site No:** 1231

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

**Subject No:** 12311862

**Subject Initials:** ---

**Generated By:**

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

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#	Date Time of Assessment	Arterial Blood Gases PaO2	FiO2 (Fraction of Inhaled Oxygen)	Form Instance
1.				<a href="#">Repeating Pages</a>

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**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Oct/21/2020

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

**Site No:** 1231

**Subject No:** 12311862

**Generated By:**

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**Form:** OXYGENATION PARAMETERS

**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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**Oxygenation Parameters**

1.	Date Time of Assessment:	//
2.	Arterial Blood Gases PaO2 (mmHg):	[ ]
3.	FiO2 (Fraction of Inhaled Oxygen):	[ ]

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**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1

**Form:** CONCOMITANT MEDICATIONS -  
VASOPRESSORS

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

**Site No:** 1231

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

**Subject No:** 12311862

**Subject Initials:** ---

**Generated By:**

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

(b) (4)

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

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Oct/21/2020

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

**Site No:** 1231

**Subject No:** 12311862

**Generated By:**

(b) (4)

**Form:** CONCOMITANT MEDICATIONS -  
VASOPRESSORS

**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.	Start Date:	//
6.	Ongoing?	

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**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1

**Form:** IMAGING

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

**Site No:** 1231

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

**Subject No:** 12311862

**Subject Initials:** ---

**Generated By:**

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

(b) (4)

#	Date of Assessment	Location of Assessment	Imaging Method	Overall Assessment	Form Instance
1.					<a href="#">Repeating Pages</a>

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Oct/21/2020

**Form:** IMAGING

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

**Form Status:** Not Started

**Site No:** 1231

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

**Subject No:** 12311862

**Subject Initials:** ---

**Generated By:**

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

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**Imaging**

1.	Date of Assessment:	//
2.	Location of Assessment:	
3.	Type of Imaging Exam:	
4.	Assessment:	

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**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 2 -  
Unscheduled Visit on Dec/12/2020

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

**Site No:** 1231

**Subject No:** 12311862

**Generated By:**

(b) (4)

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

**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](#)

**Date of Visit**

1.	Date of Visit	Dec/12/2020
2.	Erroneous Visit	

**COVID-19 Illness Visit**

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

090177e196ae2ea4\Final\Final On: 01-Apr-2021 03:19 (GMT)

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 2 -  
Unscheduled Visit on Dec/12/2020

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

**Form Version:** 10-Dec-2020 02:29

**Form Status:** Data Complete, Frozen, Not Complete

**Site No:** 1231

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

**Subject No:** 12311862

**Subject Initials:** ---

**Generated By:**

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

(b) (4)

[eCRF Audit Trail History](#)

**Signs and Symptoms**

1.	Date of Assessment:	Dec/12/2020
2.	Date of First Symptom Started:	Nov/27/2020
3.	Symptoms Ongoing?	NO Date of Last Symptom Resolved: Dec/17/2020

**Symptoms**

4.a	Symptoms:	FEVER
	Was symptom present?	NO
4.b	Symptoms:	NEW OR INCREASED COUGH
	Was symptom present?	YES
4.c	Symptoms:	NEW OR INCREASED SHORTNESS OF BREATH
	Was symptom present?	YES
4.d	Symptoms:	CHILLS
	Was symptom present?	NO
4.e	Symptoms:	NEW OR INCREASED MUSCLE PAIN
	Was symptom present?	NO

090177e196ae2ea4\Final\Final On: 01-Apr-2021 03:19 (GMT)

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 2 -  
Unscheduled Visit on Dec/12/2020

**Form Version:** 10-Dec-2020 02:29

**Site No:** 1231

**Subject No:** 12311862

**Generated By:**

(b) (4)

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

**Form Status:** Data Complete, Frozen, Not Complete

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

**Subject Initials:** ---

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

4.f	Symptoms:	NEW LOSS OF TASTE OR SMELL
	Was symptom present?	NO
4.g	Symptoms:	NEW OR INCREASED SORE THROAT
	Was symptom present?	NO
4.h	Symptoms:	DIARRHEA
	Was symptom present?	NO
4.i	Symptoms:	VOMITING
	Was symptom present?	NO
<b>Symptoms - Other</b>		
5.a	Symptoms - Other Text:	[Hypotension symptoms while making physical effort]
5.b	Symptoms - Other Text:	[Blurred vision]
5.c	Symptoms - Other Text:	[Dizziness]
5.d	Symptoms - Other Text:	[Palpitations]

090177e196ae2ea4\Final\Final On: 01-Apr-2021 03:19 (GMT)

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 2

**Form:** MICROBIOLOGY SPECIMEN

**Form Version:** 06-Jul-2020 21:54

**Site No:** 1231

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

**Subject No:** 12311862

**Subject Initials:** ---

**Generated By:**

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

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#	Date of Collection	Specimen Type	Specimen Collection Location	Assay Code and Description	Device Type	Form Instance
1.	Dec/9/2020	SWABBED MATERIAL	NASOPHARYNX	SEVERE ACUTE RESPIRATORY SYNDROME CORONAVIRUS 2	SARS-COV-2 DIAGNOSTIC TEST	<a href="#">Repeating Pages</a>
2.	Dec/12/2020	SWABBED MATERIAL	NASOPHARYNX	SEVERE ACUTE RESPIRATORY SYNDROME CORONAVIRUS 2	SARS-COV-2 DIAGNOSTIC TEST	<a href="#">Repeating Pages</a>

090177e196ae2ea4\Final\Final On: 01-Apr-2021 03:19 (GMT)

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 2 -  
Unscheduled Visit on Dec/12/2020

**Form:** MICROBIOLOGY SPECIMEN

**Form Version:** 06-Jul-2020 21:54

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

**Site No:** 1231

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

**Subject No:** 12311862

**Subject Initials:** ---

**Generated By:**

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

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[Form Audit Trail](#)

**Microbiology Specimen**

1.	Actual Date of Collection:	Dec/9/2020
2.	Specimen Type:	SWABBED MATERIAL
3.	Specimen Collection Location:	NASOPHARYNX
4.	Assay Code and Description:	SEVERE ACUTE RESP SYNDROME CORONAVIRUS 2
5.	Device Type:	SARS-COV-2 DIAGNOSTIC TEST
6.	Trade Name:	OTHER
7.	Test Result:	NEGATIVE
8.	Comments/Findings/Details:	[Subject got swabbed at "Hospital Posadas"]
9.	Trade Name Other, Specify:	[NALT Unknown]

090177e196ae2ea4\Final\Final On: 01-Apr-2021 03:19 (GMT)

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 2 -  
Unscheduled Visit on Dec/12/2020

**Form:** MICROBIOLOGY SPECIMEN

**Form Version:** 06-Jul-2020 21:54

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

**Site No:** 1231

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

**Subject No:** 12311862

**Subject Initials:** ---

**Generated By:**

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

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[eCRF Audit Trail History](#)

[Form Audit Trail](#)

### Microbiology Specimen

1.	Actual Date of Collection:	Dec/12/2020
2.	Specimen Type:	SWABBED MATERIAL
3.	Specimen Collection Location:	NASOPHARYNX
4.	Assay Code and Description:	SEVERE ACUTE RESP SYNDROME CORONAVIRUS 2
5.	Device Type:	SARS-COV-2 DIAGNOSTIC TEST
6.	Trade Name:	ATILA BIOSYSTEMS IAMP COVID-19 DETECTION KIT
7.	Test Result:	NEGATIVE
8.	Comments/Findings/Details:	[ ]
9.	Trade Name Other, Specify:	[ ]

090177e196ae2ea4\Final\Final On: 01-Apr-2021 03:19 (GMT)



**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 2 -  
Unscheduled Visit on Dec/12/2020

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

**Site No:** 1231

**Subject No:** 12311862

**Generated By:**

(b) (4)

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

**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](#)

**Electronic Sample Tracking**

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

**Aliquot**

Please enter barcode for each aliquot.

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

090177e196ae2ea4\Final\Final On: 01-Apr-2021 03:19 (GMT)

**Header Text:** C4591001**Visit:** POT\_COVID\_ILL 2 -  
Unscheduled Visit on Dec/12/2020**Form:** ELECTRONIC SAMPLE TRACKING - NASAL  
SWAB**Form Version:** 22-Apr-2020 21:03**Form Status:** Data Complete, Frozen, Verified**Site No:** 1231**Site Name:** (1231) Hospital Militar Central Cirujano  
Mayor Dr. Cosme Argerich**Subject No:** 12311862**Subject Initials:** ---**Generated By:****Generated Time (GMT):** 29-Mar-2021 16:45

(b) (4)

**eCRF Audit Trail History****Electronic Sample Tracking**

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB
3.	Sample Collected?	YES Date of Collection: Dec/12/2020
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	[BPWSYG]
-----	-----------	----------

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 2 -  
Unscheduled Visit on Dec/12/2020

**Form:** HEALTH CARE UTILIZATION

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

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

**Site No:** 1231

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

**Subject No:** 12311862

**Subject Initials:** ---

**Generated By:**

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

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[eCRF Audit Trail History](#)

**Health Care Utilization**

1.a	Physician or Healthcare Professional:	SPECIALIST
	Occurrence of Visits or Contacts:	NO
1.b	Physician or Healthcare Professional:	EMERGENCY ROOM
	Occurrence of Visits or Contacts:	NO
1.c	Physician or Healthcare Professional:	PRIMARY CARE PHYSICIAN
	Occurrence of Visits or Contacts:	NO
1.d	Physician or Healthcare Professional:	URGENT CARE
	Occurrence of Visits or Contacts:	YES Number of Visits or Contacts: [2]

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**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 2 -  
Unscheduled Visit on Dec/12/2020

**Form:** HEALTH CARE UTILIZATION

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

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

**Site No:** 1231

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

**Subject No:** 12311862

**Subject Initials:** ---

**Generated By:**

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

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1.e	Physician or Healthcare Professional:	TELEPHONE CONSULTATION
	Occurrence of Visits or Contacts:	NO
1.f	Physician or Healthcare Professional:	OTHER
	Occurrence of Visits or Contacts:	NO
<b>Health Care Utilization Other</b>		
2.	Other Type of Practitioner Specify:	[ ]
<b>Health Care Utilization</b>		
3.	Has the subject been hospitalized due to potential COVID-19 illness?	NO

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**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 2

**Form:** RESPIRATORY TREATMENT

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

**Site No:** 1231

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

**Subject No:** 12311862

**Subject Initials:** ---

**Generated By:**

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

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#	Treatment Identifier	Con Non-Drug Treatments Pre-specified	Treatm ent	Treatm ent	Start D ate	Form Instanc e
1.	[ ]			[ ]		<a href="#">Repeating Pages</a>

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 2 -  
Unscheduled Visit on Dec/12/2020

**Form:** RESPIRATORY TREATMENT

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

**Form Status:** Not Started

**Site No:** 1231

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

**Subject No:** 12311862

**Subject Initials:** ---

**Generated By:**

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

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**Respiratory Treatment**

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

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**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 2 -  
Unscheduled Visit on Dec/12/2020

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

**Site No:** 1231

**Subject No:** 12311862

**Generated By:**

(b) (4)

**Form:** ILLNESS DETAILS

**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](#)

**Illness Details**

1.	Category of Clinical Event:	POTENTIAL COVID-19 ILLNESS
2.	Was a diagnosis obtained for Potential COVID-19 Illness?	NO
3.	Toxicity Grade:	2

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**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 2

**Form:** ILLNESS DETAILS - SEVERE

**Form Version:** 17-Jul-2020 21:55

**Site No:** 1231

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

**Subject No:** 12311862

**Subject Initials:** ---

**Generated By:**

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

(b) (4)

#	Category of Clinical Event:	Subcategory of Clinical Event	Diagnosis Obtained	Toxicity Grade	Form Instance
1.					<a href="#">Repeating Pages</a>



**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 2 -  
Unscheduled Visit on Dec/12/2020

**Form:** ILLNESS DETAILS - SEVERE

**Form Version:** 17-Jul-2020 21:55

**Form Status:** Not Started

**Site No:** 1231

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

**Subject No:** 12311862

**Subject Initials:** ---

**Generated By:**

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

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**Illness Details**

1.	Category of Clinical Event:	
2.	Subcategory of Clinical Event:	
3.	Was a diagnosis obtained?	
4.	Toxicity Grade:	

090177e196ae2ea4\Final\Final On: 01-Apr-2021 03:19 (GMT)

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 2

**Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY

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

**Site No:** 1231

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

**Subject No:** 12311862

**Subject Initials:** ---

**Generated By:**

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

(b) (4)

#	Category for Lab Test	Vendor Name	Collection Date:	Specimen Type	Lab Result			Form Instance
1.		[ ]			Sponsor-Defined Identifier	Test:	Result:	<a href="#">Repeating Pages</a>

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 2 -  
Unscheduled Visit on Dec/12/2020

**Form:** LOCAL LABORATORY DATA - REPEATING  
CHEMISTRY

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

**Form Status:** Not Started

**Site No:** 1231

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

**Subject No:** 12311862

**Subject Initials:** ---

**Generated By:**

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

(b) (4)

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**Lab Chemistry Details**

1.	Lab Panel:	
2.	Laboratory Name and Address	[ ]
3.	Collection Date:	//
4.	Specimen Type:	

**Lab Result**

5.	Sponsor ID:	[ ]
	Test:	
	Result:	[ ]
	Not Done:	
	LNMT	Low [ ] High [ ] Unit

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**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 2

**Form:** LOCAL LABORATORY DATA - REPEATING Hematology

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

**Site No:** 1231

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

**Subject No:** 12311862

**Subject Initials:** ---

**Generated By:**

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

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#	Category f or Lab Tes t	Vendor Nam e (DERIVED )	Collecti on Date:	Specim en Type	Lab Result			Form Instan ce
1.					Sponsor-Defi ned Identifie r	Te st:	Res ult:	<a href="#">Repeating Pages</a>

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 2 -  
Unscheduled Visit on Dec/12/2020

**Form:** LOCAL LABORATORY DATA - REPEATING  
Hematology

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

**Form Status:** Not Started

**Site No:** 1231

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

**Subject No:** 12311862

**Subject Initials:** ---

**Generated By:**

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

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**Laboratory Data Hematology**

1.	Lab Panel:	
2.	Laboratory Name and Address	[ ]
3.	Collection Date:	//
4.	Specimen Type:	

**Lab Result**

5.	Sponsor ID:	[ ]
	Test:	
	Result:	[ ]
	Not Done:	
	LNMT	Low [ ] High [ ] Unit

090177e196ae2ea4\Final\Final On: 01-Apr-2021 03:19 (GMT)

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 2

**Form:** VITAL SIGNS - COVID

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

**Site No:** 1231

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

**Subject No:** 12311862

**Subject Initials:** ---

**Generated By:**

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

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#	Date:	Vital Signs Details			Form Instance
1.		<b>Record Identifier:</b>	<b>Systolic:</b>	<b>Diastolic:</b>	<a href="#">Repeating Pages</a>

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 2 -  
Unscheduled Visit on Dec/12/2020

**Form:** VITAL SIGNS - COVID

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

**Form Status:** Not Started

**Site No:** 1231

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

**Subject No:** 12311862

**Subject Initials:** ---

**Generated By:**

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

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**Vital Signs**

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

**Vital Signs Details**

2.	Record Identifier:	
	Systolic:	[ ]
	Diastolic:	[ ]
	Respiratory Rate in respirations/minute:	[ ]
	Heart Rate in beats/minute:	[ ]

090177e196ae2ea4\Final\Final On: 01-Apr-2021 03:19 (GMT)

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 2

**Form:** VITAL SIGNS - PULSE OX ROOM AIR

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

**Site No:** 1231

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

**Subject No:** 12311862

**Subject Initials:** ---

**Generated By:**

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

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#	Date:	Vital Signs Details		Form Instance
1.		<b>Record Identifier:</b>	<b>Oxygen Saturation</b>	<a href="#">Repeating Pages</a>



**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 2 -  
Unscheduled Visit on Dec/12/2020

**Form:** VITAL SIGNS - PULSE OX ROOM AIR

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

**Form Status:** Not Started

**Site No:** 1231

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

**Subject No:** 12311862

**Subject Initials:** ---

**Generated By:**

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

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**Vital Signs**

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

**Vital Signs Details**

2.	Record Identifier:	
	SPO2 Pulse Oximetry %	[ ]

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**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 2

**Form:** OXYGENATION PARAMETERS

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

**Site No:** 1231

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

**Subject No:** 12311862

**Subject Initials:** ---

**Generated By:**

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

(b) (4)

#	Date Time of Assessment	Arterial Blood Gases PaO2	FiO2 (Fraction of Inhaled Oxygen)	Form Instance
1.				<a href="#">Repeating Pages</a>

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 2 -  
Unscheduled Visit on Dec/12/2020

**Form:** OXYGENATION PARAMETERS

**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:** 12311862

**Subject Initials:** ---

**Generated By:**

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

(b) (4)

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**Oxygenation Parameters**

1.	Date Time of Assessment:	//
2.	Arterial Blood Gases PaO2 (mmHg):	[ ]
3.	FiO2 (Fraction of Inhaled Oxygen):	[ ]

090177e196ae2ea4\Final\Final On: 01-Apr-2021 03:19 (GMT)

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 2

**Form:** CONCOMITANT MEDICATIONS -  
VASOPRESSORS

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

**Site No:** 1231

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

**Subject No:** 12311862

**Subject Initials:** ---

**Generated By:**

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

(b) (4)

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

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 2 -  
Unscheduled Visit on Dec/12/2020

**Form:** CONCOMITANT MEDICATIONS -  
VASOPRESSORS

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

**Form Status:** Not Started

**Site No:** 1231

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

**Subject No:** 12311862

**Subject Initials:** ---

**Generated By:**

**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.	Start Date:	//
6.	Ongoing?	

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**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 2

**Form:** IMAGING

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

**Site No:** 1231

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

**Subject No:** 12311862

**Subject Initials:** ---

**Generated By:**

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

(b) (4)

#	Date of Assessment	Location of Assessment	Imaging Method	Overall Assessment	Form Instance
1.					<a href="#">Repeating Pages</a>

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 2 -  
Unscheduled Visit on Dec/12/2020

**Form:** IMAGING

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

**Form Status:** Not Started

**Site No:** 1231

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

**Subject No:** 12311862

**Subject Initials:** ---

**Generated By:**

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

(b) (4)

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**Imaging**

1.	Date of Assessment:	//
2.	Location of Assessment:	
3.	Type of Imaging Exam:	
4.	Assessment:	

090177e196ae2ea4\Final\Final On: 01-Apr-2021 03:19 (GMT)

**Header Text:** C4591001

**Visit:** POT\_COVID\_CONVA 1 -  
Unscheduled Visit on Nov/19/2020

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

**Site No:** 1231

**Subject No:** 12311862

**Generated By:**

(b) (4)

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

**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](#)

**Date of Visit**

1.	Date of Visit	Nov/19/2020
2.	Erroneous Visit	

**COVID-19 Illness Visit**

3.	COVID-19 Illness Visit:	COVID_A1
----	-------------------------	----------

090177e196ae2ea4\Final\Final On: 01-Apr-2021 03:19 (GMT)



**Header Text:** C4591001

**Visit:** POT\_COVID\_CONVA 1 -  
Unscheduled Visit on Nov/19/2020

**Form:** ELECTRONIC SAMPLE TRACKING -  
IMMUNOGENICITY

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

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

**Site No:** 1231

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

**Subject No:** 12311862

**Subject Initials:** ---

**Generated By:**

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

(b) (4)

[eCRF Audit Trail History](#)

**Electronic Sample Tracking**

1.	Data Origin	SITE
2.	Sample Type	SERUM
3.	Sample Collected?	YES Date of Collection: Nov/19/2020
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	[BPXJDK]
5.b	Sample ID	[BRVMC8]
5.c	Sample ID	[BRVMCG]

090177e196ae2ea4\Final\Final On: 01-Apr-2021 03:19 (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:** 12311862      **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:** 12311862      **Subject Initials:** ---

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

**Unplanned Assessments**

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

**Header Text:** C4591001

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

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

**Site No:** 1231

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

**Subject No:** 12311862

**Subject Initials:** ---

**Generated By:**

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

(b) (4)

[eCRF Audit Trail History](#)

**Disposition - Treatment**

1.	Date of Completion/Discontinuation /Death :	Oct/13/2020
2.	Phase of Disposition:	VACCINATION
3.	Status:	COMPLETED
4.	Specify Status:	[ ]

090177e196ae2ea4\Final\Final On: 01-Apr-2021 03:19 (GMT)

**Header Text:** C4591001

**Visit:** Follow-Up - Unscheduled

**Form:** DISPOSITION - FOLLOW-UP

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

**Form Status:** Not Started

**Site No:** 1231

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

**Subject No:** 12311862

**Subject Initials:** ---

**Generated By:**

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

(b) (4)

**Disposition - Follow-Up**

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

090177e196ae2ea4\Final\Final On: 01-Apr-2021 03:19 (GMT)

**Header Text:** C4591001

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

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

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

**Subject No:** 12311862 **Subject Initials:** ---

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

(b) (4)

**Date of Visit**

1.	Date of Visit	//
2.	Erroneous Visit	

**COVID-19 Repeat Swab**

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

**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:** 12311862      **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	[ ]
----	-----------	-----

090177e196ae2ea4\Final\Final On: 01-Apr-2021 03:19 (GMT)

**Header Text:** C4591001

**Visit:** Unplanned Vaccination -  
Unscheduled

**Form:** DATE OF VISIT

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

**Form Status:** Not Started

**Site No:** 1231

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

**Subject No:** 12311862

**Subject Initials:** ---

**Generated By:**

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

(b) (4)

**Date of Visit**

1.	Date of Visit	//
2.	Erroneous Visit	



**Header Text:** C4591001

**Visit:** Unplanned Vaccination -  
Unscheduled

**Form:** VITAL SIGNS - TEMP

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

**Form Status:** Not Started

**Site No:** 1231

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

**Subject No:** 12311862

**Subject Initials:** ---

**Generated By:**

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

(b) (4)

**Vital Signs**

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

**Vital Signs Details**

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

090177e196ae2ea4\Final\Final On: 01-Apr-2021 03:19 (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:** 12311862

**Subject Initials:** ---

**Generated By:**

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

(b) (4)

**Vaccination**

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

090177e196ae2ea4\Final\Final On: 01-Apr-2021 03:19 (GMT)

**Header Text:** C4591001

**Visit:** Unplanned Vaccination -  
Unscheduled

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

**Site No:** 1231

**Subject No:** 12311862

**Generated By:**

(b) (4)

**Form:** CONTACT OUTCOME - MONTH 1

**Form Status:** Not Started

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

**Subject Initials:** ---

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

**Contact Outcome**

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

**Header Text:** C4591001

**Visit:** Unplanned Vaccination -  
Unscheduled

**Form:** 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:** 12311862

**Subject Initials:** ---

**Generated By:**

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

(b) (4)

**Contact Outcome**

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

**Header Text:** C4591001

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

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

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

**Subject No:** 12311862 **Subject Initials:** ---

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

(b) (4)

**Date of Visit**

1.	Date of Visit	//
2.	Erroneous Visit	

**Header Text:** C4591001

**Visit:** V201\_SURVEIL\_CONSENT -  
Unscheduled

**Form:** INFORMED CONSENT - ASYMPTOMATIC  
SURVEILLANCE

**Form Version:** 14-Jan-2021 02:29

**Form Status:** Not Started

**Site No:** 1231

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

**Subject No:** 12311862

**Subject Initials:** ---

**Generated By:**

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

(b) (4)

**Informed Consent - Asymptomatic Surveillance**

1. Consent Was:

**Header Text:** C4591001**Visit:** V201\_SURVEIL\_CONSENT -  
Unscheduled**Form:** ELECTRONIC SAMPLE TRACKING -  
IMMUNOGENICITY**Form Version:** 22-Apr-2020 21:03**Form Status:** Not Started**Site No:** 1231**Site Name:** (1231) Hospital Militar Central Cirujano  
Mayor Dr. Cosme Argerich**Subject No:** 12311862**Subject Initials:** ---**Generated By:****Generated Time (GMT):** 29-Mar-2021 16:45

(b) (4)

**Electronic Sample Tracking**

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

**Aliquot**

Please enter barcode for each aliquot.

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

**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:** 12311862**Subject Initials:** ---**Generated By:****Generated Time (GMT):** 29-Mar-2021 16:45

(b) (4)

**Electronic Sample Tracking**

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

**Aliquot**

Please enter barcode for each aliquot.

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



**Header Text:** C4591001

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

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

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

**Site No:** 1231

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

**Subject No:** 12311862

**Subject Initials:** ---

**Generated By:**

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

(b) (4)

[eCRF Audit Trail History](#)

**Date of Visit**

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

**Header Text:** C4591001

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

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

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

**Site No:** 1231

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

**Subject No:** 12311862

**Subject Initials:** ---

**Generated By:**

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

(b) (4)

[eCRF Audit Trail History](#)

**Further Vaccination Confirmation**

1.	Select appropriate response - Is participant willing to return for Vaccination 3?	Participant is willing to return for Vaccination 3 Participant is: eligible per other protocol allowance(s) and confirmed to have received only placebo at Vaccination 1/2
----	---	---

**Header Text:** C4591001

**Visit:** V101\_VAX3

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

**Site No:** 1231

**Subject No:** 12311862

**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:** V101\_VAX3

**Form:** INFORMED CONSENT - FURTHER  
VACCINATION

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

**Form Status:** Not Started

**Site No:** 1231

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

**Subject No:** 12311862

**Subject Initials:** ---

**Generated By:**

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

(b) (4)

**Informed Consent - Further Vaccination**

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

**Header Text:** C4591001

**Visit:** V101\_VAX3

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

**Form Version:** 28-Mar-2021 02:25

**Form Status:** Not Started

**Site No:** 1231

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

**Subject No:** 12311862

**Subject Initials:** ---

**Generated By:**

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

(b) (4)

**Inclusion Criteria Not Met**

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

**Exclusion Criteria Met**

2.	Description of Exclusion Criterion Met	
----	--	--

**Header Text:** C4591001

**Visit:** V101\_VAX3

**Form:** DISPOSITION - SCREENING FOR FURTHER VACCINATION

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

**Form Status:** Not Started

**Site No:** 1231

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

**Subject No:** 12311862

**Subject Initials:** ---

**Generated By:**

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

(b) (4)

**Disposition - Screening for Further Vaccination**

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

090177e196ae2ea4\Final\Final On: 01-Apr-2021 03:19 (GMT)

**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:** 12311862

**Subject Initials:** ---

**Generated By:**

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

(b) (4)

#	Category	AE Identifier	Adverse Event	Start Date	Is the Adverse Event Still Ongoing	Form Instance
1.	ADVERSE EVENT	1	Severe aortic stenosis	Oct/13/2020 08:00	YES	<a href="#">Repeating Pages</a>
2.	ADVERSE EVENT	2	pulmonary nodules	Jan/4/2021 10:00	NO End Date Time: Feb/23/2021 20:46	<a href="#">Repeating Pages</a>

090177e196ae2ea4\Final\Final On: 01-Apr-2021 03:19 (GMT)

**Header Text:** C4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1231

**Subject No:** 12311862

**Generated By:**

(b) (4)

**Form:** ADVERSE EVENT REPORT

**Form Status:** Data Complete, Locked

**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)	[Severe aortic stenosis]
4.	Start Date Time:	Oct/13/2020 08:00
5.	Is the adverse event still ongoing?	YES
6.	Toxicity Grade:	3

090177e196ae2ea4\Final\Final On: 01-Apr-2021 03:19 (GMT)



**Header Text:** C4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1231

**Subject No:** 12311862

**Generated By:**

(b) (4)

**Form:** ADVERSE EVENT REPORT

**Form Status:** Data Complete, Locked

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

**Subject Initials:** ---

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

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

090177e196ae2ea4\Final\Final On: 01-Apr-2021 03:19 (GMT)

**Header Text:** C4591001

**Visit:** Logs - Unscheduled

**Form:** ADVERSE EVENT REPORT

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

**Form Status:** Data Complete, Locked

**Site No:** 1231

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

**Subject No:** 12311862

**Subject Initials:** ---

**Generated By:**

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

(b) (4)

10.	Latest Action Taken with Study Treatment:	NOT APPLICABLE
11.	Was a Concomitant Medication given?	YES
12.	Was a Non-Drug Treatment given?	NO
13.	What was the outcome of this adverse event?:	RECOVERING/RESOLVING
14.	Did the adverse event cause the subject to be discontinued from the study?	NO
15.	Serious Adverse Event Number: For Pfizer Use Only	[2020504970]

090177e196ae2ea4\Final\Final On: 01-Apr-2021 03:19 (GMT)

**Header Text:** C4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1231

**Subject No:** 12311862

**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)	[pulmonary nodules]
4.	Start Date Time:	Jan/4/2021 10:00
5.	Is the adverse event still ongoing?	NO End Date Time: Feb/23/2021 20:46
6.	Toxicity Grade:	1

090177e196ae2ea4\Final\Final On: 01-Apr-2021 03:19 (GMT)

**Header Text:** C4591001

**Visit:** Logs - Unscheduled

**Form:** ADVERSE EVENT REPORT

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

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

**Site No:** 1231

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

**Subject No:** 12311862

**Subject Initials:** ---

**Generated By:**

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

(b) (4)

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

090177e196ae2ea4\Final\Final On: 01-Apr-2021 03:19 (GMT)

**Header Text:** C4591001

**Visit:** Logs - Unscheduled

**Form:** ADVERSE EVENT REPORT

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

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

**Site No:** 1231

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

**Subject No:** 12311862

**Subject Initials:** ---

**Generated By:**

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

(b) (4)

11.	Was a Concomitant Medication given?	NO
12.	Was a Non-Drug Treatment given?	NO
13.	What was the outcome of this adverse event?:	RECOVERED/RESOLVED 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	[ ]

090177e196ae2ea4\Final\Final On: 01-Apr-2021 03:19 (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:** 12311862

**Subject Initials:** ---

**Generated By:**

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

(b) (4)

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

**Header Text:** C4591001

**Visit:** Logs - Unscheduled

**Form:** MEDICATION ERROR

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

**Form Status:** Not Started

**Site No:** 1231

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

**Subject No:** 12311862

**Subject Initials:** ---

**Generated By:**

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

(b) (4)

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**Medication Error**

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

090177e196ae2ea4\Final\Final On: 01-Apr-2021 03:19 (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:** 12311862

**Subject Initials:** ---

**Generated By:**

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

(b) (4)

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



**Header Text:** C4591001

**Visit:** Logs - Unscheduled

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

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

**Form Status:** Not Started

**Site No:** 1231

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

**Subject No:** 12311862

**Subject Initials:** ---

**Generated By:**

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

(b) (4)

[Back to Form](#)

**Concomitant Medications**

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

090177e196ae2ea4\Final\Final On: 01-Apr-2021 03:19 (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:** 12311862

**Subject Initials:** ---

**Generated By:**

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

(b) (4)

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

**Header Text:** C4591001

**Visit:** Logs - Unscheduled

**Form:** CONCOMITANT MEDICATIONS - PROHIBITED

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

**Form Status:** Not Started

**Site No:** 1231

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

**Subject No:** 12311862

**Subject Initials:** ---

**Generated By:**

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

(b) (4)

[Back to Form](#)

**Concomitant Medications**

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

090177e196ae2ea4\Final\Final On: 01-Apr-2021 03:19 (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:** 12311862

**Subject Initials:** ---

**Generated By:**

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

(b) (4)

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

**Header Text:** C4591001

**Visit:** Logs - Unscheduled

**Form:** RADIATION TREATMENT

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

**Form Status:** Not Started

**Site No:** 1231

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

**Subject No:** 12311862

**Subject Initials:** ---

**Generated By:**

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

(b) (4)

[Back to Form](#)

**Radiation Treatment**

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

090177e196ae2ea4\Final\Final On: 01-Apr-2021 03:19 (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:** 12311862

**Subject Initials:** ---

**Generated By:**

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

(b) (4)

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

**Header Text:** C4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1231

**Subject No:** 12311862

**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

[Back to Form](#)

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

**Header Text:** C4591001

**Visit:** UNPLANNED\_BOOSTER\_CONTACT **Form:** DATE OF VISIT

- Unscheduled

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

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

**Subject No:** 12311862 **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:** 12311862

**Subject Initials:** ---

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

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

**Booster Dose Trigger Form**

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

**Header Text:** C4591001

**Visit:** Disposition - Unscheduled

**Form:** TREATMENT UNBLINDED

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

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

**Site No:** 1231

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

**Subject No:** 12311862

**Subject Initials:** ---

**Generated By:**

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

(b) (4)

[eCRF Audit Trail History](#)

**Treatment Unblinded**

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

**Header Text:** C4591001

**Visit:** Disposition - Unscheduled

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

**Site No:** 1231

**Subject No:** 12311862

**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	//
	:	

**Header Text:** C4591001

**Visit:** Disposition - Unscheduled

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

**Site No:** 1231

**Subject No:** 12311862

**Generated By:**

(b) (4)

**Form:** DEATH DETAILS CODED

**Form Status:** Not Started

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

**Subject Initials:** ---

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

**Death Details**

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

**Cause of Death**

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

**Header Text:** C4591001

**Visit:** Subject Status - Unscheduled

**Form:** SUBJECT STATUS

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

**Form Status:** Data Complete, Verified

**Site No:** 1231

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

**Subject No:** 12311862

**Subject Initials:** ---

**Generated By:**

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

(b) (4)

[eCRF Audit Trail History](#)

**Subject Status**

1.	Subject Status	FOLLOW-UP
2.	Subject Status Date	Oct/13/2020

**Header Text:** C4591001

**Visit:** Investigator Signature -  
Unscheduled

**Form:** CASEBOOK SIGNATURE FORM

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

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

**Site No:** 1231

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

**Subject No:** 12311862

**Subject Initials:** ---

**Generated By:**

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

(b) (4)

[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:** 12311862

**Subject Initials:** ---

**Generated By:**

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

(b) (4)

[Audit Trail](#)

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

- CRF\_Sign

Name	Signature Meaning	Date	Type	Action
(b) (6) [Redacted]	Approved	Mar-23-2021 12:21:15 (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.

090177e196ae2ea4\Final\Final On: 01-Apr-2021 03:19 (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:** 12311862

**Subject Initials:** ---

**Generated By:**

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

(b) (4)

[Back to Form](#)

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

- CRF\_Sign

Name	Signature Meaning	Date	Type	Action
(b) (6)	Approved	Mar-23-2021 12:21:15 (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.

Martina Davalli	N/A	Mar-22-2021 16:51:02 (UTC-03:00) City of Buenos Aires		Edit - All signatures invalidated
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**Affidavit:**

N/A

Yanina Rivera	Approved	Mar-16-2021 15:31:59 (UTC-03:00) City of Buenos Aires	BOOK	Signed
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090177e196ae2ea4\Final\Final On: 01-Apr-2021 03:19 (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:** 12311862

**Subject Initials:** ---

**Generated By:**

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

(b) (4)

**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) [Redacted]	N/A	Mar-10-2021 10:32:23 (UTC-03:00) City of Buenos Aires		Edit - All signatures invalidated
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**Affidavit:**

N/A

(b) (6) [Redacted]	Approved	Mar-09-2021 11:27:00 (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.

090177e196ae2ea4\Final\Final On: 01-Apr-2021 03:19 (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:** 12311862

**Subject Initials:** ---

**Generated By:**

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

(b) (4)

Martina Davalli	N/A	Feb-19-2021 10:37:16 (UTC-03:00) City of Buenos Aires		Edit - All signatures invalidated
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**Affidavit:**  
N/A

(b) (6)	Approved	Feb-17-2021 20:19:09 (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-12-2021 16:19:54 (UTC-03:00) City of Buenos Aires		Edit - All signatures invalidated
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**Affidavit:**  
N/A

(b) (6)	Approved	Jan-20-2021 17:51:32 (UTC-03:00) City of Buenos Aires	BOOK	Signed
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090177e196ae2ea4\Final\Final On: 01-Apr-2021 03:19 (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:** 12311862

**Subject Initials:** ---

**Generated By:**

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

(b) (4)

**Affidavit:**

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

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

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

(b) (6)	N/A	Dec-12-2020 10:49:53 (UTC-03:00) City of Buenos Aires		Edit - All signatures invalidated
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**Affidavit:**

N/A

(b) (6)	Approved	Nov-25-2020 16:51:27 (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.

090177e196ae2ea4\Final\Final On: 01-Apr-2021 03:19 (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:** 12311862

**Subject Initials:** ---

**Generated By:**

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

(b) (4)

(b) (6)	N/A	Nov-19-2020 14:54:44 (UTC-03:00) City of Buenos Aires		Edit - All signatures invalidated
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**Affidavit:**  
N/A

Fernando Polack	Approved	Nov-04-2020 09:35:00 (UTC-03:00) City of Buenos Aires	BOOK	Signed
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**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	Nov-03-2020 20:02:33 (UTC-03:00) City of Buenos Aires		Edit - All signatures invalidated
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**Affidavit:**  
N/A

(b) (6)	Approved	Oct-23-2020 12:45:04 (UTC-03:00) City of Buenos Aires	BOOK	Signed
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090177e196ae2ea4\Final\Final On: 01-Apr-2021 03:19 (GMT)

**Header Text:** C4591001

**Visit:** Investigator Signature -  
Unscheduled

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

**Site No:** 1231

**Subject No:** 12311862

**Generated By:**

(b) (4)

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

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

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

**Subject Initials:** ---

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

**Affidavit:**

By my dated signature below, I, (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.

090177e196ae2ea4\Final\Final On: 01-Apr-2021 03:19 (GMT)

**Header Text:** C4591001

**Visit:** COHORT\_SELECTION

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

**Site No:** 1231

**Subject No:** 12311862

**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

[Back to Form](#)

*1. Select appropriate response - Protocol version*

Date	Location	User	Value	Reason
Aug-17-2020 19:38:30 (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-17-2020 19:38:30 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> STAGE 3 COHOR TS	Initial Entry

090177e196ae2ea4\Final\Final On: 01-Apr-2021 03:19 (GMT)

**Header Text:** C4591001

**Visit:** COHORT\_SELECTION

**Form:** MAIN INFORMED CONSENT - 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:** 12311862

**Subject Initials:** ---

**Generated By:**

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

(b) (4)

[Back to Form](#)

*1. Consent Was:*

Date	Location	User	Value	Reason
Aug-17-2020 19:38:39 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> OBTAINED Date Written Con sent Obtained  Aug/17/2020	Initial Entry

090177e196ae2ea4\Final\Final On: 01-Apr-2021 03:19 (GMT)

**Header Text:** C4591001

**Visit:** COHORT\_SELECTION

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

**Site No:** 1231

**Subject No:** 12311862

**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-17-2020 17:33:05 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 12311862	Item copied from previous form

**2. Birth Date:**

Date	Location	User	Value	Reason
Aug-17-2020 17:33:02 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> (b) (6)/1989	Enrollment Entry

**3. Sex:**

Date	Location	User	Value	Reason
Aug-17-2020 19:38:48 (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-17-2020 19:38:48	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> HISPANIC OR LA	Initial Entry

090177e196ae2ea4\Final\Final On: 01-Apr-2021 03:19 (GMT)



**Header Text:** C4591001

**Visit:** COHORT\_SELECTION

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

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

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

**Site No:** 1231

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

**Subject No:** 12311862

**Subject Initials:** ---

**Generated By:**

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

(b) (4)

(UTC-03:00) City of Buenos Aires		(b) (4), (b) (6)	TINO(A) OR OF SPANISH ORIGIN
----------------------------------	--	------------------	------------------------------

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

Date	Location	User	Value	Reason
Aug-17-2020 19:38:48 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> WHITE	Initial Entry

090177e196ae2ea4\Final\Final On: 01-Apr-2021 03:19 (GMT)

**Header Text:** C4591001

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

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

**Site No:** 1231

**Subject No:** 12311862

**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

[Back to Form](#)

*1. Date of Visit*

Date	Location	User	Value	Reason
Aug-17-2020 19:39:07 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Aug/17/2020	Initial Entry

**Header Text:** C4591001

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

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

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

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

**Site No:** 1231

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

**Subject No:** 12311862

**Subject Initials:** ---

**Generated By:**

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

(b) (4)

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*1.a*

Date	Location	User	Value	Reason
Aug-17-2020 19:39:28 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Incl 1</b> <b>usio</b> <b>n N</b> <b>um</b> <b>ber</b> <b>:</b> <b>Cri</b> Male or fema <b>teri</b> le participant <b>on</b> s between the <b>Des</b> ages of 18 an <b>crip</b> d 55 years, in <b>tion</b> clusive, 65 a <b>:</b> nd 85 years, i nclusive, or 1 8 and 85 year s, inclusive, a t randomizati on (dependen t upon study stage) <b>Cri</b> YES <b>teri</b> <b>on</b> <b>met</b> <b>?:</b>	Initial Entry

090177e196ae2ea4\Final\Final On: 01-Apr-2021 03:19 (GMT)

**Header Text:** C4591001

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

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

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

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

**Site No:** 1231

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

**Subject No:** 12311862

**Subject Initials:** ---

**Generated By:**

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

(b) (4)

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***1.a Inclusion Number:***

Date	Location	User	Value	Reason
Aug-17-2020 19:39:28 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 1	Initial Entry

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

Date	Location	User	Value	Reason
Aug-17-2020 19:39:28 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Male or female par ticipants between t he ages of 18 and 5 5 years, inclusive, 65 and 85 years, in clusive, or 18 and 85 years, inclusive, at randomization (d	Initial Entry

090177e196ae2ea4\Final\Final On: 01-Apr-2021 03:19 (GMT)

**Header Text:** C4591001

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

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**Generated By:**

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

(b) (4)

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**1.a Criterion met?**

Date	Location	User	Value	Reason
Aug-17-2020 19:39:28 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

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

Date	Location	User	Value	Reason
Aug-17-2020 19:39:28 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> IN01A00	Initial Entry

**1.b**

Date	Location	User	Value	Reason
Aug-17-2020 19:39:28 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Incl 2 usio n N um ber:	Initial Entry

090177e196ae2ea4\Final\Final On: 01-Apr-2021 03:19 (GMT)

**Header Text:** C4591001

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

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Mayor Dr. Cosme Argerich

**Subject No:** 12311862

**Subject Initials:** ---

**Generated By:**

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

(b) (4)

			<p><b>Crit Participants</b> <b>erio</b> who are willi <b>n D</b> ng and able t <b>escr</b> o comply wit <b>ipti</b> h all schedul <b>on:</b> ed visits, vac cination plan , laboratory t ests, lifestyle consideratio ns, and other study proced ures</p> <p><b>Crit YES</b> <b>erio</b> <b>n m</b> <b>et?:</b></p> <p><b>Crit IN02A00</b> <b>erio</b> <b>n I</b> <b>D: (</b> <b>For</b> <b>Pfiz</b> <b>er u</b> <b>se o</b> <b>nly)</b> <b>:</b></p>	
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**Header Text:** C4591001

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

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

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

**Subject No:** 12311862

**Subject Initials:** ---

**Generated By:**

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(b) (4)

**1.b Inclusion Number:**

Date	Location	User	Value	Reason
Aug-17-2020 19:39:28 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 2	Initial Entry

**1.b Criterion Description:**

Date	Location	User	Value	Reason
Aug-17-2020 19:39:28 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Participants who are willing and able to comply with all scheduled visits, vaccination plan, laboratory tests, lifestyle considerations, and other study procedures	Initial Entry

**1.b Criterion met?**

Date	Location	User	Value	Reason
Aug-17-2020 19:39:28 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

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

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**Header Text:** C4591001

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**Site Name:** (1231) Hospital Militar Central Cirujano  
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**Subject No:** 12311862

**Subject Initials:** ---

**Generated By:**

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

(b) (4)

Date	Location	User	Value	Reason
Aug-17-2020 19:39:28 (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-17-2020 19:39:28 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Incl 3</b> <b>usio</b> <b>n N</b> <b>um</b> <b>ber:</b> <b>Crit</b> Healthy parti <b>erio</b> cipants who <b>n D</b> are determin <b>escr</b> ed by medica <b>ipti</b> l history, phy <b>on:</b> sical examin ation, and cli nical judgme nt of the inve stigator to be eligible for i nclusion in t he study	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:** 12311862

**Generated By:**

(b) (4)

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

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

**Subject Initials:** ---

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

			<p><b>Crit YES erio n m et?: Crit IN03A00 erio n I D: ( For Pfiz er u se o nly) :</b></p>	
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(b) (4)

***1.c Inclusion Number:***

Date	Location	User	Value	Reason
Aug-17-2020 19:39:28 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 3	Initial Entry

***1.c Criterion Description:***

Date	Location	User	Value	Reason
Aug-17-2020 19:39:28 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Healthy participant s who are determin ed by medical histo ry, physical examin ation, and clinical j udgment of the inv estigator to be eligi ble for inclusion in the study	Initial Entry

***1.c Criterion met?***

Date	Location	User	Value	Reason
Aug-17-2020 19:39:28 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

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

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**Header Text:** C4591001

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

**Subject No:** 12311862

**Subject Initials:** ---

**Generated By:**

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

(b) (4)

Date	Location	User	Value	Reason
Aug-17-2020 19:39:28 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> IN03A00	Initial Entry

*1.d*

Date	Location	User	Value	Reason
Aug-17-2020 19:39:28 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Incl 4</b> <b>usio</b> <b>n N</b> <b>um</b> <b>ber:</b> <b>Crit</b> Capable of g <b>erio</b> iving person <b>n D</b> al signed inf <b>escr</b> ormed conse <b>ipti</b> nt, which inc <b>on:</b> ludes compli ance with the requirements and restrictio ns listed in t he ICD and i n this protoc ol	Initial Entry

090177e196ae2ea4\Final\Final On: 01-Apr-2021 03:19 (GMT)

**Header Text:** C4591001

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

**Form:** INCLUSION/EXCLUSION CRITERIA - eCRF  
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**Site No:** 1231

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

**Subject No:** 12311862

**Subject Initials:** ---

**Generated By:**

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

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			<p><b>Crit YES</b></p> <p><b>erio</b></p> <p><b>n m</b></p> <p><b>et?:</b></p> <p><b>Crit IN04A00</b></p> <p><b>erio</b></p> <p><b>n I</b></p> <p><b>D: (</b></p> <p><b>For</b></p> <p><b>Pfiz</b></p> <p><b>er u</b></p> <p><b>se o</b></p> <p><b>nly)</b></p> <p><b>:</b></p>	
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Mayor Dr. Cosme Argerich

**Subject No:** 12311862

**Subject Initials:** ---

**Generated By:**

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

(b) (4)

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

Date	Location	User	Value	Reason
Aug-17-2020 19:39:28 (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-17-2020 19:39:28 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Capable of giving personal signed inf ormed consent, wh ich includes compli ance with the requi rements and restric tions listed in the I CD and in this prot ocol	Initial Entry

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

Date	Location	User	Value	Reason
Aug-17-2020 19:39:28 (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)***

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**Header Text:** C4591001

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

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

**Subject No:** 12311862

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

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Date	Location	User	Value	Reason
Aug-17-2020 19:39:28 (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-17-2020 19:39:28 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Exc 1</b> <b>lusi</b> <b>on</b> <b>Nu</b> <b>mb</b> <b>er:</b> <b>Crit</b> Other medic <b>erio</b> al or psychiat <b>n D</b> ric condition <b>escr</b> incl. recent ( <b>ipti</b> within past y <b>on:</b> ear) or active suicidal ideat ion/behavior/ lab abnormal ity that may i ncrease the ri sk of study p articipation	Initial Entry

090177e196ae2ea4\Final\Final On: 01-Apr-2021 03:19 (GMT)

**Header Text:** C4591001

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

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

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**2.a Exclusion Number:**

Date	Location	User	Value	Reason
Aug-17-2020 19:39:28 (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-17-2020 19:39:28 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Other medical or p sychiatric conditio n incl. recent (withi n past year) or acti	Initial Entry

090177e196ae2ea4\Final\Final On: 01-Apr-2021 03:19 (GMT)

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

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**2.a Criterion met?**

Date	Location	User	Value	Reason
Aug-17-2020 19:39:28 (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-17-2020 19:39:28 (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-17-2020 19:39:28 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Excl 2 usio n Nu mbe	Initial Entry

090177e196ae2ea4\Final\Final On: 01-Apr-2021 03:19 (GMT)



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**Subject Initials:** ---

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

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(b) (4)

**2.b Exclusion Number:**

Date	Location	User	Value	Reason
Aug-17-2020 19:39:28 (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-17-2020 19:39:28 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Known infection w ith human immuno deficiency virus (H IV), hepatitis C vir us (HCV), or hepat itis B virus (HBV)	Initial Entry

**2.b Criterion met?**

Date	Location	User	Value	Reason
Aug-17-2020 19:39:28 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

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

Date	Location	User	Value	Reason
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090177e196ae2ea4\Final\Final On: 01-Apr-2021 03:19 (GMT)

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**Generated By:**

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(b) (4)

Aug-17-2020 19:39:28 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> EX02A00	Initial Entry
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2.c

Date	Location	User	Value	Reason
Aug-17-2020 19:39:28 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Exc 3</b> <b>lusi</b> <b>on</b> <b>Nu</b> <b>mbe</b> <b>r:</b> <b>Crit</b> History of se <b>erio</b> vere adverse <b>n D</b> reaction asso <b>escri</b> ciated with a <b>ipti</b> vaccine and/ <b>on:</b> or severe all ergic reactio n (eg, anaph ylaxis) to an y component of the study i ntervention(s )	Initial Entry

090177e196ae2ea4\Final\Final On: 01-Apr-2021 03:19 (GMT)

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Mayor Dr. Cosme Argerich

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			<b>Crit NO erio n m et?: Crit EX03A00 erio n I D: ( For Pfiz er u se o nly) :</b>	
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090177e196ae2ea4\Final\Final On: 01-Apr-2021 03:19 (GMT)

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(b) (4)

**2.c Exclusion Number:**

Date	Location	User	Value	Reason
Aug-17-2020 19:39:28 (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-17-2020 19:39:28 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> History of severe a dverse reaction ass ociated with a vacc ine and/or severe al lergic reaction (eg, anaphylaxis) to any component of the s tudy intervention(s )	Initial Entry

**2.c Criterion met?**

Date	Location	User	Value	Reason
Aug-17-2020 19:39:28 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

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

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**Header Text:** C4591001

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

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

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

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

**Site No:** 1231

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

**Subject No:** 12311862

**Subject Initials:** ---

**Generated By:**

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

(b) (4)

Date	Location	User	Value	Reason
Aug-17-2020 19:39:28 (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-17-2020 19:39:28 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Exclus 4</b> <b>ion Nu</b> <b>mber:</b> <b>Criteria Receipt o</b> <b>on Des f medicati</b> <b>criptio ons inten</b> <b>n: ded to pre</b> <b>vent COV</b> <b>ID-19</b> <b>Criteria NO</b> <b>on met</b> <b>?:</b> <b>Criteria EX04A00</b> <b>on ID:</b> <b>(For Pf</b> <b>izer us</b> <b>e only)</b> <b>:</b>	Initial Entry

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Header Text: C4591001

Visit: V1\_DAY1\_VAX1\_L

Form: INCLUSION/EXCLUSION CRITERIA - eCRF  
Audit Trail History

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Site No: 1231

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

Subject No: 12311862

Subject Initials: ---

Generated By:

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

(b) (4)

**2.d Exclusion Number:**

Date	Location	User	Value	Reason
Aug-17-2020 19:39:28 (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-17-2020 19:39:28 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Receipt of medicati ons intended to pre vent COVID-19	Initial Entry

**2.d Criterion met?**

Date	Location	User	Value	Reason
Aug-17-2020 19:39:28 (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-17-2020 19:39:28 (UTC-03:00) City	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> EX04A00	Initial Entry

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**Header Text:** C4591001

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

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

**Site No:** 1231

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

**Subject No:** 12311862

**Subject Initials:** ---

**Generated By:**

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

(b) (4)

of Buenos Aires				
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2.e

Date	Location	User	Value	Reason
Aug-17-2020 19:39:28 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Excl 8</b> <b>usio</b> <b>n N</b> <b>umb</b> <b>er:</b> <b>Crit Immunocom</b> <b>erio promised ind</b> <b>n D ividuals with</b> <b>eser known or su</b> <b>iptio spected imm</b> <b>n: unodeficienc</b> <b>y, as determi</b> <b>ned by histor</b> <b>y and/or lab</b> <b>oratory/phys</b> <b>ical examina</b> <b>tion</b> <b>Crit NO</b> <b>erio</b> <b>n m</b> <b>et?:</b>	Initial Entry

090177e196ae2ea4\Final\Final On: 01-Apr-2021 03:19 (GMT)



**Header Text:** C4591001

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

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**Site No:** 1231

**Subject No:** 12311862

**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>Crit EX08A00 erion ID : (F or P fizer use only ):</b>	
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**Header Text:** C4591001

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

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**Subject Initials:** ---

**Generated By:**

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

(b) (4)

**2.e Exclusion Number:**

Date	Location	User	Value	Reason
Aug-17-2020 19:39:28 (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-17-2020 19:39:28 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Immunocompromi sed individuals wit h known or suspect ed immunodeficien cy, as determined b y history and/or lab oratory/physical ex amination	Initial Entry

**2.e Criterion met?**

Date	Location	User	Value	Reason
Aug-17-2020 19:39:28 (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)**

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**Header Text:** C4591001

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

**Subject No:** 12311862

**Subject Initials:** ---

**Generated By:**

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

(b) (4)

Date	Location	User	Value	Reason
Aug-17-2020 19:39:28 (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-17-2020 19:39:28 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>  <b>Excl 10</b> <b>usio</b> <b>n N</b> <b>um</b> <b>ber:</b>  <b>Crit Bleeding dia</b> <b>erio thesis or con</b> <b>n D dition associ</b> <b>escr ated with pro</b> <b>ipti longed bleed</b> <b>on: ing that woul</b> <b>d, in the opin</b> <b>ion of the in</b> <b>vestigator, c</b> <b>ontraindicate</b> <b>intramuscula</b> <b>r injection</b>  <b>Crit NO</b> <b>erio</b> <b>n m</b> <b>et?:</b>	Initial Entry

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**Header Text:** C4591001

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**Site No:** 1231

**Subject No:** 12311862

**Generated By:**

(b) (4)

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

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

**Subject Initials:** ---

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			<b>Crit EX10A00 erio n I D: ( For Pfiz er u se o nly) :</b>	
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Header Text: C4591001

Visit: V1\_DAY1\_VAX1\_L

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Site Name: (1231) Hospital Militar Central Cirujano  
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Subject No: 12311862

Subject Initials: ---

Generated By:

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(b) (4)

**2.f Exclusion Number:**

Date	Location	User	Value	Reason
Aug-17-2020 19:39:28 (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-17-2020 19:39:28 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Bleeding diathesis or condition associ ated with prolonge d bleeding that wo uld, in the opinion of the investigator, contraindicate intra muscular injection	Initial Entry

**2.f Criterion met?**

Date	Location	User	Value	Reason
Aug-17-2020 19:39:28 (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)**

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

**Subject No:** 12311862

**Subject Initials:** ---

**Generated By:**

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

(b) (4)

Date	Location	User	Value	Reason
Aug-17-2020 19:39:28 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> EX10A00	Initial Entry

2.g

Date	Location	User	Value	Reason
Aug-17-2020 19:39:28 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Exclusi 11</b> <b>on Nu</b> <b>mber:</b> <b>Criteri Women</b> <b>on Desc who are</b> <b>ription: pregnant</b> <b>or breast</b> <b>feeding</b> <b>Criteri NO</b> <b>on met</b> <b>?:</b> <b>Criteri EX11A0</b> <b>on ID: ( 0</b> <b>For Pfi</b> <b>zer use</b> <b>only):</b>	Initial Entry

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**Header Text:** C4591001

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

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**Site No:** 1231

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

**Subject No:** 12311862

**Subject Initials:** ---

**Generated By:**

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

(b) (4)

**2.g Exclusion Number:**

Date	Location	User	Value	Reason
Aug-17-2020 19:39:28 (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-17-2020 19:39:28 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Women who are pr egnant or breastfee ding	Initial Entry

**2.g Criterion met?**

Date	Location	User	Value	Reason
Aug-17-2020 19:39:28 (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-17-2020 19:39:28 (UTC-03:00) City	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> EX11A00	Initial Entry

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**Header Text:** C4591001

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

**Subject No:** 12311862

**Subject Initials:** ---

**Generated By:**

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

(b) (4)

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**2.h**

Date	Location	User	Value	Reason
Aug-17-2020 19:39:28 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Exclusion Number:</b> 12 <b>Criterion Description:</b> Previous vaccination with any coronavirus vaccine <b>Criterion met?:</b> NO <b>Criterion ID:</b> EX12A0 <b>(For Pflizer use only):</b>	Initial Entry

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Header Text: C4591001

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Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1231

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

Subject No: 12311862

Subject Initials: ---

Generated By:

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(b) (4)

**2.h Exclusion Number:**

Date	Location	User	Value	Reason
Aug-17-2020 19:39:28 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 12	Initial Entry

**2.h Criterion Description:**

Date	Location	User	Value	Reason
Aug-17-2020 19:39:28 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Previous vaccinati on with any corona virus vaccine	Initial Entry

**2.h Criterion met?**

Date	Location	User	Value	Reason
Aug-17-2020 19:39:28 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

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

Date	Location	User	Value	Reason
Aug-17-2020 19:39:28 (UTC-03:00) City	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> EX12A00	Initial Entry

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(b) (4)

of Buenos Aires				
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**2.i**

Date	Location	User	Value	Reason
Aug-17-2020 19:39:28 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Excl 13</b> <b>usion</b> <b>Num</b> <b>ber:</b> <b>Crite</b> Subjects wh <b>tion</b> o receive i <b>Desc</b> mmunosup <b>ripti</b> pressive the <b>on:</b> rapy, such a s cytotoxic agents or sy stemic corti costeroids  <b>Crite</b> NO <b>tion</b> <b>met?</b> : <b>Crite</b> EX13A01 <b>tion</b> <b>ID:</b> ( <b>For</b> <b>Pfize</b> <b>r use</b> <b>only)</b> :	Initial Entry

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**Header Text:** C4591001

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(b) (4)

**2.i Exclusion Number:**

Date	Location	User	Value	Reason
Aug-17-2020 19:39:28 (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-17-2020 19:39:28 (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-17-2020 19:39:28 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

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

Date	Location	User	Value	Reason
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Mayor Dr. Cosme Argerich

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(b) (4)

Aug-17-2020 19:39:28 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> EX13A01	Initial Entry
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2.j

Date	Location	User	Value	Reason
Aug-17-2020 19:39:28 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Excl 15</b> <b>usio</b> <b>n N</b> <b>um</b> <b>ber:</b> <b>Crit</b> Receipt of bl <b>erio</b> ood/plasma <b>n D</b> products or i <b>escr</b> mmunoglob <b>ipti</b> ulin, from 60 <b>on:</b> days before s tudy interve ntion admini stration or pl anned receip t throughout the study  <b>Crit</b> NO <b>erio</b> <b>n m</b> <b>et?:</b>	Initial Entry

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			<b>Crit EX14A01 erion ID : (F or P fize r us e on ly):</b>	
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(b) (4)

**2.j Exclusion Number:**

Date	Location	User	Value	Reason
Aug-17-2020 19:39:28 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 15	Initial Entry

**2.j Criterion Description:**

Date	Location	User	Value	Reason
Aug-17-2020 19:39:28 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Receipt of blood/pl asma products or i mmunoglobulin, fr om 60 days before study intervention administration or p lanned receipt thro ughout the study	Initial Entry

**2.j Criterion met?**

Date	Location	User	Value	Reason
Aug-17-2020 19:39:28 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

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

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(b) (4)

Date	Location	User	Value	Reason
Aug-17-2020 19:39:28 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> EX14A01	Initial Entry

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2.k

Date	Location	User	Value	Reason
Aug-17-2020 19:39:28 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Excl 16</b> <b>usio</b> <b>n N</b> <b>umb</b> <b>er:</b> <b>Crit Participatio</b> <b>erio n in other st</b> <b>n De udies involv</b> <b>scri ing study in</b> <b>ptio tervention</b> <b>n: within 28 d</b> <b>ays prior to</b> <b>study entry</b> <b>and/or durin</b> <b>g study part</b> <b>icipation</b> <b>Crit NO</b> <b>erio</b> <b>n m</b> <b>et?:</b>	Initial Entry

090177e196ae2ea4\Final\Final On: 01-Apr-2021 03:19 (GMT)



**Header Text:** C4591001

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

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

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

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

**Site No:** 1231

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

**Subject No:** 12311862

**Subject Initials:** ---

**Generated By:**

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

(b) (4)

			<b>Crit EX15A01</b> <b>erio</b> <b>n ID</b> <b>: (Fo</b> <b>r Pfi</b> <b>zer</b> <b>use</b> <b>only</b> <b>):</b>	
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Header Text: C4591001

Visit: V1\_DAY1\_VAX1\_L

Form: INCLUSION/EXCLUSION CRITERIA - eCRF  
Audit Trail History

Form Version: 30-Jul-2020 21:27

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Site No: 1231

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

Subject No: 12311862

Subject Initials: ---

Generated By:

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

(b) (4)

**2.k Exclusion Number:**

Date	Location	User	Value	Reason
Aug-17-2020 19:39:28 (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-17-2020 19:39:28 (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-17-2020 19:39:28 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

090177e196ae2ea4\Final\Final On: 01-Apr-2021 03:19 (GMT)

Header Text: C4591001

Visit: V1\_DAY1\_VAX1\_L

Form: INCLUSION/EXCLUSION CRITERIA - eCRF  
Audit Trail History

Form Version: 30-Jul-2020 21:27

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1231

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

Subject No: 12311862

Subject Initials: ---

Generated By:

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

(b) (4)

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

Date	Location	User	Value	Reason
Aug-17-2020 19:39:28 (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-17-2020 19:39:28 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Excl 17 usion Num ber: <b>Crite</b> Previous pa <b>ription</b> rticipation i <b>Desc</b> n other stu <b>ripti</b> dies involvi <b>on:</b> ng study in tervention containing lipid nanop articles  <b>Crite</b> NO <b>ription</b> <b>met?</b> :	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:** 12311862

**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>Crite EX16A01 rion ID: ( For Pfize r use only) :</b>	
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Header Text: C4591001

Visit: V1\_DAY1\_VAX1\_L

Form: INCLUSION/EXCLUSION CRITERIA - eCRF  
Audit Trail History

Form Version: 30-Jul-2020 21:27

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1231

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

Subject No: 12311862

Subject Initials: ---

Generated By:

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

(b) (4)

**2.1 Exclusion Number:**

Date	Location	User	Value	Reason
Aug-17-2020 19:39:28 (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-17-2020 19:39:28 (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-17-2020 19:39:28 (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)**

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**Header Text:** C4591001

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

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

**Site No:** 1231

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

**Subject No:** 12311862

**Subject Initials:** ---

**Generated By:**

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

(b) (4)

Date	Location	User	Value	Reason
Aug-17-2020 19:39:28 (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-17-2020 19:39:28 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Exc 22 lusi on Nu mb er:	Initial Entry

090177e196ae2ea4\Final\Final On: 01-Apr-2021 03:19 (GMT)

**Header Text:** C4591001

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

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

**Site No:** 1231

**Subject No:** 12311862

**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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Header Text: C4591001

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Form: INCLUSION/EXCLUSION CRITERIA - eCRF  
Audit Trail History

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Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1231

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

Subject No: 12311862

Subject Initials: ---

Generated By:

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

(b) (4)

**2.m Exclusion Number:**

Date	Location	User	Value	Reason
Aug-17-2020 19:39:28 (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-17-2020 19:39:28 (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-17-2020 19:39:28 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

090177e196ae2ea4\Final\Final On: 01-Apr-2021 03:19 (GMT)



**Header Text:** C4591001

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

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

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

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

**Site No:** 1231

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

**Subject No:** 12311862

**Subject Initials:** ---

**Generated By:**

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

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

Date	Location	User	Value	Reason
Aug-17-2020 19:39:28 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> EX21A01	Initial Entry

090177e196ae2ea4\Final\Final On: 01-Apr-2021 03:19 (GMT)

**Header Text:** C4591001

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

**Form:** DISPOSITION - SCREENING - 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:** 12311862

**Subject Initials:** ---

**Generated By:**

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

(b) (4)

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

Date	Location	User	Value	Reason
Aug-17-2020 19:39:41 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Aug/17/2020	Initial Entry

**2. Phase of Disposition:**

Date	Location	User	Value	Reason
Aug-17-2020 19:39:41 (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-17-2020 19:39:41 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> COMPLETED	Initial Entry

090177e196ae2ea4\Final\Final On: 01-Apr-2021 03:19 (GMT)

**Header Text:** C4591001

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

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

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

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

**Site No:** 1231

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

**Subject No:** 12311862

**Subject Initials:** ---

**Generated By:**

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

(b) (4)

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*1.a*

Date	Location	User	Value	Reason
Mar-10-2021 10:32:40 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Line/M 1</b> <b>H Num</b> <b>ber:</b> <b>Medica Bicuspid</b> <b>I Histo aortic val</b> <b>ry Ter ve</b> <b>m:</b> <b>Start D Jun/1/20</b> <b>ate: 04</b> <b>Ongoin NO</b> <b>g: End Da</b> <b>te:</b>  Mar/2 /2021	New Information
Mar-10-2021 10:32:23 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Line/M 1</b> <b>H Numb</b> <b>er:</b> <b>Medical Bicuspi</b> <b>History d aortic</b> <b>Term: valve</b>	New Information

090177e196ae2ea4\Final\Final On: 01-Apr-2021 03:19 (GMT)

**Header Text:** C4591001

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

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

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

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

**Site No:** 1231

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

**Subject No:** 12311862

**Subject Initials:** ---

**Generated By:**

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

(b) (4)

			<b>Start Date:</b> Jun/1/2004 <b>Ongoing:</b> YES	
Aug-17-2020 19:40:19 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> Line/MH Number: 1 <b>Medical History Term:</b> Bicuspid aortic valve <b>Start Date:</b> Jun/10/2000 <b>Ongoing:</b> YES	Initial Entry

**1.a Line/MH Number:**

Date	Location	User	Value	Reason
Aug-17-2020 19:40:19 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 1	Initial Entry

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

Date	Location	User	Value	Reason
Aug-17-2020 19:40:19	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Bicuspid aortic val	Initial Entry

090177e196ae2ea4\Final\Final On: 01-Apr-2021 03:19 (GMT)

**Header Text:** C4591001

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

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

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

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

**Site No:** 1231

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

**Subject No:** 12311862

**Subject Initials:** ---

**Generated By:**

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

(b) (4)

(UTC-03:00) City of Buenos Aires		(b) (4), (b) (6)	ve	
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**1.a Start Date:**

Date	Location	User	Value	Reason
Mar-10-2021 10:32:23 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Jun/1/2004	New Information
Aug-17-2020 19:40:19 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Jun/10/2000	Initial Entry

**1.a Ongoing:**

Date	Location	User	Value	Reason
Mar-10-2021 10:32:40 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO End Date: Mar/2/2021	New Information
Aug-17-2020 19:40:19 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

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**Header Text:** C4591001

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

**Form:** VITAL SIGNS - BASELINE - eCRF Audit Trail History

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

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

**Site No:** 1231

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

**Subject No:** 12311862

**Subject Initials:** ---

**Generated By:**

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

(b) (4)

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**1. Date:**

Date	Location	User	Value	Reason
Aug-17-2020 19:40:44 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Aug/17/2020	Initial Entry

**2. Weight:**

Date	Location	User	Value	Reason
Aug-17-2020 19:40:44 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 61.0	Initial Entry

**3. Unit:**

Date	Location	User	Value	Reason
Aug-17-2020 19:40:44 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> kg	Initial Entry

**4. Height:**

Date	Location	User	Value	Reason
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090177e196ae2ea4\Final\Final On: 01-Apr-2021 03:19 (GMT)

**Header Text:** C4591001

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

**Form:** VITAL SIGNS - BASELINE - eCRF Audit Trail History

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

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

**Site No:** 1231

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

**Subject No:** 12311862

**Subject Initials:** ---

**Generated By:**

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

(b) (4)

Aug-17-2020 19:40:44 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 171.0	Initial Entry
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**5. Unit:**

Date	Location	User	Value	Reason
Aug-17-2020 19:40:44 (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-17-2020 19:40:44 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 20.9	Initial Entry

**7.a**

Date	Location	User	Value	Reason
Aug-17-2020 19:40:44 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Record Id 1 entifier:: Temperat 36.2 ure:</b>	Initial Entry

090177e196ae2ea4\Final\Final On: 01-Apr-2021 03:19 (GMT)

**Header Text:** C4591001

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

**Form:** VITAL SIGNS - BASELINE - eCRF Audit Trail History

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

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

**Site No:** 1231

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

**Subject No:** 12311862

**Subject Initials:** ---

**Generated By:**

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

(b) (4)

**Temperature Unit:**  
**Temperature Location:** ORAL CAVITY

**7.a Record Identifier:**

Date	Location	User	Value	Reason
Aug-17-2020 19:40:44 (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-17-2020 19:40:44 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 36.2	Initial Entry

**7.a Unit:**

Date	Location	User	Value	Reason
Aug-17-2020 19:40:44 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> C	Initial Entry

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**Header Text:** C4591001

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

**Form:** VITAL SIGNS - BASELINE - eCRF Audit Trail History

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

**Site No:** 1231

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

**Subject No:** 12311862

**Subject Initials:** ---

**Generated By:**

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

(b) (4)

**7.a Temperature Location:**

Date	Location	User	Value	Reason
Aug-17-2020 19:40:44 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> ORAL CAVITY	Initial Entry

**Header Text:** C4591001

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

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

**Site No:** 1231

**Subject No:** 12311862

**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-17-2020 19:40:58 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Aug/17/2020	Initial Entry

**2. Randomization Number:**

Date	Location	User	Value	Reason
Aug-17-2020 19:40:58 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 53495	Initial Entry

090177e196ae2ea4\Final\Final On: 01-Apr-2021 03:19 (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:** 12311862

**Subject Initials:** ---

**Generated By:**

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(b) (4)

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**1. Data Origin**

Date	Location	User	Value	Reason
Aug-17-2020 19:41:08 (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-17-2020 19:41:08 (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-21-2020 10:32:44 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Aug-18-2020 16:22:45 (UTC-03:00)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	DM Query: Sample Collected?' is

090177e196ae2ea4\Final\Final On: 01-Apr-2021 03:19 (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:** 12311862

**Subject Initials:** ---

**Generated By:**

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

(b) (4)

City of Buenos Aires				Yes, however no barcodes are entered. Please review and correct as appropriate.
Aug-17-2020 19:41:08 (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-17-2020 19:41:08 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES Date of Collection:  Aug/17/2020	Initial Entry

**5.a**

Date	Location	User	Value	Reason
Aug-21-2020 10:32:44 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	Romina Barrera (b) (4)	<b>Data Entry:</b> <b>Sample ID</b> BPHZ7 : Y	Initial Entry

**5.a Sample ID**

090177e196ae2ea4\Final\Final On: 01-Apr-2021 03:19 (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:** 12311862

**Subject Initials:** ---

**Generated By:**

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

(b) (4)

Date	Location	User	Value	Reason
Aug-21-2020 10:32:44 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	Romina Barrera (b) (4)	<b>Data Entry:</b> BPHZ7Y	Initial Entry

**5.b**

Date	Location	User	Value	Reason
Aug-21-2020 10:32:58 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	Romina Barrera (b) (4)	<b>Data Entry:</b> Sample ID BPHZ7 : Z	Initial Entry

**5.b Sample ID**

Date	Location	User	Value	Reason
Aug-21-2020 10:32:58 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	Romina Barrera (b) (4)	<b>Data Entry:</b> BPHZ7Z	Initial Entry

**5.c**

Date	Location	User	Value	Reason
Aug-22-2020 09:31:07 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sample ID BHWST : T	Initial Entry

090177e196ae2ea4\Final\Final On: 01-Apr-2021 03:19 (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:** 12311862

**Subject Initials:** ---

**Generated By:**

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

(b) (4)

**5.c Sample ID**

Date	Location	User	Value	Reason
Aug-22-2020 09:31:07 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BHWSTT	Initial Entry

**5.d**

Date	Location	User	Value	Reason
Aug-22-2020 09:31:15 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sample I BHWST D: V	Initial Entry

**5.d Sample ID**

Date	Location	User	Value	Reason
Aug-22-2020 09:31:15 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BHWSTV	Initial Entry

**5.e**

Date	Location	User	Value	Reason
Aug-22-2020 09:31:24 (UTC-03:00) City	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sample I BHWST D: W	Initial Entry

090177e196ae2ea4\Final\Final On: 01-Apr-2021 03:19 (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:** 12311862

**Subject Initials:** ---

**Generated By:**

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

(b) (4)

of Buenos Aires				
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**5.e Sample ID**

Date	Location	User	Value	Reason
Aug-22-2020 09:31:24 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6) [Redacted]	<b>Data Entry:</b> BHWSTW	Initial Entry

090177e196ae2ea4\Final\Final On: 01-Apr-2021 03:19 (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:** 12311862

**Subject Initials:** ---

**Generated By:**

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

(b) (4)

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**1. Data Origin**

Date	Location	User	Value	Reason
Aug-17-2020 19:41:14 (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
Aug-17-2020 19:41:14 (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
Aug-18-2020 10:58:48 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Aug-17-2020 19:41:14 (UTC-03:00)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however

090177e196ae2ea4\Final\Final On: 01-Apr-2021 03:19 (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:** 12311862

**Subject Initials:** ---

**Generated By:**

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

(b) (4)

City of Buenos Aires				no barcodes are entered. Please review and correct as appropriate.
Aug-17-2020 19:41:14 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES Date of Collection:  Aug/17/2020	Initial Entry

**5.a**

Date	Location	User	Value	Reason
Aug-18-2020 10:58:48 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample I BHWS</b> <b>D: RJ</b>	Initial Entry

**5.a Sample ID**

Date	Location	User	Value	Reason
Aug-18-2020 10:58:48 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BHWSRJ	Initial Entry

090177e196ae2ea4\Final\Final On: 01-Apr-2021 03:19 (GMT)

**Header Text:** C4591001

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

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

**Site No:** 1231

**Subject No:** 12311862

**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

[Back to Form](#)

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

Date	Location	User	Value	Reason
Aug-17-2020 19:41:40 (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-17-2020 19:41:40 (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-17-2020 19:41:40 (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-17-2020 19:41:40	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Aug/17/2020 18:36	Initial Entry

090177e196ae2ea4\Final\Final On: 01-Apr-2021 03:19 (GMT)

**Header Text:** C4591001

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

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

**Site No:** 1231

**Subject No:** 12311862

**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

(UTC-03:00) City of Buenos Aires

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

**5. Anatomical Location:**

Date	Location	User	Value	Reason
Aug-17-2020 19:41:40 (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-17-2020 19:41:40 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> LEFT	Initial Entry

**7. Route:**

Date	Location	User	Value	Reason
Aug-17-2020 19:41:40 (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-17-2020	ACV0PFEINFP6000	auto calc	<b>Data Entry:</b>	Initial Entry

090177e196ae2ea4\Final\Final On: 01-Apr-2021 03:19 (GMT)

**Header Text:** C4591001

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

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

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

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

**Site No:** 1231

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

**Subject No:** 12311862

**Subject Initials:** ---

**Generated By:**

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

(b) (4)

19:41:40 (UTC-03:00) City of Buenos Aires	(autocalc)	THE PROTOCOL SPE CIFIED OBSERVATIO N PERIOD
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**11. Was the subject observed for at least the protocol specified observation period after investigational product administration?**

Date	Location	User	Value	Reason
Aug-17-2020 19:41:40 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

090177e196ae2ea4\Final\Final On: 01-Apr-2021 03:19 (GMT)

**Header Text:** C4591001

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

**Form:** REACTOGENICITY DIARY - eCRF Audit Trail History

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

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

**Site No:** 1231

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

**Subject No:** 12311862

**Subject Initials:** ---

**Generated By:**

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

(b) (4)

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*1. Select appropriate response - Reactogenicity diary collection*

Date	Location	User	Value	Reason
Aug-17-2020 19:41:47 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO - REACTOGE NICITY E-DIARY NOT COLLECTE D FOR THIS SUB JECT	Initial Entry

090177e196ae2ea4\Final\Final On: 01-Apr-2021 03:19 (GMT)

**Header Text:** C4591001

**Visit:** V2\_VAX2\_L

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

**Site No:** 1231

**Subject No:** 12311862

**Generated By:**

(b) (4)

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

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

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

**Subject Initials:** ---

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

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*1. Date of Visit*

Date	Location	User	Value	Reason
Sep-09-2020 17:44:28 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sep/9/2020	Initial Entry

090177e196ae2ea4\Final\Final On: 01-Apr-2021 03:19 (GMT)

**Header Text:** C4591001

**Visit:** V2\_VAX2\_L

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

**Site No:** 1231

**Subject No:** 12311862

**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-09-2020 17:44:40 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sep/9/2020	Initial Entry

**2.a**

Date	Location	User	Value	Reason
Sep-09-2020 17:44:40 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Record Id 1</b> <b>entifier::</b> <b>Temperat 36.9</b> <b>ure:</b> <b>Temperat C</b> <b>ure Unit:</b> <b>Temperat ORAL</b> <b>ure Locat CAVI</b> <b>ion:: TY</b>	Initial Entry

**2.a Record Identifier:**

Date	Location	User	Value	Reason
Sep-09-2020 17:44:40 (UTC-03:00) City	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 1	Initial Entry

090177e196ae2ea4\Final\Final On: 01-Apr-2021 03:19 (GMT)

**Header Text:** C4591001

**Visit:** V2\_VAX2\_L

**Form:** VITAL SIGNS - TEMP - eCRF Audit Trail History

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

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

**Site No:** 1231

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

**Subject No:** 12311862

**Subject Initials:** ---

**Generated By:**

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

(b) (4)

of Buenos Aires				
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**2.a Temperature:**

Date	Location	User	Value	Reason
Sep-09-2020 17:44:40 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 36.9	Initial Entry

**2.a Unit:**

Date	Location	User	Value	Reason
Sep-09-2020 17:44:40 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> C	Initial Entry

**2.a Temperature Location:**

Date	Location	User	Value	Reason
Sep-09-2020 17:44:40 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> ORAL CAVITY	Initial Entry

090177e196ae2ea4\Final\Final On: 01-Apr-2021 03:19 (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:** 12311862

**Subject Initials:** ---

**Generated By:**

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

(b) (4)

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**1. Data Origin**

Date	Location	User	Value	Reason
Sep-09-2020 17:44:54 (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
Sep-09-2020 17:44:54 (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-10-2020 09:43:34 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Sep-09-2020 19:02:20 (UTC-03:00)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	'Sample Collected?' is Yes, however

090177e196ae2ea4\Final\Final On: 01-Apr-2021 03:19 (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: 12311862

Subject Initials: ---

Generated By:

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

(b) (4)

City of Buenos Aires		(b) (4), (b) (6)		no barcodes are entered. Please review and correct as appropriate.
Sep-09-2020 17:44:54 (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.
Sep-09-2020 17:44:54 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES Date of Collection: Sep/9/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Sep-10-2020 09:43:34 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	Romina Barrera (b) (4)	<b>Data Entry:</b> <b>Sample ID</b> BP1YX : 4	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
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090177e196ae2ea4\Final\Final On: 01-Apr-2021 03:19 (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:** 12311862

**Subject Initials:** ---

**Generated By:**

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

(b) (4)

Sep-10-2020 09:43:34 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	Romina Barrera (b) (4)	<b>Data Entry:</b> BP1YX4	Initial Entry
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**Header Text:** C4591001

**Visit:** V2\_VAX2\_L

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

**Site No:** 1231

**Subject No:** 12311862

**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-09-2020 17:45:10 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**2. Treatment Name**

Date	Location	User	Value	Reason
Sep-09-2020 17:45:10 (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-09-2020 17:45:10 (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-09-2020 17:45:10	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sep/9/2020 16:16	Initial Entry

090177e196ae2ea4\Final\Final On: 01-Apr-2021 03:19 (GMT)

**Header Text:** C4591001

**Visit:** V2\_VAX2\_L

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

**Site No:** 1231

**Subject No:** 12311862

**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

(UTC-03:00) City of Buenos Aires

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

**5. Anatomical Location:**

Date	Location	User	Value	Reason
Sep-09-2020 17:45:10 (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-09-2020 17:45:10 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> RIGHT	Initial Entry

**7. Route:**

Date	Location	User	Value	Reason
Sep-09-2020 17:45:10 (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-09-2020	ACV0PFEINFP6000	auto calc	<b>Data Entry:</b>	Initial Entry

090177e196ae2ea4\Final\Final On: 01-Apr-2021 03:19 (GMT)

**Header Text:** C4591001

**Visit:** V2\_VAX2\_L

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

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

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

**Site No:** 1231

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

**Subject No:** 12311862

**Subject Initials:** ---

**Generated By:**

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

(b) (4)

17:45:10 (UTC-03:00) City of Buenos Aires	(autocalc)	THE PROTOCOL SPE CIFIED OBSERVATIO N PERIOD
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**11. Was the subject observed for at least the protocol specified observation period after investigational product administration?**

Date	Location	User	Value	Reason
Sep-09-2020 17:45:10 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

090177e196ae2ea4\Final\Final On: 01-Apr-2021 03:19 (GMT)

**Header Text:** C4591001

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

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

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

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

**Site No:** 1231

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

**Subject No:** 12311862

**Subject Initials:** ---

**Generated By:**

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

(b) (4)

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*1. Date of Visit*

Date	Location	User	Value	Reason
Oct-14-2020 09:41:26 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6) [Redacted]	<b>Data Entry:</b> Oct/13/2020	Initial Entry

090177e196ae2ea4\Final\Final On: 01-Apr-2021 03:19 (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:** 12311862 **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-14-2020 09:34:11 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SITE	Initial Entry

**2. Sample Type**

Date	Location	User	Value	Reason
Oct-14-2020 09:34:11 (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-14-2020 09:34:27 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Oct-14-2020 09:34:11 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes

090177e196ae2ea4\Final\Final On: 01-Apr-2021 03:19 (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: 12311862

Subject Initials: ---

Generated By:

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

(b) (4)

				are entered. Please review and correct as appropriate.
Oct-14-2020 09:34:11 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES Date of Collection:  Oct/13/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Oct-14-2020 09:34:27 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sample ID BRXPZ : L	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Oct-14-2020 09:34:27 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BRXPZL	Initial Entry

5.b

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

090177e196ae2ea4\Final\Final On: 01-Apr-2021 03:19 (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:** 12311862

**Subject Initials:** ---

**Generated By:**

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(b) (4)

10:07:55 (UTC-03:00) City of Buenos Aires		(b) (4), (b) (6)	<b>Sample ID</b> BRXR0 : 1	
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**5.b Sample ID**

Date	Location	User	Value	Reason
Oct-14-2020 10:07:55 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BRXR01	Initial Entry

**5.c**

Date	Location	User	Value	Reason
Oct-14-2020 11:46:08 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample ID</b> BPT7T : P	Initial Entry

**5.c Sample ID**

Date	Location	User	Value	Reason
Oct-14-2020 11:46:08 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BPT7TP	Initial Entry

090177e196ae2ea4\Final\Final On: 01-Apr-2021 03:19 (GMT)

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Oct/21/2020

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

**Site No:** 1231

**Subject No:** 12311862

**Generated By:**

(b) (4)

**Form:** DATE OF VISIT - ILLNESS ONSET - 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 of Visit*

Date	Location	User	Value	Reason
Oct-23-2020 09:13:04 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Oct-23-2020 09:11:57 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Deleted	Close Auto Query
Oct-23-2020 09:11:08 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Candidate	Date of Visit is completed but Date of Assessment in the Signs and Symptoms form is missing. Please review and update as appropriate.
Oct-23-2020 09:11:08 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	Date of Visit is completed but Date of Collection in both Nasal

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**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Oct/21/2020

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

**Site No:** 1231

**Subject No:** 12311862

**Generated By:**

(b) (4)

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

				Swab Self and Nasal Swab are missing. Please review and update as appropriate.
Oct-23-2020 09:11:08 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Oct/21/2020	Initial Entry

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

Date	Location	User	Value	Reason
Oct-23-2020 09:11:08 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> COVID_A	Initial Entry

090177e196ae2ea4\Final\Final On: 01-Apr-2021 03:19 (GMT)

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Oct/21/2020

**Form Version:** 10-Oct-2020 16:02

**Site No:** 1231

**Subject No:** 12311862

**Generated By:**

(b) (4)

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

Date	Location	User	Value	Reason
Oct-23-2020 09:11:57 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Oct/21/2020	Initial Entry

**2. Date of First Symptom Started:**

Date	Location	User	Value	Reason
Jan-15-2021 08:45:18 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Clos ed	Response satisfies query
Jan-13-2021 16:02:43 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Ans wered	The symptoms on COVID B were updated. Thank you
Jan-13-2021 13:55:50 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Open ed	Per clinical chart the patient with effort expermented blurred vision, dizziness,palpitations with stop date

090177e196ae2ea4\Final\Final On: 01-Apr-2021 03:19 (GMT)

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Oct/21/2020

**Form Version:** 10-Oct-2020 16:02

**Site No:** 1231

**Subject No:** 12311862

**Generated By:**

(b) (4)

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

				12dec2020.Please review chart and update if necessary.
Oct-23-2020 09:11:57 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Oct/13/2020	Initial Entry

**3. Symptoms Ongoing?**

Date	Location	User	Value	Reason
Nov-03-2020 20:02:33 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO Date of Last Symptom Resolved:  Nov/2/2020	New Information
Oct-23-2020 09:11:57 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

**4.a**

Date	Location	User	Value	Reason
Oct-23-2020 09:11:57 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptoms:</b> FEVE R	Initial Entry

090177e196ae2ea4\Final\Final On: 01-Apr-2021 03:19 (GMT)

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Oct/21/2020

**Form Version:** 10-Oct-2020 16:02

**Site No:** 1231

**Subject No:** 12311862

**Generated By:**

(b) (4)

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

			<b>Symptom Pre NO sent:</b>	
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**4.a Symptoms:**

Date	Location	User	Value	Reason
Oct-23-2020 09:11:57 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> FEVER	Initial Entry

**4.a Was symptom present?**

Date	Location	User	Value	Reason
Oct-23-2020 09:11:57 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**4.b**

Date	Location	User	Value	Reason
Oct-23-2020 09:11:57 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sympto NEW OR IN ms:</b> CREASED COUGH <b>Sympto NO m Pres ent:</b>	Initial Entry

090177e196ae2ea4\Final\Final On: 01-Apr-2021 03:19 (GMT)

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Oct/21/2020

**Form Version:** 10-Oct-2020 16:02

**Site No:** 1231

**Subject No:** 12311862

**Generated By:**

(b) (4)

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

**4.b Symptoms:**

Date	Location	User	Value	Reason
Oct-23-2020 09:11:57 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NEW OR INCREASE D COUGH	Initial Entry

**4.b Was symptom present?**

Date	Location	User	Value	Reason
Oct-23-2020 09:11:57 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**4.c**

Date	Location	User	Value	Reason
Oct-23-2020 09:11:57 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symp</b> NEW OR INC <b>toms:</b> REASED SH ORTNESS OF BREATH  <b>Symp</b> YES <b>tom P</b> <b>resent</b> :	Initial Entry

090177e196ae2ea4\Final\Final On: 01-Apr-2021 03:19 (GMT)



**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Oct/21/2020

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**Site No:** 1231

**Subject No:** 12311862

**Generated By:**

(b) (4)

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

**4.c Symptoms:**

Date	Location	User	Value	Reason
Oct-23-2020 09:11:57 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NEW OR INCREASE D SHORTNESS OF B REATH	Initial Entry

**4.c Was symptom present?**

Date	Location	User	Value	Reason
Oct-23-2020 09:11:57 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

**4.d**

Date	Location	User	Value	Reason
Oct-23-2020 09:11:57 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptoms:</b> CHIL LS <b>Symptom Pre NO sent:</b>	Initial Entry

090177e196ae2ea4\Final\Final On: 01-Apr-2021 03:19 (GMT)

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Oct/21/2020

**Form Version:** 10-Oct-2020 16:02

**Site No:** 1231

**Subject No:** 12311862

**Generated By:**

(b) (4)

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

**4.d Symptoms:**

Date	Location	User	Value	Reason
Oct-23-2020 09:11:57 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> CHILLS	Initial Entry

**4.d Was symptom present?**

Date	Location	User	Value	Reason
Oct-23-2020 09:11:57 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**4.e**

Date	Location	User	Value	Reason
Oct-23-2020 09:11:57 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sympt NEW OR IN oms: CREASED M USCLE PAIN  Sympt NO om Pr esent:	Initial Entry

090177e196ae2ea4\Final\Final On: 01-Apr-2021 03:19 (GMT)

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Oct/21/2020

**Form Version:** 10-Oct-2020 16:02

**Site No:** 1231

**Subject No:** 12311862

**Generated By:**

(b) (4)

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

**4.e Symptoms:**

Date	Location	User	Value	Reason
Oct-23-2020 09:11:57 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NEW OR INCREASE D MUSCLE PAIN	Initial Entry

**4.e Was symptom present?**

Date	Location	User	Value	Reason
Oct-23-2020 09:11:57 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**4.f**

Date	Location	User	Value	Reason
Oct-23-2020 09:11:57 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sympt</b> NEW LOSS <b>oms:</b> OF TASTE O R SMELL <b>Sympt</b> NO <b>om Pre</b> <b>sent:</b>	Initial Entry

090177e196ae2ea4\Final\Final On: 01-Apr-2021 03:19 (GMT)

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Oct/21/2020

**Form Version:** 10-Oct-2020 16:02

**Site No:** 1231

**Subject No:** 12311862

**Generated By:**

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

**4.f Symptoms:**

Date	Location	User	Value	Reason
Oct-23-2020 09:11:57 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NEW LOSS OF TAST E OR SMELL	Initial Entry

**4.f Was symptom present?**

Date	Location	User	Value	Reason
Oct-23-2020 09:11:57 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**4.g**

Date	Location	User	Value	Reason
Oct-23-2020 09:11:57 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sympt</b> NEW OR IN <b>oms:</b> CREASED S ORE THROA T <b>Sympt</b> NO <b>om Pr</b> <b>esent:</b>	Initial Entry

090177e196ae2ea4\Final\Final On: 01-Apr-2021 03:19 (GMT)

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Oct/21/2020

**Form Version:** 10-Oct-2020 16:02

**Site No:** 1231

**Subject No:** 12311862

**Generated By:**

(b) (4)

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

**4.g Symptoms:**

Date	Location	User	Value	Reason
Oct-23-2020 09:11:57 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NEW OR INCREASE D SORE THROAT	Initial Entry

**4.g Was symptom present?**

Date	Location	User	Value	Reason
Oct-23-2020 09:11:57 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**4.h**

Date	Location	User	Value	Reason
Oct-23-2020 09:11:57 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptoms:</b> DIARR HEA <b>Symptom P</b> NO <b>resent:</b>	Initial Entry

090177e196ae2ea4\Final\Final On: 01-Apr-2021 03:19 (GMT)

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Oct/21/2020

**Form Version:** 10-Oct-2020 16:02

**Site No:** 1231

**Subject No:** 12311862

**Generated By:**

(b) (4)

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

**4.h Symptoms:**

Date	Location	User	Value	Reason
Oct-23-2020 09:11:57 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> DIARRHEA	Initial Entry

**4.h Was symptom present?**

Date	Location	User	Value	Reason
Oct-23-2020 09:11:57 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**4.i**

Date	Location	User	Value	Reason
Oct-23-2020 09:11:57 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptoms:</b> VOMIT ING <b>Symptom P</b> NO <b>resent:</b>	Initial Entry

090177e196ae2ea4\Final\Final On: 01-Apr-2021 03:19 (GMT)

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Oct/21/2020

**Form Version:** 10-Oct-2020 16:02

**Site No:** 1231

**Subject No:** 12311862

**Generated By:**

(b) (4)

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

**4.i Symptoms:**

Date	Location	User	Value	Reason
Oct-23-2020 09:11:57 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> VOMITING	Initial Entry

**4.i Was symptom present?**

Date	Location	User	Value	Reason
Oct-23-2020 09:11:57 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

090177e196ae2ea4\Final\Final On: 01-Apr-2021 03:19 (GMT)

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Oct/21/2020

**Form Version:** 06-Jul-2020 21:54

**Site No:** 1231

**Subject No:** 12311862

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

**Form:** MICROBIOLOGY SPECIMEN - 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
Oct-23-2020 09:12:29 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Created	



**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Oct/21/2020

**Form Version:** 06-Jul-2020 21:54

**Site No:** 1231

**Subject No:** 12311862

**Generated By:**

(b) (4)

**Form:** MICROBIOLOGY SPECIMEN - 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. Actual Date of Collection:**

Date	Location	User	Value	Reason
Oct-23-2020 09:12:29 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Oct/21/2020	Initial Entry

**2. Specimen Type:**

Date	Location	User	Value	Reason
Oct-23-2020 09:12:29 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> SWABBED MATERI AL	Initial Entry

**3. Specimen Collection Location:**

Date	Location	User	Value	Reason
Oct-23-2020 09:12:29 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NASOPHARYNX	Initial Entry

**4. Assay Code and Description:**

Date	Location	User	Value	Reason
Oct-23-2020 09:12:29	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SEVERE ACUTE RES	Initial Entry

090177e196ae2ea4\Final\Final On: 01-Apr-2021 03:19 (GMT)

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Oct/21/2020

**Form Version:** 06-Jul-2020 21:54

**Site No:** 1231

**Subject No:** 12311862

**Generated By:**

(b) (4)

**Form:** MICROBIOLOGY SPECIMEN - 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

(UTC-03:00) City  
of Buenos Aires

P SYNDROME CORO  
NAVIRUS 2

**5. Device Type:**

Date	Location	User	Value	Reason
Oct-23-2020 09:12:29 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SARS-COV-2 DIAGN OSTIC TEST	Initial Entry

**6. Trade Name:**

Date	Location	User	Value	Reason
Oct-23-2020 09:12:29 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> ATILA BIOSYSTEM S IAMP COVID-19 D ETECTION KIT	Initial Entry

**7. Test Result:**

Date	Location	User	Value	Reason
Oct-23-2020 09:12:29 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NEGATIVE	Initial Entry

090177e196ae2ea4\Final\Final On: 01-Apr-2021 03:19 (GMT)

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Oct/21/2020

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

**Site No:** 1231

**Subject No:** 12311862

**Generated By:**

(b) (4)

**Form:** ELECTRONIC SAMPLE TRACKING - NASAL  
SWAB SELF - 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. Data Origin**

Date	Location	User	Value	Reason
Oct-23-2020 09:12:51 (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-23-2020 09:12:51 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> NASAL_SWAB_SELF	Initial Entry

**3. Sample Collected?**

Date	Location	User	Value	Reason
Oct-23-2020 09:12:51 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**4. If no sample was collected or sample was not collected according to protocol, please provide reason:**

Date	Location	User	Value	Reason
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090177e196ae2ea4\Final\Final On: 01-Apr-2021 03:19 (GMT)

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Oct/21/2020

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

**Site No:** 1231

**Subject No:** 12311862

**Generated By:**

(b) (4)

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

Oct-23-2020 09:12:51 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sample collected by th e physician team	Initial Entry
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**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Oct/21/2020

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

**Site No:** 1231

**Subject No:** 12311862

**Generated By:**

(b) (4)

**Form:** ELECTRONIC SAMPLE TRACKING - NASAL  
SWAB - 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. Data Origin**

Date	Location	User	Value	Reason
Oct-23-2020 09:13:04 (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-23-2020 09:13:04 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> NASAL_SWAB	Initial Entry

**3. Sample Collected?**

Date	Location	User	Value	Reason
Oct-23-2020 11:32:25 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Oct-23-2020 11:01:42 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	DM: 'Sample Collected?' is Yes, however no barcodes

090177e196ae2ea4\Final\Final On: 01-Apr-2021 03:19 (GMT)

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Oct/21/2020

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

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

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

**Site No:** 1231

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

**Subject No:** 12311862

**Subject Initials:** ---

**Generated By:**

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

(b) (4)

				are entered. Please review and correct as appropriate.
Oct-23-2020 09:13:04 (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-23-2020 09:13:04 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6) [redacted] [redacted]	<b>Data Entry:</b> YES Date of Collection:  Oct/21/2020	Initial Entry

**5.a**

Date	Location	User	Value	Reason
Oct-23-2020 11:32:25 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6) [redacted]	<b>Data Entry:</b> <b>Sample ID</b> BPT7X : 4	Initial Entry

**5.a Sample ID**

Date	Location	User	Value	Reason
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090177e196ae2ea4\Final\Final On: 01-Apr-2021 03:19 (GMT)

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Oct/21/2020

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

**Site No:** 1231

**Subject No:** 12311862

**Generated By:**

(b) (4)

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

Oct-23-2020 11:32:25 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BPT7X4	Initial Entry
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**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Oct/21/2020

**Form Version:** 10-Oct-2020 15:59

**Site No:** 1231

**Subject No:** 12311862

**Generated By:**

(b) (4)

**Form:** HEALTH CARE UTILIZATION - 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.a*

Date	Location	User	Value	Reason
Oct-23-2020 09:13:17 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Type of Practitioner:</b> SPECIALIST IALIS T <b>Occurrence of NO Visits or Contacts:</b>	Initial Entry

*1.a Physician or Healthcare Professional:*

Date	Location	User	Value	Reason
Oct-23-2020 09:13:17 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> SPECIALIST	Initial Entry

*1.a Occurrence of Visits or Contacts:*

Date	Location	User	Value	Reason
Oct-23-2020 09:13:17 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

090177e196ae2ea4\Final\Final On: 01-Apr-2021 03:19 (GMT)



**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Oct/21/2020

**Form Version:** 10-Oct-2020 15:59

**Site No:** 1231

**Subject No:** 12311862

**Generated By:**

(b) (4)

**Form:** HEALTH CARE UTILIZATION - 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

**1.b**

Date	Location	User	Value	Reason
Oct-23-2020 09:13:17 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Type of Practitioner:</b> EMERG ENCY ROOM <b>Occurrence of Visits or Contacts:</b> NO	Initial Entry

**1.b Physician or Healthcare Professional:**

Date	Location	User	Value	Reason
Oct-23-2020 09:13:17 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> EMERGENCY ROOM	Initial Entry

**1.b Occurrence of Visits or Contacts:**

Date	Location	User	Value	Reason
Oct-23-2020 09:13:17 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**1.c**

Date	Location	User	Value	Reason
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090177e196ae2ea4\Final\Final On: 01-Apr-2021 03:19 (GMT)

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Oct/21/2020

**Form:** HEALTH CARE UTILIZATION - eCRF Audit  
Trail History

**Form Version:** 10-Oct-2020 15:59

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

**Site No:** 1231

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

**Subject No:** 12311862

**Subject Initials:** ---

**Generated By:**

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

(b) (4)

Oct-23-2020 09:13:17 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Type of Pr</b> PRIMAR <b>actioner:</b> Y CARE PHYSICI AN <b>Occurren</b> NO <b>ce of Visit</b> <b>s or Conta</b> <b>cts:</b>	Initial Entry
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***1.c Physician or Healthcare Professional:***

Date	Location	User	Value	Reason
Oct-23-2020 09:13:17 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> PRIMARY CARE PH YSICIAN	Initial Entry

***1.c Occurrence of Visits or Contacts:***

Date	Location	User	Value	Reason
Oct-23-2020 09:13:17 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

***1.d***

Date	Location	User	Value	Reason
Oct-23-2020	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>	Initial Entry

090177e196ae2ea4\Final\Final On: 01-Apr-2021 03:19 (GMT)

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Oct/21/2020

**Form Version:** 10-Oct-2020 15:59

**Site No:** 1231

**Subject No:** 12311862

**Generated By:**

(b) (4)

**Form:** HEALTH CARE UTILIZATION - 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

09:13:17 (UTC-03:00) City of Buenos Aires	(b) (4), (b) (6)	<b>Type of Practitioner:</b> URGE NT CA RE	<b>Occurrence of Visits or Contacts:</b> NO
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***1.d Physician or Healthcare Professional:***

Date	Location	User	Value	Reason
Oct-23-2020 09:13:17 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> URGENT CARE	Initial Entry

***1.d Occurrence of Visits or Contacts:***

Date	Location	User	Value	Reason
Oct-23-2020 09:13:17 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

***1.e***

Date	Location	User	Value	Reason
Oct-23-2020 09:13:17 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Type of Practitioner:</b> TELEPH ONE CO NSULTA	Initial Entry

090177e196ae2ea4\Final\Final On: 01-Apr-2021 03:19 (GMT)



**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Oct/21/2020

**Form:** HEALTH CARE UTILIZATION - eCRF Audit  
Trail History

**Form Version:** 10-Oct-2020 15:59

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

**Site No:** 1231

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

**Subject No:** 12311862

**Subject Initials:** ---

**Generated By:**

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

(b) (4)

			<b>Occurrence of NO Visits or Conta cts:</b>	
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***1.f Physician or Healthcare Professional:***

Date	Location	User	Value	Reason
Oct-23-2020 09:13:17 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> OTHER	Initial Entry

***1.f Occurrence of Visits or Contacts:***

Date	Location	User	Value	Reason
Oct-23-2020 09:13:17 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

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

Date	Location	User	Value	Reason
Oct-23-2020 09:13:17 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

090177e196ae2ea4\Final\Final On: 01-Apr-2021 03:19 (GMT)

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Oct/21/2020

**Form:** ILLNESS DETAILS - eCRF Audit Trail History

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

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

**Site No:** 1231

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

**Subject No:** 12311862

**Subject Initials:** ---

**Generated By:**

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

(b) (4)

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**1. Category of Clinical Event:**

Date	Location	User	Value	Reason
Oct-23-2020 09:13:34 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> POTENTIAL COVID- 19 ILLNESS	Initial Entry

**2. Was a diagnosis obtained for Potential COVID-19 Illness?**

Date	Location	User	Value	Reason
Jan-13-2021 12:41:36 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	Salim Bouguermouh (b) (4)	Query 2: Closed	Response satisfies query
Jan-13-2021 12:41:36 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	Salim Bouguermouh (b) (4)	Query 1: Closed	Response satisfies query
Jan-12-2021 12:39:41 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	Martina Davalli (b) (4)	Query 1: Answered	No diagnosis was made as symptoms were not specific. Thank you.
Jan-12-2021 12:38:03	ACV0PFEINFP6000	Martina Davalli	Query 2: Answered	No diagnosis was made. The

090177e196ae2ea4\Final\Final On: 01-Apr-2021 03:19 (GMT)

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Oct/21/2020

**Form:** ILLNESS DETAILS - eCRF Audit Trail History

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

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

**Site No:** 1231

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

**Subject No:** 12311862

**Subject Initials:** ---

**Generated By:**

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

(b) (4)

(UTC-03:00) City of Buenos Aires		(b) (4)		diagnosis to severe aortic stenosis was made later. Thank you.
Jan-09-2021 00:38:46 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	Salim Bouguermouh (b) (4)	Query 2: Opened	Clin: Please consider updating the diagnosis to SEVERE AORTIC STENOSIS on the COVID-19 CRF ILLNESS DETAILS form
Jan-09-2021 00:36:48 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	Salim Bouguermouh (b) (4)	Query 1: Opened	Medical monitor: Please note that this diagnosis should not be limited to Respiratory Illness Diagnoses. Record any diagnosis (where available) for

090177e196ae2ea4\Final\Final On: 01-Apr-2021 03:19 (GMT)

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Oct/21/2020

**Form:** ILLNESS DETAILS - eCRF Audit Trail History

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

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

**Site No:** 1231

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

**Subject No:** 12311862

**Subject Initials:** ---

**Generated By:**

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

(b) (4)

				the illness and in relation to reported symptoms, even if the diagnosis is not respiratory related
Oct-23-2020 09:13:34 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**3. Toxicity Grade:**

Date	Location	User	Value	Reason
Oct-23-2020 09:13:34 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 2	Initial Entry

090177e196ae2ea4\Final\Final On: 01-Apr-2021 03:19 (GMT)



**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 2 -  
Unscheduled Visit on Dec/12/2020

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

**Site No:** 1231

**Subject No:** 12311862

**Generated By:**

(b) (4)

**Form:** DATE OF VISIT - ILLNESS ONSET - 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 of Visit*

Date	Location	User	Value	Reason
Dec-14-2020 12:22:24 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Dec-14-2020 12:18:51 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Dec/12/2020	Transcription Error
Dec-14-2020 05:36:29 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	Date of Visit is completed but Date of Collection in both Nasal Swab Self and Nasal Swab are missing. Please review and update as appropriate.
Dec-12-2020 10:51:40 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Deleted	Close Auto Query

090177e196ae2ea4\Final\Final On: 01-Apr-2021 03:19 (GMT)

**Header Text:** C4591001**Visit:** POT\_COVID\_ILL 2 -  
Unscheduled Visit on Dec/12/2020**Form Version:** 22-Apr-2020 21:03**Site No:** 1231**Subject No:** 12311862**Generated By:**

(b) (4)

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

Dec-12-2020 10:49:52 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Candidate	Date of Visit is completed but Date of Assessment in the Signs and Symptoms form is missing. Please review and update as appropriate.
Dec-12-2020 10:49:52 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	Date of Visit is completed but Date of Collection in both Nasal Swab Self and Nasal Swab are missing. Please review and update as appropriate.
Dec-12-2020 10:49:52 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Dec/11/2020	Initial Entry

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

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

**Visit:** POT\_COVID\_ILL 2 -  
Unscheduled Visit on Dec/12/2020

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

**Site No:** 1231

**Subject No:** 12311862

**Generated By:**

(b) (4)

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

Dec-12-2020 10:49:52 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> COVID_B	Initial Entry
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**Header Text:** C4591001**Visit:** POT\_COVID\_ILL 2 -  
Unscheduled Visit on Dec/12/2020**Form Version:** 10-Dec-2020 02:29**Site No:** 1231**Subject No:** 12311862**Generated By:**

(b) (4)

**Form:** SIGNS AND SYMPTOMS OF POTENTIAL  
COVID-19 - eCRF Audit Trail History**Form Status:** Data Complete, Frozen, Not Complete**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. Date of Assessment:**

Date	Location	User	Value	Reason
Dec-14-2020 12:19:10 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Dec-14-2020 12:19:10 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Dec/12/2020	Transcription Error
Dec-14-2020 12:18:51 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	Date of assessment is not same as Date Visit. Please check and correct.
Dec-12-2020 10:51:40 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Dec/11/2020	Initial Entry

**2. Date of First Symptom Started:**

Date	Location	User	Value	Reason
Jan-13-2021 13:53:37	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Delet ed	Query is invalid or does not apply

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**Subject No:** 12311862

**Generated By:**

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(UTC-03:00) City of Buenos Aires		(b) (4), (b) (6)		
Dec-16-2020 15:11:01 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Candi date	Per clinical chart the patient with effort expermented blurred vision, dizziness,palpitations with stop date 12dec2020.Please review chart and update if necessary.
Dec-12-2020 10:51:40 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Nov/27/2020	Initial Entry

**3. Symptoms Ongoing?**

Date	Location	User	Value	Reason
Feb-15-2021 12:14:48 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Closed	Response satisfies query
Feb-12-2021 16:19:54 (UTC-03:00) City of Buenos	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Answered	New Information

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Aires				
Feb-12-2021 16:19:54 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	<b>Data Entry:</b> NO Date of Last Symptom Resolved :  Dec/17/2020	New Information
Feb-12-2021 09:13:00 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED] [REDACTED]	Query 2: Opened	60 days have passed since the Date of First Symptom Started and Ongoing is YES. Please confirm if symptoms are truly ongoing. Else, please enter Date of Last Symptom Resolved.
Dec-17-2020 16:45:21 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	Nicole Zalchandler (b) (4)	Query 1: Closed	Response satisfies query
Dec-16-2020 16:29:05 (UTC-03:00)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Transcription Error

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City of Buenos Aires				
Dec-16-2020 16:29:05 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	Santiago Corradetti (b) (4)	<b>Data Entry:</b> YES	Transcription Error
Dec-16-2020 15:08:55 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	Per clinical chart the symptoms are ongoing on 12dec2020 .Please review chart and update if necessary.
Dec-16-2020 13:45:34 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO Date of Last Symptom Resolved :  Dec/12/2020	New Information
Dec-12-2020 10:51:40 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

4.a

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Date	Location	User	Value	Reason
Dec-12-2020 10:51:40 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptoms:</b> FEVE R <b>Symptom Pre NO sent:</b>	Initial Entry

**4.a Symptoms:**

Date	Location	User	Value	Reason
Dec-12-2020 10:51:40 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> FEVER	Initial Entry

**4.a Was symptom present?**

Date	Location	User	Value	Reason
Dec-12-2020 10:51:40 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**4.b**

Date	Location	User	Value	Reason
Dec-12-2020 10:51:40 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sympt NEW OR IN oms: CREASED</b>	Initial Entry

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			COUGH	
			<b>Symptom Present:</b> YES	

**4.b Symptoms:**

Date	Location	User	Value	Reason
Dec-12-2020 10:51:40 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NEW OR INCREASE D COUGH	Initial Entry

**4.b Was symptom present?**

Date	Location	User	Value	Reason
Dec-12-2020 10:51:40 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

**4.c**

Date	Location	User	Value	Reason
Dec-12-2020 10:51:40 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptoms:</b> NEW OR INC CREASED SHORTNESS OF BREATH	Initial Entry

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Symp YES  
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**4.c Symptoms:**

Date	Location	User	Value	Reason
Dec-12-2020 10:51:40 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NEW OR INCREASE D SHORTNESS OF B REATH	Initial Entry

**4.c Was symptom present?**

Date	Location	User	Value	Reason
Dec-12-2020 10:51:40 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

**4.d**

Date	Location	User	Value	Reason
Dec-12-2020 10:51:40 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptoms:</b> CHIL LS <b>Symptom Pr</b> NO <b>esent:</b>	Initial Entry

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(b) (4)

**4.d Symptoms:**

Date	Location	User	Value	Reason
Dec-12-2020 10:51:40 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> CHILLS	Initial Entry

**4.d Was symptom present?**

Date	Location	User	Value	Reason
Dec-12-2020 10:51:40 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**4.e**

Date	Location	User	Value	Reason
Dec-12-2020 10:51:40 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptom</b> NEW OR IN <b>oms:</b> CREASED MUSCLE PA IN <b>Symptom Pr</b> <b>esent:</b>	Initial Entry

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**4.e Symptoms:**

Date	Location	User	Value	Reason
Dec-12-2020 10:51:40 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NEW OR INCREASE D MUSCLE PAIN	Initial Entry

**4.e Was symptom present?**

Date	Location	User	Value	Reason
Dec-12-2020 10:51:40 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**4.f**

Date	Location	User	Value	Reason
Dec-12-2020 10:51:40 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sympt</b> NEW LOSS <b>oms:</b> OF TASTE OR SMELL <b>Sympt</b> NO <b>om Pre</b> <b>sent:</b>	Initial Entry

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(b) (4)

**4.f Symptoms:**

Date	Location	User	Value	Reason
Dec-12-2020 10:51:40 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NEW LOSS OF TAS TE OR SMELL	Initial Entry

**4.f Was symptom present?**

Date	Location	User	Value	Reason
Dec-12-2020 10:51:40 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**4.g**

Date	Location	User	Value	Reason
Dec-12-2020 10:51:40 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sympt</b> NEW OR IN <b>oms:</b> CREASED S ORE THROA T <b>Sympt</b> NO <b>om Pr</b> <b>esent:</b>	Initial Entry

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(b) (4)

**4.g Symptoms:**

Date	Location	User	Value	Reason
Dec-12-2020 10:51:40 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NEW OR INCREASE D SORE THROAT	Initial Entry

**4.g Was symptom present?**

Date	Location	User	Value	Reason
Dec-12-2020 10:51:40 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**4.h**

Date	Location	User	Value	Reason
Dec-12-2020 10:51:40 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptoms:</b> DIARR HEA <b>Symptom P NO resent:</b>	Initial Entry

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**4.h Symptoms:**

Date	Location	User	Value	Reason
Dec-12-2020 10:51:40 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> DIARRHEA	Initial Entry

**4.h Was symptom present?**

Date	Location	User	Value	Reason
Dec-12-2020 10:51:40 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**4.i**

Date	Location	User	Value	Reason
Dec-12-2020 10:51:40 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptoms:</b> VOMIT ING <b>Symptom P NO</b> <b>resent:</b>	Initial Entry

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**4.i Symptoms:**

Date	Location	User	Value	Reason
Dec-12-2020 10:51:40 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> VOMITING	Initial Entry

**4.i Was symptom present?**

Date	Location	User	Value	Reason
Dec-12-2020 10:51:40 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**5.a**

Date	Location	User	Value	Reason
Dec-12-2020 10:52:36 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Symptoms - hypotension symptoms while making physical effort	Initial Entry

**5.a Symptoms - Other Text:**

Date	Location	User	Value	Reason
Dec-12-2020 10:52:36	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Hypotension symptom	Initial Entry

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(UTC-03:00) City of Buenos Aires		(b) (4), (b) (6)	s while making physical effort	
----------------------------------	--	------------------	--------------------------------	--

**5.b**

Date	Location	User	Value	Reason
Jan-13-2021 16:00:55 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Symptoms Blurred - Other: vision	Initial Entry

**5.b Symptoms - Other Text:**

Date	Location	User	Value	Reason
Jan-13-2021 16:00:55 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Blurred vision	Initial Entry

**5.c**

Date	Location	User	Value	Reason
Jan-13-2021 16:01:15 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Symptoms - Dizziness Other: ess	Initial Entry

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**5.c Symptoms - Other Text:**

Date	Location	User	Value	Reason
Jan-13-2021 16:01:15 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Dizziness	Initial Entry

**5.d**

Date	Location	User	Value	Reason
Jan-13-2021 16:01:26 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptoms -</b> Palpita <b>Other:</b> tions	Initial Entry

**5.d Symptoms - Other Text:**

Date	Location	User	Value	Reason
Jan-13-2021 16:01:26 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Palpitations	Initial Entry

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Date	Location	User	Value	Reason
Dec-12-2020 10:59:18 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Created	

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 2 -  
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**Form:** MICROBIOLOGY SPECIMEN - Audit Trail

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Dec-14-2020 12:21:56 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Created	

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**1. Actual Date of Collection:**

Date	Location	User	Value	Reason
Dec-12-2020 10:59:18 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Dec/9/2020	Initial Entry

**2. Specimen Type:**

Date	Location	User	Value	Reason
Dec-12-2020 10:59:18 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> SWABBED MATERI AL	Initial Entry

**3. Specimen Collection Location:**

Date	Location	User	Value	Reason
Dec-15-2020 11:23:35 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Dec-14-2020 11:11:05 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	New Information

090177e196ae2ea4\Final\Final On: 01-Apr-2021 03:19 (GMT)

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 2 -  
Unscheduled Visit on Dec/12/2020

**Form:** MICROBIOLOGY SPECIMEN - eCRF Audit Trail  
History

**Form Version:** 06-Jul-2020 21:54

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

**Site No:** 1231

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

**Subject No:** 12311862

**Subject Initials:** ---

**Generated By:**

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

(b) (4)

Dec-14-2020 11:11:05 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	Santiago Corradetti (b) (4)	<b>Data Entry:</b> NASOPHARYNX	New Information
Dec-14-2020 03:12:06 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	DM: Please complete this item. Thank you.

**4. Assay Code and Description:**

Date	Location	User	Value	Reason
Dec-12-2020 10:59:18 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SEVERE ACUTE RES P SYNDROME CORO NAVIRUS 2	Initial Entry

**5. Device Type:**

Date	Location	User	Value	Reason
Dec-12-2020 10:59:18 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SARS-COV-2 DIAGN OSTIC TEST	Initial Entry

**6. Trade Name:**

Date	Location	User	Value	Reason
Dec-12-2020 10:59:18	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> OTHER	Initial Entry

090177e196ae2ea4\Final\Final On: 01-Apr-2021 03:19 (GMT)

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 2 -  
Unscheduled Visit on Dec/12/2020

**Form:** MICROBIOLOGY SPECIMEN - eCRF Audit Trail  
History

**Form Version:** 06-Jul-2020 21:54

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

**Site No:** 1231

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

**Subject No:** 12311862

**Subject Initials:** ---

**Generated By:**

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

(b) (4)

(UTC-03:00) City of Buenos Aires		(b) (4), (b) (6)		
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**7. Test Result:**

Date	Location	User	Value	Reason
Dec-12-2020 10:59:18 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NEGATIVE	Initial Entry

**8. Comments/Findings/Details:**

Date	Location	User	Value	Reason
Dec-12-2020 10:59:18 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Subject got swabbed at "Hospital Posadas"	Initial Entry

**9. Trade Name Other, Specify:**

Date	Location	User	Value	Reason
Dec-12-2020 10:59:18 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NALT Unknown	Initial Entry

090177e196ae2ea4\Final\Final On: 01-Apr-2021 03:19 (GMT)

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 2 -  
Unscheduled Visit on Dec/12/2020

**Form:** MICROBIOLOGY SPECIMEN - eCRF Audit Trail  
History

**Form Version:** 06-Jul-2020 21:54

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

**Site No:** 1231

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

**Subject No:** 12311862

**Subject Initials:** ---

**Generated By:**

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

(b) (4)

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**1. Actual Date of Collection:**

Date	Location	User	Value	Reason
Dec-14-2020 12:21:56 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Dec/12/2020	Initial Entry

**2. Specimen Type:**

Date	Location	User	Value	Reason
Dec-14-2020 12:21:56 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> SWABBED MATERI AL	Initial Entry

**3. Specimen Collection Location:**

Date	Location	User	Value	Reason
Dec-14-2020 12:21:56 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NASOPHARYNX	Initial Entry

**4. Assay Code and Description:**

Date	Location	User	Value	Reason
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090177e196ae2ea4\Final\Final On: 01-Apr-2021 03:19 (GMT)



**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 2 -  
Unscheduled Visit on Dec/12/2020

**Form:** MICROBIOLOGY SPECIMEN - eCRF Audit Trail  
History

**Form Version:** 06-Jul-2020 21:54

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

**Site No:** 1231

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

**Subject No:** 12311862

**Subject Initials:** ---

**Generated By:**

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

(b) (4)

Dec-14-2020 12:21:56 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SEVERE ACUTE RES P SYNDROME CORO NAVIRUS 2	Initial Entry
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**5. Device Type:**

Date	Location	User	Value	Reason
Dec-14-2020 12:21:56 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SARS-COV-2 DIAGN OSTIC TEST	Initial Entry

**6. Trade Name:**

Date	Location	User	Value	Reason
Dec-14-2020 12:21:56 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> ATILA BIOSYSTEM S IAMP COVID-19 DETECTION KIT	Initial Entry

**7. Test Result:**

Date	Location	User	Value	Reason
Dec-14-2020 12:21:56 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NEGATIVE	Initial Entry

090177e196ae2ea4\Final\Final On: 01-Apr-2021 03:19 (GMT)

**Header Text:** C4591001**Visit:** POT\_COVID\_ILL 2 -  
Unscheduled Visit on Dec/12/2020**Form Version:** 22-Apr-2020 21:03**Site No:** 1231**Subject No:** 12311862**Generated By:**

(b) (4)

**Form:** ELECTRONIC SAMPLE TRACKING - NASAL  
SWAB SELF - 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[Back to Form](#)**1. Data Origin**

Date	Location	User	Value	Reason
Dec-14-2020 12:22:13 (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
Dec-14-2020 12:22:13 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> NASAL_SWAB_SELF	Initial Entry

**3. Sample Collected?**

Date	Location	User	Value	Reason
Dec-14-2020 12:22:13 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED] [REDACTED] [REDACTED]	<b>Data Entry:</b> NO	Initial Entry

**4. If no sample was collected or sample was not collected according to protocol, please provide reason:**

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

**Visit:** POT\_COVID\_ILL 2 -  
Unscheduled Visit on Dec/12/2020

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

**Site No:** 1231

**Subject No:** 12311862

**Generated By:**

(b) (4)

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

Dec-14-2020 12:22:13 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> sample collected by a team physician	Initial Entry
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**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 2 -  
Unscheduled Visit on Dec/12/2020

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

**Site No:** 1231

**Subject No:** 12311862

**Generated By:**

(b) (4)

**Form:** ELECTRONIC SAMPLE TRACKING - NASAL  
SWAB - 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. Data Origin**

Date	Location	User	Value	Reason
Dec-14-2020 12:22:24 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SITE	Initial Entry

**2. Sample Type**

Date	Location	User	Value	Reason
Dec-14-2020 12:22:24 (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
Dec-14-2020 12:47:45 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Dec-14-2020 12:22:24 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes

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**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 2 -  
Unscheduled Visit on Dec/12/2020

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

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

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

**Site No:** 1231

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

**Subject No:** 12311862

**Subject Initials:** ---

**Generated By:**

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

(b) (4)

				are entered. Please review and correct as appropriate.
Dec-14-2020 12:22:24 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES Date of Collection:  Dec/12/2020	Initial Entry

**5.a**

Date	Location	User	Value	Reason
Dec-14-2020 12:47:45 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sample I BPWSY D: G	Initial Entry

**5.a Sample ID**

Date	Location	User	Value	Reason
Dec-14-2020 12:47:45 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BPWSYG	Initial Entry

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**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 2 -  
Unscheduled Visit on Dec/12/2020

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

**Site No:** 1231

**Subject No:** 12311862

**Generated By:**

(b) (4)

**Form:** HEALTH CARE UTILIZATION - 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.a*

Date	Location	User	Value	Reason
Dec-14-2020 11:18:27 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	Santiago Corradetti (b) (4)	<b>Data Entry:</b> <b>Type of Pra</b> SPE <b>ctitioner:</b> CIAL IST <b>Occurrence</b> NO <b>of Visits or</b> <b>Contacts:</b>	Initial Entry
Dec-12-2020 10:58:06 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Type of Pra</b> SPE <b>ctitioner:</b> CIAL IST <b>Occurrence</b> <b>of Visits or</b> <b>Contacts:</b>	Initial Entry

*1.a Physician or Healthcare Professional:*

Date	Location	User	Value	Reason
Dec-12-2020 10:58:06 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> SPECIALIST	Initial Entry

*1.a Occurrence of Visits or Contacts:*

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**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 2 -  
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**Form:** HEALTH CARE UTILIZATION - eCRF Audit  
Trail History

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

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

**Site No:** 1231

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

**Subject No:** 12311862

**Subject Initials:** ---

**Generated By:**

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

(b) (4)

Date	Location	User	Value	Reason
Dec-14-2020 11:18:27 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	Santiago Corradetti (b) (4)	<b>Data Entry:</b> NO	Initial Entry

**1.b**

Date	Location	User	Value	Reason
Dec-14-2020 11:16:58 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	Santiago Corradetti (b) (4)	<b>Data Entry:</b> <b>Type of P</b> EMER <b>ractitione</b> GENC <b>r:</b> Y ROO M <b>Occurren</b> NO <b>ce of Visit</b> <b>s or Cont</b> <b>acts:</b>	Translation mistake
Dec-12-2020 10:58:06 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Type of</b> EMERG <b>Practiti</b> ENCY R <b>oner:</b> OOM <b>Occurr</b> YES <b>ence of</b> <i>Number</i> <b>Visits o</b> <i>of Visits</i> <b>r Conta</b> <i>or Conta</i> <b>cts:</b> <i>acts:</i>  1	Initial Entry

090177e196ae2ea4\Final\Final On: 01-Apr-2021 03:19 (GMT)

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 2 -  
Unscheduled Visit on Dec/12/2020

**Form:** HEALTH CARE UTILIZATION - eCRF Audit  
Trail History

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

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

**Site No:** 1231

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

**Subject No:** 12311862

**Subject Initials:** ---

**Generated By:**

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

(b) (4)

**1.b Physician or Healthcare Professional:**

Date	Location	User	Value	Reason
Dec-12-2020 10:58:06 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> EMERGENCY ROO M	Initial Entry

**1.b Occurrence of Visits or Contacts:**

Date	Location	User	Value	Reason
Dec-14-2020 11:16:58 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	Santiago Corradetti (b) (4)	<b>Data Entry:</b> NO	Translation mistake
Dec-12-2020 10:58:06 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES <i>Number of Visits or Contacts:</i>  1	Initial Entry

**1.c**

Date	Location	User	Value	Reason
Dec-14-2020 11:18:27 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	Santiago Corradetti (b) (4)	<b>Data Entry:</b> <b>Type of Practitioner:</b> PRIMA RY CAR E PHYS ICIAN	Initial Entry

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**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 2 -  
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**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1231

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

**Subject No:** 12311862

**Subject Initials:** ---

**Generated By:**

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

(b) (4)

			<b>Occurrence of Visits or Contacts:</b>	
Dec-12-2020 10:58:06 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Type of Practitioner:</b> PRIMARY CARE PHYSICIAN <b>Occurrence of Visits or Contacts:</b>	Initial Entry

***1.c Physician or Healthcare Professional:***

Date	Location	User	Value	Reason
Dec-12-2020 10:58:06 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> PRIMARY CARE PHYSICIAN	Initial Entry

***1.c Occurrence of Visits or Contacts:***

Date	Location	User	Value	Reason
Dec-14-2020 11:18:27 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	Santiago Corradetti (b) (4)	<b>Data Entry:</b> NO	Initial Entry

090177e196ae2ea4\Final\Final On: 01-Apr-2021 03:19 (GMT)

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 2 -  
Unscheduled Visit on Dec/12/2020

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

**Site No:** 1231

**Subject No:** 12311862

**Generated By:**

(b) (4)

**Form:** HEALTH CARE UTILIZATION - 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

*1.d*

Date	Location	User	Value	Reason
Dec-14-2020 11:18:27 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	Santiago Corradetti (b) (4)	<b>Data Entry:</b> <b>Type of Practitioner:</b> URGENT CARE <b>Occurrence of Visits or Contacts:</b> YES Number of Visits or Contacts: 2	Initial Entry
Dec-12-2020 10:58:06 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Type of Practitioner:</b> URGENT CARE <b>Occurrence of Visits or Contacts:</b>	Initial Entry

090177e196ae2ea4\Final\Final On: 01-Apr-2021 03:19 (GMT)

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 2 -  
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**Form:** HEALTH CARE UTILIZATION - eCRF Audit  
Trail History

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

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

**Site No:** 1231

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

**Subject No:** 12311862

**Subject Initials:** ---

**Generated By:**

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

(b) (4)

***1.d Physician or Healthcare Professional:***

Date	Location	User	Value	Reason
Dec-12-2020 10:58:06 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> URGENT CARE	Initial Entry

***1.d Occurrence of Visits or Contacts:***

Date	Location	User	Value	Reason
Dec-14-2020 11:18:27 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	Santiago Corradetti (b) (4)	<b>Data Entry:</b> YES <i>Number of Visits o r Contacts:</i>  2	Initial Entry

***1.e***

Date	Location	User	Value	Reason
Dec-14-2020 11:18:27 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	Santiago Corradetti (b) (4)	<b>Data Entry:</b> <b>Type of TELEPH Practitio ONE CO ner: NSULTA TION</b>  <b>Occurre NO nce of Vi sits or C ontacts:</b>	Initial Entry

090177e196ae2ea4\Final\Final On: 01-Apr-2021 03:19 (GMT)

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 2 -  
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**Form:** HEALTH CARE UTILIZATION - eCRF Audit  
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**Form Version:** 10-Dec-2020 02:26

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

**Site No:** 1231

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

**Subject No:** 12311862

**Subject Initials:** ---

**Generated By:**

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

(b) (4)

Dec-12-2020 10:58:06 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Type of</b> TELEPH <b>Practitio</b> ONE CO <b>ner:</b> NSULTA TION  <b>Occurre nce of Vi sits or C ontacts:</b>	Initial Entry
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***I.e Physician or Healthcare Professional:***

Date	Location	User	Value	Reason
Dec-12-2020 10:58:06 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> TELEPHONE CONS ULTATION	Initial Entry

***I.e Occurrence of Visits or Contacts:***

Date	Location	User	Value	Reason
Dec-14-2020 11:18:27 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	Santiago Corradetti (b) (4)	<b>Data Entry:</b> NO	Initial Entry

***I.f***

Date	Location	User	Value	Reason
Dec-14-2020	ACV0PFEINFP6000	Santiago	<b>Data Entry:</b>	Initial Entry

090177e196ae2ea4\Final\Final On: 01-Apr-2021 03:19 (GMT)

**Header Text:** C4591001**Visit:** POT\_COVID\_ILL 2 -  
Unscheduled Visit on Dec/12/2020**Form Version:** 10-Dec-2020 02:26**Site No:** 1231**Subject No:** 12311862**Generated By:**

(b) (4)

**Form:** HEALTH CARE UTILIZATION - 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

11:18:27 (UTC-03:00) City of Buenos Aires		Corradetti (b) (4)	<b>Type of Practitioner:</b> OT HE R <b>Occurrence of Visits or Contacts:</b> NO	
Dec-12-2020 10:58:06 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Type of Practitioner:</b> OT HE R <b>Occurrence of Visits or Contacts:</b>	Initial Entry

***1.f Physician or Healthcare Professional:***

Date	Location	User	Value	Reason
Dec-12-2020 10:58:06 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> OTHER	Initial Entry

***1.f Occurrence of Visits or Contacts:***

Date	Location	User	Value	Reason
Dec-14-2020 11:18:27 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	Santiago Corradetti (b) (4)	<b>Data Entry:</b> NO	Initial Entry

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 2 -  
Unscheduled Visit on Dec/12/2020

**Form:** HEALTH CARE UTILIZATION - eCRF Audit  
Trail History

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

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

**Site No:** 1231

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

**Subject No:** 12311862

**Subject Initials:** ---

**Generated By:**

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

(b) (4)

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

Date	Location	User	Value	Reason
Dec-15-2020 05:30:28 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6) [Redacted]	Query 1: Closed	Response satisfies query
Dec-14-2020 11:18:27 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Initial Entry
Dec-14-2020 11:18:27 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	Santiago Corradetti (b) (4)	<b>Data Entry:</b> NO	Initial Entry
Dec-14-2020 03:14:26 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6) [Redacted]	Query 1: Opened	DM: Please complete details on field # 3.a, 3.c, 3.d, 3.e, 3.f and 5. Thank you.

090177e196ae2ea4\Final\Final On: 01-Apr-2021 03:19 (GMT)

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 2 -  
Unscheduled Visit on Dec/12/2020

**Form:** ILLNESS DETAILS - eCRF Audit Trail History

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

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

**Site No:** 1231

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

**Subject No:** 12311862

**Subject Initials:** ---

**Generated By:**

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

(b) (4)

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**1. Category of Clinical Event:**

Date	Location	User	Value	Reason
Dec-16-2020 13:46:23 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> POTENTIAL COVID- 19 ILLNESS	Initial Entry

**2. Was a diagnosis obtained for Potential COVID-19 Illness?**

Date	Location	User	Value	Reason
Dec-16-2020 13:46:23 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**3. Toxicity Grade:**

Date	Location	User	Value	Reason
Dec-16-2020 13:46:23 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 2	Initial Entry

090177e196ae2ea4\Final\Final On: 01-Apr-2021 03:19 (GMT)

**Header Text:** C4591001

**Visit:** POT\_COVID\_CONVA 1 -  
Unscheduled Visit on Nov/19/2020

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

**Site No:** 1231

**Subject No:** 12311862

**Generated By:**

(b) (4)

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

Date	Location	User	Value	Reason
Nov-19-2020 14:54:43 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Nov/19/2020	Initial Entry

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

Date	Location	User	Value	Reason
Nov-19-2020 14:54:43 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> COVID_A1	Initial Entry

090177e196ae2ea4\Final\Final On: 01-Apr-2021 03:19 (GMT)



**Header Text:** C4591001

**Visit:** POT\_COVID\_CONVA 1 -  
Unscheduled Visit on Nov/19/2020

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

**Site No:** 1231

**Subject No:** 12311862

**Generated By:**

(b) (4)

**Form:** ELECTRONIC SAMPLE TRACKING -  
IMMUNOGENICITY - 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. Data Origin**

Date	Location	User	Value	Reason
Nov-19-2020 14:54:53 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SITE	Initial Entry

**2. Sample Type**

Date	Location	User	Value	Reason
Nov-19-2020 14:54:53 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SERUM	Initial Entry

**3. Sample Collected?**

Date	Location	User	Value	Reason
Nov-20-2020 09:29:21 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Nov-19-2020 14:54:53 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes

090177e196ae2ea4\Final\Final On: 01-Apr-2021 03:19 (GMT)

**Header Text:** C4591001

**Visit:** POT\_COVID\_CONVA 1 -  
Unscheduled Visit on Nov/19/2020

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

**Site No:** 1231

**Subject No:** 12311862

**Generated By:**

(b) (4)

**Form:** ELECTRONIC SAMPLE TRACKING -  
IMMUNOGENICITY - 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

				are entered. Please review and correct as appropriate.
Nov-19-2020 14:54:53 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES Date of Collection:  Nov/19/2020	Initial Entry

**5.a**

Date	Location	User	Value	Reason
Nov-20-2020 09:29:21 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sample ID BPXJD : K	Initial Entry

**5.a Sample ID**

Date	Location	User	Value	Reason
Nov-20-2020 09:29:21 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BPXJDK	Initial Entry

**5.b**

Date	Location	User	Value	Reason
Nov-20-2020	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>	Initial Entry

090177e196ae2ea4\Final\Final On: 01-Apr-2021 03:19 (GMT)

**Header Text:** C4591001

**Visit:** POT\_COVID\_CONVA 1 -  
Unscheduled Visit on Nov/19/2020

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

**Site No:** 1231

**Subject No:** 12311862

**Generated By:**

(b) (4)

**Form:** ELECTRONIC SAMPLE TRACKING -  
IMMUNOGENICITY - 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

09:58:54  
(UTC-03:00) City  
of Buenos Aires

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

**Sample ID BRVMC**  
:  
8

**5.b Sample ID**

Date	Location	User	Value	Reason
Nov-20-2020 09:58:54 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BRVMC8	Initial Entry

**5.c**

Date	Location	User	Value	Reason
Nov-20-2020 10:14:15 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample I</b> BRVMC <b>D:</b> G	Initial Entry

**5.c Sample ID**

Date	Location	User	Value	Reason
Nov-20-2020 10:14:15 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BRVMCG	Initial Entry

090177e196ae2ea4\Final\Final On: 01-Apr-2021 03:19 (GMT)

**Header Text:** C4591001

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

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

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

**Site No:** 1231

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

**Subject No:** 12311862

**Subject Initials:** ---

**Generated By:**

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

(b) (4)

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

Date	Location	User	Value	Reason
Oct-14-2020 09:42:15 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Oct/13/2020	Initial Entry

**2. Phase of Disposition:**

Date	Location	User	Value	Reason
Oct-14-2020 09:42:15 (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 09:42:15 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> COMPLETED	Initial Entry

090177e196ae2ea4\Final\Final On: 01-Apr-2021 03:19 (GMT)

**Header Text:** C4591001

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

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

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

**Site No:** 1231

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

**Subject No:** 12311862

**Subject Initials:** ---

**Generated By:**

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

(b) (4)

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*1. Date of Visit*

Date	Location	User	Value	Reason
Mar-22-2021 16:51:02 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	Martina Davalli (b) (4)	<b>Data Entry:</b> Mar/22/2021	Initial Entry

090177e196ae2ea4\Final\Final On: 01-Apr-2021 03:19 (GMT)

**Header Text:** C4591001

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

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

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

**Subject No:** 12311862 **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
Mar-22-2021 16:51:33 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Mar-22-2021 16:51:18 (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.
Mar-22-2021 16:51:18 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	Martina Davalli (b) (4)	<b>Data Entry:</b> Participant is willin g to return for Vacc ination 3 Participant is:  eligible per othe r protocol allow ance(s) and conf	Initial Entry

090177e196ae2ea4\Final\Final On: 01-Apr-2021 03:19 (GMT)

**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, Verified

**Site No:** 1231

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

**Subject No:** 12311862

**Subject Initials:** ---

**Generated By:**

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

(b) (4)

			irmed to have re ceived only plac ebo at Vaccinati on 1/2	
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**Header Text:** C4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1231

**Subject No:** 12311862

**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
Dec-19-2020 11:33:22 (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:** 12311862

**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
Feb-19-2021 10:37:16 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	Martina Davalli (b) (4)	Form Created	

090177e196ae2ea4\Final\Final On: 01-Apr-2021 03:19 (GMT)

**Header Text:** C4591001

**Visit:** Logs - Unscheduled

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

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

**Form Status:** Data Complete, Locked

**Site No:** 1231

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

**Subject No:** 12311862

**Subject Initials:** ---

**Generated By:**

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

(b) (4)

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**1. Category:**

Date	Location	User	Value	Reason
Dec-19-2020 11:33:22 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> ADVERSE EVENT	Initial Entry

**2. AE ID:**

Date	Location	User	Value	Reason
Dec-19-2020 11:33:22 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 1	Initial Entry

**3. Adverse Event:**

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

Date	Location	User	Value	Reason
Jan-07-2021 11:33:49 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Dec-28-2020 11:35:28 (UTC-03:00) City of Buenos	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	It's clarified that the acronym PHT described in the echocardiogram

090177e196ae2ea4\Final\Final On: 01-Apr-2021 03:19 (GMT)

**Header Text:** C4591001

**Visit:** Logs - Unscheduled

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

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

**Form Status:** Data Complete, Locked

**Site No:** 1231

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

**Subject No:** 12311862

**Subject Initials:** ---

**Generated By:**

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

(b) (4)

Aires				does not correspond to Pulmonary Hypertension. It is a term of echocardiography: interval of time that it takes for the maximum transvalvular gradient to fall to half its initial value
Dec-21-2020 19:07:52 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	Clinical On review of the SAE report for Aortic Stenosis, an event of Pulmonary Hypertension has been mentioned, yet it does not appear in the CRF. Please review for safety and update AE log CRF if appropriate.
Dec-19-2020 11:33:22 (UTC-03:00) City of Buenos	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Severe aortic stenosis	Initial Entry

090177e196ae2ea4\Final\Final On: 01-Apr-2021 03:19 (GMT)

**Header Text:** C4591001

**Visit:** Logs - Unscheduled

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

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

**Form Status:** Data Complete, Locked

**Site No:** 1231

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

**Subject No:** 12311862

**Subject Initials:** ---

**Generated By:**

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

(b) (4)

Aires				
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**4. Start Date Time:**

Date	Location	User	Value	Reason
Dec-19-2020 11:33:22 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Oct/13/2020 08:00	Initial Entry

**5. Is the adverse event still ongoing?**

Date	Location	User	Value	Reason
Mar-02-2021 16:54:26 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Feb-27-2021 21:54:05 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	In FU sent on 25FEB, it was clarified that the status is "not recovered".
Feb-26-2021 00:06:35 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	CLINICAL End date for event Aortic Stenosis is NONE (and aortic valve surgery is

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**Header Text:** C4591001

**Visit:** Logs - Unscheduled

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

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

**Form Status:** Data Complete, Locked

**Site No:** 1231

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

**Subject No:** 12311862

**Subject Initials:** ---

**Generated By:**

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

(b) (4)

				scheduled); however, SAE report received an end date of 04Feb21. Please review end date, harmonize reporting and update where applicable
Dec-19-2020 11:33:22 (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
Dec-19-2020 11:33:22 (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**

090177e196ae2ea4\Final\Final On: 01-Apr-2021 03:19 (GMT)

**Header Text:** C4591001

**Visit:** Logs - Unscheduled

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

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

**Form Status:** Data Complete, Locked

**Site No:** 1231

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

**Subject No:** 12311862

**Subject Initials:** ---

**Generated By:**

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

(b) (4)

*prevent above outcomes).*

Date	Location	User	Value	Reason
Jan-07-2021 11:34:08 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Closed	Response satisfies query
Jan-04-2021 16:27:27 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Answered	This information was sent in the follow up SAE form on 23DEC.
Dec-31-2020 21:27:12 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Reissued: Opened	Clinical – Thank you. If NO hospital COVID test was performed is known, please submit this information on a follow-up SAE form, as pertinent information for this trial.
Dec-25-2020 20:05:02 (UTC-03:00)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Answered	I clarify that COVID testing was not

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**Header Text:** C4591001

**Visit:** Logs - Unscheduled

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

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

**Form Status:** Data Complete, Locked

**Site No:** 1231

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

**Subject No:** 12311862

**Subject Initials:** ---

**Generated By:**

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

(b) (4)

City of Buenos Aires				performed during hospitalization. As informed in the initial Form the patient as a negative PCR SARS-COV-2 on 09Dec2020.
Dec-22-2020 09:11:06 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Dec-21-2020 18:54:58 (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 [add AER#] to document if COVID testing was performed in the Hospital (YES/NO or info not available) and if

090177e196ae2ea4\Final\Final On: 01-Apr-2021 03:19 (GMT)

**Header Text:** C4591001

**Visit:** Logs - Unscheduled

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

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

**Form Status:** Data Complete, Locked

**Site No:** 1231

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

**Subject No:** 12311862

**Subject Initials:** ---

**Generated By:**

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

(b) (4)

				yes, the date and results.
Dec-19-2020 11:33:22 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	For AE Severe aortic stenosis: Response to "Is the adverse event serious?" is 'Yes' but "Serious Adverse Event Number" is blank.
Dec-19-2020 11:33:22 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES Is this serious event associated with congenital anomaly or birth defect?  YES  Did this serious event result in death?  NO  Did this serious event require or prolong hospitaliza	Initial Entry

090177e196ae2ea4\Final\Final On: 01-Apr-2021 03:19 (GMT)



**Header Text:** C4591001

**Visit:** Logs - Unscheduled

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

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

**Form Status:** Data Complete, Locked

**Site No:** 1231

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

**Subject No:** 12311862

**Subject Initials:** ---

**Generated By:**

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

(b) (4)

			tion?	
			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.

Date	Location	User	Value	Reason
Dec-19-2020 11:33:22 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**Header Text:** C4591001

**Visit:** Logs - Unscheduled

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

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

**Form Status:** Data Complete, Locked

**Site No:** 1231

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

**Subject No:** 12311862

**Subject Initials:** ---

**Generated By:**

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

(b) (4)

**9. Is this event related to study treatment:**

Date	Location	User	Value	Reason
Dec-19-2020 11:33:22 (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  <i>If Other, specify:</i>  history of bicuspid aortic valve	Initial Entry

**10. Latest Action Taken with Study Treatment:**

Date	Location	User	Value	Reason
Dec-19-2020 11:33:22 (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-07-2021 11:39:36 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query

090177e196ae2ea4\Final\Final On: 01-Apr-2021 03:19 (GMT)

**Header Text:** C4591001

**Visit:** Logs - Unscheduled

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

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

**Form Status:** Data Complete, Locked

**Site No:** 1231

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

**Subject No:** 12311862

**Subject Initials:** ---

**Generated By:**

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

(b) (4)

Dec-30-2020 13:23:09 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	SAE follow up form was sent with this information
Dec-30-2020 13:23:09 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	<b>Data Entry:</b> YES	SAE follow up form was sent with this information
Dec-27-2020 13:21:40 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Query 1: Reissued: Opened	CLINICAL Con Med for Event of aortic stenosis is YES; however, SAE report does not indicate any medical treatment for this event. Please review, harmonize reporting, & add Con med info to SAE if Con Meds were received.
Dec-25-2020 20:05:44 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	New Information

090177e196ae2ea4\Final\Final On: 01-Apr-2021 03:19 (GMT)

**Header Text:** C4591001

**Visit:** Logs - Unscheduled

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

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

**Form Status:** Data Complete, Locked

**Site No:** 1231

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

**Subject No:** 12311862

**Subject Initials:** ---

**Generated By:**

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

(b) (4)

Dec-25-2020 20:05:44 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	<b>Data Entry:</b> NO	New Information
Dec-21-2020 18:52:22 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Query 1: Opened	CLINICAL Con Med for Event of aortic stenosis is YES; however, SAE report does not indicate any medical treatment for this event. Please review, harmonize reporting, & add Con med info to SAE if Con Meds were received.
Dec-19-2020 11:33:22 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	<b>Data Entry:</b> YES	Initial Entry

**12. Was a Non-Drug Treatment given?**

Date	Location	User	Value	Reason
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090177e196ae2ea4\Final\Final On: 01-Apr-2021 03:19 (GMT)

**Header Text:** C4591001

**Visit:** Logs - Unscheduled

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

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

**Form Status:** Data Complete, Locked

**Site No:** 1231

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

**Subject No:** 12311862

**Subject Initials:** ---

**Generated By:**

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

(b) (4)

Dec-19-2020 11:33:22 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry
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**13. What was the outcome of this adverse event?:**

Date	Location	User	Value	Reason
Mar-09-2021 08:25:19 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry</b> : REC OVE RING /RES OLVI NG	New Information
Mar-02-2021 06:17:33 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Clo sed	Response satisfies query
Feb-26-2021 04:01:23 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Rei ssued: Candi date	Pending SDB update

090177e196ae2ea4\Final\Final On: 01-Apr-2021 03:19 (GMT)

**Header Text:** C4591001

**Visit:** Logs - Unscheduled

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

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

**Form Status:** Data Complete, Locked

**Site No:** 1231

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

**Subject No:** 12311862

**Subject Initials:** ---

**Generated By:**

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

(b) (4)

Feb-25-2021 13:32:09 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	FU SAE form was sent with the update information.
Feb-23-2021 23:35:25 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	SAE RECON:AER#2020504970,outcome was reported as RECOVERED/RESOLVED to Safety DB however, recorded as NOT RECOVERED/NOT RESOLVED on AE CRF. Please confirm correct outcome. If safety update is required, please submit a follow-up form.
Dec-19-2020 11:33:22 (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
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090177e196ae2ea4\Final\Final On: 01-Apr-2021 03:19 (GMT)

**Header Text:** C4591001

**Visit:** Logs - Unscheduled

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

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

**Form Status:** Data Complete, Locked

**Site No:** 1231

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

**Subject No:** 12311862

**Subject Initials:** ---

**Generated By:**

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

(b) (4)

Dec-19-2020 11:33:22 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry
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**15. Serious Adverse Event Number: For Pfizer Use Only**

Date	Location	User	Value	Reason
Dec-22-2020 09:11:06 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 2020504970	Initial Entry

090177e196ae2ea4\Final\Final On: 01-Apr-2021 03:19 (GMT)

**Header Text:** C4591001

**Visit:** Logs - Unscheduled

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

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

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

**Site No:** 1231

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

**Subject No:** 12311862

**Subject Initials:** ---

**Generated By:**

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

(b) (4)

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**1. Category:**

Date	Location	User	Value	Reason
Feb-19-2021 10:37:16 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> ADVERSE EVENT	Initial Entry

**2. AE ID:**

Date	Location	User	Value	Reason
Feb-19-2021 10:37:16 (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-19-2021 10:37:16 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	Martina Davalli (b) (4)	<b>Data Entry:</b> pulmonary nodules	Initial Entry

**4. Start Date Time:**

Date	Location	User	Value	Reason
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090177e196ae2ea4\Final\Final On: 01-Apr-2021 03:19 (GMT)



**Header Text:** C4591001

**Visit:** Logs - Unscheduled

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

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

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

**Site No:** 1231

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

**Subject No:** 12311862

**Subject Initials:** ---

**Generated By:**

**Generated Time (GMT):** 29-Mar-2021 16:45

(b) (4)

Feb-19-2021 10:37:16 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	Martina Davalli (b) (4)	<b>Data Entry:</b> Jan/4/2021 10:00	Initial Entry
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**5. Is the adverse event still ongoing?**

Date	Location	User	Value	Reason
Feb-24-2021 10:11:27 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	Martina Davalli (b) (4)	<b>Data Entry:</b> NO End Date Time: Feb/23/2021 20:46	New Information
Feb-19-2021 10:37:16 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	Martina Davalli (b) (4)	<b>Data Entry:</b> YES	Initial Entry

**6. Toxicity Grade:**

Date	Location	User	Value	Reason
Feb-19-2021 10:37:16 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	Martina Davalli (b) (4)	<b>Data Entry:</b> 1	Initial Entry

**7. Is the adverse event serious?**

**If Yes, NOTIFY PFIZER IMMEDIATELY.**

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**Header Text:** C4591001

**Visit:** Logs - Unscheduled

**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History

**Form Version:** 22-Apr-2020 21:02

**Form Status:** Data Complete, Locked, Frozen

**Site No:** 1231

**Site Name:** (1231) Hospital Militar Central Cirujano Mayor Dr. Cosme Argerich

**Subject No:** 12311862

**Subject Initials:** ---

**Generated By:**

**Generated Time (GMT):** 29-Mar-2021 16:45

(b) (4)

*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-19-2021 10:37:16 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	Martina Davalli (b) (4)	<b>Data Entry:</b> NO	Initial Entry

**8. Is this adverse event the result of a study Medication Error?**

*If Yes, record the type of medication error on the Medication Error Log.*

Date	Location	User	Value	Reason
Feb-19-2021 10:37:16 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	Martina Davalli (b) (4)	<b>Data Entry:</b> NO	Initial Entry

**9. Is this event related to study treatment:**

Date	Location	User	Value	Reason
Feb-19-2021 10:37:16 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	Martina Davalli (b) (4)	<b>Data Entry:</b> NOT RELATED If Not Related to study treatment(s), this event is due to:  OTHER	Initial Entry

090177e196ae2ea4\Final\Final On: 01-Apr-2021 03:19 (GMT)

**Header Text:** C4591001

**Visit:** Logs - Unscheduled

**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History

**Form Version:** 22-Apr-2020 21:02

**Form Status:** Data Complete, Locked, Frozen

**Site No:** 1231

**Site Name:** (1231) Hospital Militar Central Cirujano Mayor Dr. Cosme Argerich

**Subject No:** 12311862

**Subject Initials:** ---

**Generated By:**

**Generated Time (GMT):** 29-Mar-2021 16:45

(b) (4)

				<i>If Other, specify:</i>
				unknown

**10. Latest Action Taken with Study Treatment:**

Date	Location	User	Value	Reason
Feb-19-2021 10:37:16 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	Martina Davalli (b) (4)	<b>Data Entry:</b> NOT APPLICABLE	Initial Entry

**11. Was a Concomitant Medication given?**

Date	Location	User	Value	Reason
Feb-24-2021 18:21:25 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4)	Query 1: Closed	Response satisfies query
Feb-24-2021 10:17:14 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Initial Entry
Feb-24-2021 10:17:14 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4)	<b>Data Entry:</b> NO	Initial Entry

090177e196ae2ea4\Final\Final On: 01-Apr-2021 03:19 (GMT)

**Header Text:** C4591001

**Visit:** Logs - Unscheduled

**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History

**Form Version:** 22-Apr-2020 21:02

**Form Status:** Data Complete, Locked, Frozen

**Site No:** 1231

**Site Name:** (1231) Hospital Militar Central Cirujano Mayor Dr. Cosme Argerich

**Subject No:** 12311862

**Subject Initials:** ---

**Generated By:**

**Generated Time (GMT):** 29-Mar-2021 16:45

(b) (4)

Aires				
Feb-22-2021 04:26:55 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6) [Redacted]	Query 1: Opened	DM: Please complete item # 11 to 14. Thank you.

**12. Was a Non-Drug Treatment given?**

Date	Location	User	Value	Reason
Feb-24-2021 10:09:49 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	Martina Davalli [Redacted] (b) (4)	<b>Data Entry:</b> NO	Initial Entry

**13. What was the outcome of this adverse event?:**

Date	Location	User	Value	Reason
Feb-24-2021 10:10:51 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	Martina Davalli [Redacted] (b) (4)	<b>Data Entry:</b> RECOVERED/RE SOLVED WITH SEQUELAE	New Information
Feb-22-2021 11:53:17 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6) [Redacted]	<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
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090177e196ae2ea4\Final\Final On: 01-Apr-2021 03:19 (GMT)

**Header Text:** C4591001

**Visit:** Logs - Unscheduled

**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History

**Form Version:** 22-Apr-2020 21:02

**Form Status:** Data Complete, Locked, Frozen

**Site No:** 1231

**Site Name:** (1231) Hospital Militar Central Cirujano Mayor Dr. Cosme Argerich

**Subject No:** 12311862

**Subject Initials:** ---

**Generated By:**

**Generated Time (GMT):** 29-Mar-2021 16:45

(b) (4)

Feb-22-2021 11:53:17 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry
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090177e196ae2ea4\Final\Final On: 01-Apr-2021 03:19 (GMT)

**Header Text:** C4591001

**Visit:** Disposition - Unscheduled

**Form:** TREATMENT UNBLINDED - eCRF Audit Trail History

**Form Version:** 22-Apr-2020 21:03

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1231

**Site Name:** (1231) Hospital Militar Central Cirujano Mayor Dr. Cosme Argerich

**Subject No:** 12311862

**Subject Initials:** ---

**Generated By:**

**Generated Time (GMT):** 29-Mar-2021 16:45

(b) (4)

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**1. Date Treatment Unblinded :**

Date	Location	User	Value	Reason
Mar-22-2021 16:51:33 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	Martina Davalli (b) (4)	<b>Data Entry:</b> Mar/22/2021	Initial Entry

**2. Primary Reason for Unblinding:**

Date	Location	User	Value	Reason
Mar-22-2021 16:51:33 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	Martina Davalli (b) (4)	<b>Data Entry:</b> ASSESS ELIGIBILI TY FOR ADDITION AL VACCINATION	Initial Entry

090177e196ae2ea4\Final\Final On: 01-Apr-2021 03:19 (GMT)

**Header Text:** C4591001

**Visit:** Subject Status - Unscheduled

**Form Version:** 22-Apr-2020 21:03

**Site No:** 1231

**Subject No:** 12311862

**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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*1. Subject Status*

Date	Location	User	Value	Reason
Oct-14-2020 09:42:15 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> FOLLOW-UP	Initial Entry
Aug-17-2020 19:40:58 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> ENROLLED/RANDOMIZED	Initial Entry
Aug-17-2020 19:39:41 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SCREENED	Initial Entry

*2. Subject Status Date*

Date	Location	User	Value	Reason
Oct-14-2020 09:42:15 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> Oct/13/2020	Initial Entry
Aug-17-2020 19:40:58 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> Aug/17/2020	Initial Entry

090177e196ae2ea4\Final\Final On: 01-Apr-2021 03:19 (GMT)

**Header Text:** C4591001

**Visit:** Subject Status - Unscheduled

**Form Version:** 22-Apr-2020 21:03

**Site No:** 1231

**Subject No:** 12311862

**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

Aug-17-2020 19:39:41 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> Aug/17/2020	Initial Entry
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**Header Text:** C4591001

**Visit:** Investigator Signature -  
Unscheduled

**Form Version:** 22-Apr-2020 21:04

**Site No:** 1231

**Subject No:** 12311862

**Generated By:**

(b) (4)

**Form:** CASEBOOK SIGNATURE FORM - eCRF Audit  
Trail History

**Form Status:** Data Complete, Signed, Verified

**Site Name:** (1231) Hospital Militar Central Cirujano  
Mayor Dr. Cosme Argerich

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 16:45

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*1. Casebook Signature*

Date	Location	User	Value	Reason
Oct-21-2020 17:06:45 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	Romina Libster (b) (4)	<b>Data Entry:</b> Click Here to Enable	Initial Entry

090177e196ae2ea4\Final\Final On: 01-Apr-2021 03:19 (GMT)