

**Header Text:** C4591001

**Visit:** COHORT\_SELECTION

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

**Site No:** 1231

**Subject No:** 12314091

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

**Form:** COHORT\_SELECTION

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

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

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 20:34

[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	24 JUL 2020
2.	Select appropriate response - What cohort does the subject belong to?	STAGE 3 COHORTS

**Header Text:** C4591001

**Visit:** COHORT\_SELECTION

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

**Site No:** 1231

**Subject No:** 12314091

**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 20:34

[eCRF Audit Trail History](#)

**Informed Consent**

1.	Consent Was:	OBTAINED Date Written Consent Obtained Aug/26/2020
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**Header Text:** C4591001

**Visit:** COHORT\_SELECTION

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

**Site No:** 1231

**Subject No:** 12314091

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

**Form:** DEMOGRAPHY

**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 20:34

[eCRF Audit Trail History](#)

**Demography**

1.	Subject ID	[12314091]
2.	Birth Date:	(b) (6)/1962
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:** 12314091

**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 20:34

[eCRF Audit Trail History](#)

**Date of Visit**

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

**Header Text:** C4591001

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

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

**Site No:** 1231

**Subject No:** 12314091

**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 20:34

**Form Comments**

**Inclusion Criteria Not Met**

1.	Description of Inclusion Criterion Not Met	Not Applicable
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**Exclusion Criteria Met**

2.	Description of Exclusion Criterion Met	Not Applicable
----	--	----------------

**Header Text:** C4591001

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

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

**Site No:** 1231

**Subject No:** 12314091

**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 20:34

[eCRF Audit Trail History](#)

**Disposition - Screening**

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

**Header Text:** C4591001

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

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

**Site No:** 1231

**Subject No:** 12314091

**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 20:34

[eCRF Audit Trail History](#)

**Medical History Details**

1.a	Line/MH Number:	[1]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Arterial hypertension]
	Start Date:	Oct/5/2015
	Ongoing:	YES
1.b	Line/MH Number:	[2]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Asthma]
	Start Date:	Jan/23/2018
	Ongoing:	YES

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**Header Text:** C4591001

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

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

**Site No:** 1231

**Subject No:** 12314091

**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 20:34

[eCRF Audit Trail History](#)

**Vital Signs**

1.	Date:	Aug/26/2020
2.	Weight:	[112.0]
3.	Unit:	kg
4.	Height:	[174.0]
5.	Unit:	cm
6.	Body Mass Index:	[37.0]

**Vital Signs Details**

7.a	Record Identifier:	1
	Temperature:	[37.2]
	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:** 12314091

**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 20:34

[eCRF Audit Trail History](#)

**Disposition**

1.	Randomization Date :	Aug/26/2020
2.	Randomization Number:	[240847]
3.	Randomization Group:	[ ]

**Header Text:** C4591001

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

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

**Site No:** 1231

**Subject No:** 12314091

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

**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

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

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

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 20:34

[eCRF Audit Trail History](#)

**Electronic Sample Tracking**

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

**Aliquot**

Please enter barcode for each aliquot.

5.a	Sample ID	[BPT988]
5.b	Sample ID	[BPT989]
5.c	Sample ID	[BPT98B]
5.d	Sample ID	[BNVBRW]
5.e	Sample ID	[BNVBRX]

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**Header Text:** C4591001

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

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

**Site No:** 1231

**Subject No:** 12314091

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

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

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

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

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 20:34

[eCRF Audit Trail History](#)

**Electronic Sample Tracking**

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

**Aliquot**

Please enter barcode for each aliquot.

5.a	Sample ID	[BP2FC9]
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**Header Text:** C4591001

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

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

**Site No:** 1231

**Subject No:** 12314091

**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 20:34

**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/26/2020 10:02
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:** 12314091

**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 20:34

[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:** 12314091

**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 20:34

[eCRF Audit Trail History](#)

**Date of Visit**

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

**Header Text:** C4591001

**Visit:** V2\_VAX2\_L

**Form Version:** 15-Sep-2020 21:54

**Site No:** 1231

**Subject No:** 12314091

**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 20:34

[eCRF Audit Trail History](#)

**Vital Signs**

1.	Date:	Sep/14/2020
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**Vital Signs Details**

2.a	Record Identifier:	1
	Temperature:	[37.0]
	Unit:	C
	Temperature Location:	ORAL CAVITY

**Header Text:** C4591001

**Visit:** V2\_VAX2\_L

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

**Site No:** 1231

**Subject No:** 12314091

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

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

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

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

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 20:34

[eCRF Audit Trail History](#)

**Electronic Sample Tracking**

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

**Aliquot**

Please enter barcode for each aliquot.

5.a	Sample ID	[BP2FTG]
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**Header Text:** C4591001

**Visit:** V2\_VAX2\_L

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

**Site No:** 1231

**Subject No:** 12314091

**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 20:34

**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/14/2020 19:20
5.	Anatomical Location:	DELTOID MUSCLE
6.	Body Side:	LEFT
7.	Route:	INTRAMUSCULAR
8.	Actual Dose:	[ ]
9.	Unit:	
10.	Timeframe Subject Was Observed	THE PROTOCOL SPECIFIED OBSERVATION PERIOD
11.	Was the subject observed for at least the protocol specified observation period after investigational product administration?	YES

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**Header Text:** C4591001

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

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

**Site No:** 1231

**Subject No:** 12314091

**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 20:34

[eCRF Audit Trail History](#)

**Date of Visit**

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

**Header Text:** C4591001

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

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

**Site No:** 1231

**Subject No:** 12314091

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

**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

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

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

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 20:34

[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	[BPT7T3]
5.b	Sample ID	[BRXPYK]
5.c	Sample ID	[BRXPY4]

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**Header Text:** C4591001

**Visit:** V4\_MONTH6\_L

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

**Site No:** 1231

**Subject No:** 12314091

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

**Form:** DATE OF VISIT

**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 20:34

[eCRF Audit Trail History](#)

**Date of Visit**

1.	Date of Visit	Mar/19/2021
2.	Erroneous Visit	

**Header Text:** C4591001

**Visit:** V4\_MONTH6\_L

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

**Site No:** 1231

**Subject No:** 12314091

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

**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

**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 20:34

[eCRF Audit Trail History](#)

**Electronic Sample Tracking**

1.	Data Origin	SITE
2.	Sample Type	SERUM
3.	Sample Collected?	YES Date of Collection: Mar/19/2021
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[ ]

**Aliquot**

Please enter barcode for each aliquot.

5.a	Sample ID	[BS1NX5]
5.b	Sample ID	[BS1S80]
5.c	Sample ID	[BR28W6]

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**Header Text:** C4591001

**Visit:** V5\_MONTH12\_L

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

**Site No:** 1231

**Subject No:** 12314091

**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 20:34

**Date of Visit**

1.	Date of Visit	//
2.	Erroneous Visit	

**Header Text:** C4591001

**Visit:** V5\_MONTH12\_L

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

**Site No:** 1231

**Subject No:** 12314091

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

**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

**Form Status:** Not Started

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

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 20:34

**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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090177e196ae2f0e\Final\Final On: 01-Apr-2021 03:32 (GMT)

**Header Text:** C4591001

**Visit:** V6\_MONTH24\_L

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

**Site No:** 1231

**Subject No:** 12314091

**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 20:34

**Date of Visit**

1.	Date of Visit	//
2.	Erroneous Visit	



**Header Text:** C4591001

**Visit:** V6\_MONTH24\_L

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

**Site No:** 1231

**Subject No:** 12314091

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

**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

**Form Status:** Not Started

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

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 20:34

**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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090177e196ae2f0e\Final\Final On: 01-Apr-2021 03:32 (GMT)

**Header Text:** C4591001

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

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

**Form Status:** Not Started

**Site No:** 1231

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

**Subject No:** 12314091

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 20:34

Date of Visit		
1.	Date of Visit	//
2.	Erroneous Visit	
COVID-19 Illness Visit		
3.	COVID-19 Illness Visit:	

**Header Text:** C4591001

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

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

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

**Form Status:** Not Started

**Site No:** 1231

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

**Subject No:** 12314091

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 20:34

**Signs and Symptoms**

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

**Symptoms**

4.	Symptoms:	
	Was symptom present?	

**Symptoms - Other**

5.	Symptoms - Other Text:	[ ]
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090177e196ae2f0e\Final\Final On: 01-Apr-2021 03:32 (GMT)

**Header Text:** C4591001

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

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

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

**Form Status:** Not Started

**Site No:** 1231

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

**Subject No:** 12314091

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 20:34

**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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090177e196ae2f0e\Final\Final On: 01-Apr-2021 03:32 (GMT)

**Header Text:** C4591001

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

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

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

**Form Status:** Not Started

**Site No:** 1231

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

**Subject No:** 12314091

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 20:34

**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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090177e196ae2f0e\Final\Final On: 01-Apr-2021 03:32 (GMT)

**Header Text:** C4591001

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

**Form Version:** 28-Mar-2021 02:23      **Form Status:** Not Started

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

**Subject No:** 12314091      **Subject Initials:** ---

**Generated By:** (b) (4)      **Generated Time (GMT):** 29-Mar-2021 20:34

**Health Care Utilization**

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

**Health Care Utilization Other**

2.	Other Type of Practitioner Specify:	[ ]
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**Health Care Utilization**

3.	Has the subject been hospitalized due to potential COVID-19 illness?	
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090177e196ae2f0e\Final\Final On: 01-Apr-2021 03:32 (GMT)

**Header Text:** C4591001

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

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

**Form Status:** Not Started

**Site No:** 1231

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

**Subject No:** 12314091

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 20:34

**Illness Details**

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

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**Header Text:** C4591001

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

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

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

**Form Status:** Not Started

**Site No:** 1231

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

**Subject No:** 12314091

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 20:34

Date of Visit		
1.	Date of Visit	//
2.	Erroneous Visit	
COVID-19 Illness Visit		
3.	COVID-19 Illness Visit:	



**Header Text:** C4591001

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

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

**Site No:** 1231

**Subject No:** 12314091

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

**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

**Form Status:** Not Started

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

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 20:34

**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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090177e196ae2f0e\Final\Final On: 01-Apr-2021 03:32 (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:** 12314091

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 20:34

**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:** 12314091

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 20:34

**Unplanned Assessments**

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

**Header Text:** C4591001

**Visit:** End of Treatment - Unscheduled

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

**Site No:** 1231

**Subject No:** 12314091

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

**Form:** DISPOSITION - TREATMENT

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

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

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 20:34

[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:	[ ]

**Header Text:** C4591001

**Visit:** Follow-Up - Unscheduled

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

**Site No:** 1231

**Subject No:** 12314091

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

**Form:** DISPOSITION - FOLLOW-UP

**Form Status:** Not Started

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

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 20:34

**Disposition - Follow-Up**

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

**Header Text:** C4591001

**Visit:** POT\_COVID\_REPEAT\_SWAB - New      **Form:** DATE OF VISIT - REPEAT SWAB  
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:** 12314091      **Subject Initials:** ---

**Generated By:** (b) (4)      **Generated Time (GMT):** 29-Mar-2021 20:34

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:** 12314091

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 20:34

**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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090177e196ae2f0e\Final\Final On: 01-Apr-2021 03:32 (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:** 12314091

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 20:34

**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:** 12314091

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 20:34

**Vital Signs**

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

**Vital Signs Details**

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

**Header Text:** C4591001

**Visit:** Unplanned Vaccination - Unscheduled

**Form:** VACCINATION

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

**Form Status:** Not Started

**Site No:** 1231

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

**Subject No:** 12314091

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 20:34

**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?	

090177e196ae2f0e\Final\Final On: 01-Apr-2021 03:32 (GMT)

**Header Text:** C4591001

**Visit:** Unplanned Vaccination - Unscheduled

**Form:** CONTACT OUTCOME - MONTH 1

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

**Form Status:** Not Started

**Site No:** 1231

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

**Subject No:** 12314091

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 20:34

**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:** 12314091

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 20:34

**Contact Outcome**

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

**Header Text:** C4591001

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

**Form:** DATE OF VISIT

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

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

**Site No:** 1231

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

**Subject No:** 12314091

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 20:34

[eCRF Audit Trail History](#)

**Date of Visit**

1.	Date of Visit	Feb/10/2021
2.	Erroneous Visit	

**Header Text:** C4591001

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

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

**Site No:** 1231

**Subject No:** 12314091

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

**Form:** INFORMED CONSENT - ASYMPTOMATIC  
SURVEILLANCE

**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 20:34

[eCRF Audit Trail History](#)

**Informed Consent - Asymptomatic Surveillance**

1.	Consent Was:	OBTAINED Date Written Consent Obtained Feb/10/2021
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**Header Text:** C4591001

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

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

**Site No:** 1231

**Subject No:** 12314091

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

**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

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

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

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 20:34

[eCRF Audit Trail History](#)

**Electronic Sample Tracking**

1.	Data Origin	SITE
2.	Sample Type	SERUM
3.	Sample Collected?	YES Date of Collection: Feb/10/2021
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[ ]

**Aliquot**

Please enter barcode for each aliquot.

5.a	Sample ID	[BRT8T1]
5.b	Sample ID	[BR1PSN]
5.c	Sample ID	[BRT8PF]

090177e196ae2f0e\Final\Final On: 01-Apr-2021 03:32 (GMT)

**Header Text:** C4591001

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

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

**Site No:** 1231

**Subject No:** 12314091

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

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

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

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

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 20:34

[eCRF Audit Trail History](#)

**Electronic Sample Tracking**

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB
3.	Sample Collected?	YES Date of Collection: Feb/10/2021
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[ ]

**Aliquot**

Please enter barcode for each aliquot.

5.a	Sample ID	[BR1WD7]
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**Header Text:** C4591001

**Visit:** V202\_SURVEIL\_SWAB 1 -  
Unscheduled Visit on Feb/22/2021

**Form Version:** 14-Jan-2021 02:22

**Site No:** 1231

**Subject No:** 12314091

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

**Form:** DATE OF VISIT - ASYMPTOMATIC SURVEILLANCE

**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 20:34

[eCRF Audit Trail History](#)

**Date of Visit**

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

**COVID-19 Surveillance Visit**

3.	COVID-19 Surveillance Visit:	SSWAB_WEEK2
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**Header Text:** C4591001

**Visit:** V202\_SURVEIL\_SWAB 1 -  
Unscheduled Visit on Feb/22/2021

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

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

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

**Site No:** 1231

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

**Subject No:** 12314091

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 20:34

[eCRF Audit Trail History](#)

**Electronic Sample Tracking**

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB
3.	Sample Collected?	YES Date of Collection: Feb/22/2021
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[ ]

**Aliquot**

Please enter barcode for each aliquot.

5.a	Sample ID	[BRMDR5]
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090177e196ae2f0e\Final\Final On: 01-Apr-2021 03:32 (GMT)

**Header Text:** C4591001

**Visit:** V202\_SURVEIL\_SWAB 2 -  
Unscheduled Visit on Mar/04/2021

**Form Version:** 14-Jan-2021 02:22

**Site No:** 1231

**Subject No:** 12314091

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

**Form:** DATE OF VISIT - ASYMPTOMATIC SURVEILLANCE

**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 20:34

[eCRF Audit Trail History](#)

**Date of Visit**

1.	Date of Visit	Mar/4/2021
2.	Erroneous Visit	

**COVID-19 Surveillance Visit**

3.	COVID-19 Surveillance Visit:	SSWAB_WEEK4
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**Header Text:** C4591001

**Visit:** V202\_SURVEIL\_SWAB 2 -  
Unscheduled Visit on Mar/04/2021

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

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

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

**Site No:** 1231

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

**Subject No:** 12314091

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 20:34

[eCRF Audit Trail History](#)

**Electronic Sample Tracking**

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

**Aliquot**

Please enter barcode for each aliquot.

5.a	Sample ID	[BR265C]
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090177e196ae2f0e\Final\Final On: 01-Apr-2021 03:32 (GMT)

**Header Text:** C4591001

**Visit:** V202\_SURVEIL\_SWAB 3 -  
Unscheduled Visit on Mar/19/2021

**Form Version:** 14-Jan-2021 02:22

**Site No:** 1231

**Subject No:** 12314091

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

**Form:** DATE OF VISIT - ASYMPTOMATIC SURVEILLANCE

**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 20:34

[eCRF Audit Trail History](#)

**Date of Visit**

1.	Date of Visit	Mar/19/2021
2.	Erroneous Visit	

**COVID-19 Surveillance Visit**

3.	COVID-19 Surveillance Visit:	SSWAB_WEEK6
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090177e196ae2f0e\Final\Final On: 01-Apr-2021 03:32 (GMT)

**Header Text:** C4591001

**Visit:** V202\_SURVEIL\_SWAB 3 -  
Unscheduled Visit on Mar/19/2021

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

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

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

**Site No:** 1231

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

**Subject No:** 12314091

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 20:34

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**Electronic Sample Tracking**

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB
3.	Sample Collected?	YES Date of Collection: Mar/19/2021
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[ ]

**Aliquot**

Please enter barcode for each aliquot.

5.a	Sample ID	[BP8830]
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090177e196ae2f0e\Final\Final On: 01-Apr-2021 03:32 (GMT)

**Header Text:** C4591001

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

**Form:** DATE OF VISIT

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

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

**Site No:** 1231

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

**Subject No:** 12314091

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 20:34

[eCRF Audit Trail History](#)

**Date of Visit**

1.	Date of Visit	Mar/4/2021
2.	Erroneous Visit	

**Header Text:** C4591001

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

**Form:** FURTHER VACCINATION CONFIRMATION

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

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

**Site No:** 1231

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

**Subject No:** 12314091

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 20:34

[eCRF Audit Trail History](#)

**Further Vaccination Confirmation**

1.	Select appropriate response - Is participant willing to return for Vaccination 3?	Participant is willing to return for Vaccination 3 Participant is: eligible and NOT confirmed to have received only placebo at Vaccination 1/2
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**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:** 12314091

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 20:34

#	Category	AE Identifier	Adverse Event	Start Date	Is the Adverse Event Still Ongoing	Form Instance
1.	ADVERSE EVENT	1	TYPE 2 DIABETES	Jan/13/2021 08:00	YES	<a href="#">Repeating Pages</a>
2.	ADVERSE EVENT	2	Acute appendicitis	Jan/6/2021 16:00	NO End Date Time:  Jan/23/2021 12:30	<a href="#">Repeating Pages</a>

090177e196ae2f0e\Final\Final On: 01-Apr-2021 03:32 (GMT)

**Header Text:** C4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1231

**Subject No:** 12314091

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

**Form:** ADVERSE EVENT REPORT

**Form Status:** Data Complete, Verified

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

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 20:34

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**Adverse Event Report**

1.	Category:	ADVERSE EVENT
2.	AE ID:	[1]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[TYPE 2 DIABETES]
4.	Start Date Time:	Jan/13/2021 08:00
5.	Is the adverse event still ongoing?	YES
6.	Toxicity Grade:	1
7.	Is the adverse event serious?  If Yes, NOTIFY PFIZER IMMEDIATELY.  Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).	NO
8.	Is this adverse event the result of a study Medication Error? If Yes, record the type of medication error on the Medication Error Log.	NO
9.	Is this event related to study treatment:	NOT RELATED If Not Related to study treatment(s), this event is due to: OTHER If Other, specify: [Unknown]
10.	Latest Action Taken with Study Treatment:	NOT APPLICABLE

090177e196ae2f0e\Final\Final On: 01-Apr-2021 03:32 (GMT)

**Header Text:** C4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1231

**Subject No:** 12314091

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

**Form:** ADVERSE EVENT REPORT

**Form Status:** Data Complete, Verified

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

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 20:34

11.	Was a Concomitant Medication given?	YES
12.	Was a Non-Drug Treatment given?	YES
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	[ ]

**Header Text:** C4591001**Visit:** Logs - Unscheduled**Form Version:** 22-Apr-2020 21:02**Site No:** 1231**Subject No:** 12314091**Generated By:** (b) (4)**Form:** ADVERSE EVENT REPORT**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 20:34

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[Form Audit Trail](#)

**Adverse Event Report**

1.	Category:	ADVERSE EVENT
2.	AE ID:	[2]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[Accute appendicitis]
4.	Start Date Time:	Jan/6/2021 16:00
5.	Is the adverse event still ongoing?	NO End Date Time: Jan/23/2021 12:30
6.	Toxicity Grade:	3
7.	Is the adverse event serious?  If Yes, NOTIFY PFIZER IMMEDIATELY.  Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).	YES  Is this serious event associated with congenital anomaly or birth defect? NO  Did this serious event result in death? NO  Did this serious event require or prolong hospitalization? YES  Did this serious event result in persistent or significant disability/incapacity? NO  Is this serious event life threatening? NO  Other medically important serious event NO
8.	Is this adverse event the result of a study Medication Error? If Yes, record the type of medication error on the Medication Error Log.	NO

**Header Text:** C4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1231

**Subject No:** 12314091

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

**Form:** ADVERSE EVENT REPORT

**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 20:34

9.	Is this event related to study treatment:	NOT RELATED If Not Related to study treatment(s), this event is due to: OTHER If Other, specify: [unknown]
10.	Latest Action Taken with Study Treatment:	NOT APPLICABLE
11.	Was a Concomitant Medication given?	YES
12.	Was a Non-Drug Treatment given?	YES
13.	What was the outcome of this adverse event?:	RECOVERED/RESOLVED
14.	Did the adverse event cause the subject to be discontinued from the study?	NO
15.	Serious Adverse Event Number: For Pfizer Use Only	[2021148275]

090177e196ae2f0e\Final\Final On: 01-Apr-2021 03:32 (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:** 12314091

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 20:34

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

**Header Text:** C4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1231

**Subject No:** 12314091

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

**Form:** MEDICATION ERROR

**Form Status:** Not Started

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

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 20:34

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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	[ ]

090177e196ae2f0e\Final\Final On: 01-Apr-2021 03:32 (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:** 12314091

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 20:34

#	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:** 12314091

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 20:34

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**Concomitant Medications**

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

090177e196ae2f0e\Final\Final On: 01-Apr-2021 03:32 (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:** 12314091

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 20:34

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

**Header Text:** C4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1231

**Subject No:** 12314091

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

**Form:** CONCOMITANT MEDICATIONS - PROHIBITED

**Form Status:** Not Started

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

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 20:34

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**Concomitant Medications**

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

090177e196ae2f0e\Final\Final On: 01-Apr-2021 03:32 (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:** 12314091

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 20:34

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

**Header Text:** C4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1231

**Subject No:** 12314091

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

**Form:** RADIATION TREATMENT

**Form Status:** Not Started

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

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 20:34

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**Radiation Treatment**

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

**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:** 12314091

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 20:34

#	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:** 12314091

**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 20:34

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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:** 12314091

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 20:34

**Date of Visit**

1.	Date of Visit	//
2.	Erroneous Visit	



**Header Text:** C4591001

**Visit:** UNPLANNED\_BOOSTER\_CONTACT **Form:** BOOSTER DOSE TRIGGER FORM  
- Unscheduled

**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:** 12314091

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 20:34

**Booster Dose Trigger Form**

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

**Header Text:** C4591001

**Visit:** Disposition - Unscheduled

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

**Site No:** 1231

**Subject No:** 12314091

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

**Form:** TREATMENT UNBLINDED

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

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

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 20:34

[eCRF Audit Trail History](#)

**Treatment Unblinded**

1.	Date Treatment Unblinded :	Mar/4/2021
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:** 12314091

**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 20:34

**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:** 12314091

**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 20:34

**Death Details**

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

**Cause of Death**

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

**Header Text:** C4591001

**Visit:** Subject Status - Unscheduled

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

**Site No:** 1231

**Subject No:** 12314091

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

**Form:** SUBJECT STATUS

**Form Status:** Data Complete, Verified

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

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 20:34

[eCRF Audit Trail History](#)

**Subject Status**

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

090177e196ae2f0e\Final\Final On: 01-Apr-2021 03:32 (GMT)

**Header Text:** C4591001

**Visit:** Investigator Signature - Unscheduled

**Form:** CASEBOOK SIGNATURE FORM

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

**Form Status:** Data Complete, Verified

**Site No:** 1231

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

**Subject No:** 12314091

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 20:34

[eCRF Audit Trail History](#)

**Casebook Signature Form**

1.	Casebook Signature	Click Here to Enable
----	--------------------	----------------------

**Header Text:** C4591001

**Visit:** Investigator Signature - Unscheduled

**Form:** CASEBOOK SIGNATURE FORM

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

**Form Status:** Data Complete, Verified

**Site No:** 1231

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

**Subject No:** 12314091

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 20:34

[Audit Trail](#)

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

- CRF\_Sign
- CRF\_Sign\_1

Name	Signature Meaning	Date	Type	Action
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**Header Text:** C4591001

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

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

**Site No:** 1231

**Subject No:** 12314091

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

**Form:** INCLUSION/EXCLUSION CRITERIA - Comments

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

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

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 20:34

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Item	Date	User	Comment
Form	Aug-26-2020 11:23:57 (UTC-03:00) City of Buenos Aires	(b) (4), (b) (6)	Not Applicable



**Header Text:** C4591001

**Visit:** Investigator Signature - Unscheduled

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

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

**Form Status:** Data Complete, Verified

**Site No:** 1231

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

**Subject No:** 12314091

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 20:34

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

- CRF\_Sign
- CRF\_Sign\_1

Name	Signature Meaning	Date	Type	Action
(b) (6)	N/A	Mar-20-2021 11:57:18 (UTC-03:00) City of Buenos Aires		Edit - All signatures invalidated

**Affidavit:**

N/A

(b) (6)	Approved	Mar-19-2021 18:35:37 (UTC-03:00) City of Buenos Aires	BOOK	Signed
---------	----------	---	------	--------

**Affidavit:**

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

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

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

(b) (6)	N/A	Mar-19-2021 12:09:39 (UTC-03:00) City of Buenos Aires		Edit - All signatures invalidated
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**Affidavit:**

N/A

(b) (6)	Approved	Mar-06-2021 08:30:25 (UTC-03:00) City of Buenos Aires	BOOK	Signed
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090177e196ae2f0e\Final\Final On: 01-Apr-2021 03:32 (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, Verified

**Site No:** 1231

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

**Subject No:** 12314091

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 20:34

**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-24-2021 09:00:28 (UTC-03:00) City of Buenos Aires		Edit - All signatures invalidated
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**Affidavit:**

N/A

(b) (6)	Approved	Feb-17-2021 11:15:37 (UTC-03:00) City of Buenos Aires	BOOK	Signed
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**Affidavit:**

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

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

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

(b) (6)	N/A	Feb-10-2021 12:00:55 (UTC-03:00) City of Buenos Aires		Edit - All signatures invalidated
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**Affidavit:**

N/A

(b) (6)	Approved	Oct-21-2020 15:19:35 (UTC-03:00) City of Buenos Aires	BOOK	Signed
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090177e196ae2f0e\Final\Final On: 01-Apr-2021 03:32 (GMT)

**Header Text:** C4591001

**Visit:** Investigator Signature - Unscheduled

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

**Site No:** 1231

**Subject No:** 12314091

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

**Form:** CASEBOOK SIGNATURE FORM - Signature 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 20:34

**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.

**Header Text:** C4591001

**Visit:** COHORT\_SELECTION

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

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

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

**Site No:** 1231

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

**Subject No:** 12314091

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 20:34

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*1. Select appropriate response - Protocol version*

Date	Location	User	Value	Reason
Aug-26-2020 11:23:22 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 24 JUL 2020	Initial Entry

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

Date	Location	User	Value	Reason
Aug-26-2020 11:23:22 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> STAGE 3 COHORTS	Initial Entry

090177e196ae2f0e\Final\Final On: 01-Apr-2021 03:32 (GMT)

**Header Text:** C4591001

**Visit:** COHORT\_SELECTION

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

**Site No:** 1231

**Subject No:** 12314091

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

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

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

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

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 20:34

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**I. Consent Was:**

Date	Location	User	Value	Reason
Aug-26-2020 11:23:29 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> OBTAINED Date Written Consent Obtained  Aug/26/2020	Initial Entry

090177e196ae2f0e\Final\Final On: 01-Apr-2021 03:32 (GMT)

Header Text: C4591001

Visit: COHORT\_SELECTION

Form Version: 06-Jul-2020 21:55

Site No: 1231

Subject No: 12314091

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 20:34

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**1. Subject ID**

Date	Location	User	Value	Reason
Aug-26-2020 09:09:34 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 12314091	Item copied from previous form

**2. Birth Date:**

Date	Location	User	Value	Reason
Aug-26-2020 09:09:31 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> (b) (6)/1962	Enrollment Entry

**3. Sex:**

Date	Location	User	Value	Reason
Aug-26-2020 11:23:41 (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-26-2020 11:23:41 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> HISPANIC OR LATINO(A) OR OF SPANISH ORIGIN	Initial Entry

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

Date	Location	User	Value	Reason
Aug-26-2020 11:23:41 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> WHITE	Initial Entry

090177e196ae2f0e\Final\Final On: 01-Apr-2021 03:32 (GMT)

**Header Text:** C4591001

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

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

**Site No:** 1231

**Subject No:** 12314091

**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 20:34

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*1. Date of Visit*

Date	Location	User	Value	Reason
Aug-26-2020 11:23:50 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Aug/26/2020	Initial Entry

090177e196ae2f0e\Final\Final On: 01-Apr-2021 03:32 (GMT)

**Header Text:** C4591001

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

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

**Site No:** 1231

**Subject No:** 12314091

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

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

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

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

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 20:34

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

Date	Location	User	Value	Reason
Aug-26-2020 11:24:12 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Aug/26/2020	Initial Entry

**2. Phase of Disposition:**

Date	Location	User	Value	Reason
Aug-26-2020 11:24:12 (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-26-2020 11:24:12 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> COMPLETED	Initial Entry

090177e196ae2f0e\Final\Final On: 01-Apr-2021 03:32 (GMT)



Header Text: C4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 22-Apr-2020 21:03

Site No: 1231

Subject No: 12314091

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 20:34

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*I.a*

Date	Location	User	Value	Reason
Aug-26-2020 11:24:38 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> Line/MH Numbr: 1 <b>Medical History Term:</b> Arterial hypertension <b>Start Date:</b> Oct/5/2015 <b>Ongoing:</b> YES	Initial Entry

*I.a Line/MH Number:*

Date	Location	User	Value	Reason
Aug-26-2020 11:24:38 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 1	Initial Entry

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

Date	Location	User	Value	Reason
Aug-26-2020 11:24:38 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Arterial hypertension	Initial Entry

*I.a Start Date:*

Date	Location	User	Value	Reason
Aug-26-2020 11:24:38 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Oct/5/2015	Initial Entry

*I.a Ongoing:*

Date	Location	User	Value	Reason
Aug-26-2020 11:24:38 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

090177e196ae2f0e\Final\Final On: 01-Apr-2021 03:32 (GMT)

Header Text: C4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 22-Apr-2020 21:03

Site No: 1231

Subject No: 12314091

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 20:34

**I.b**

Date	Location	User	Value	Reason
Aug-26-2020 11:24:59 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Line/MH Number:</b> 2 <b>Medical History Term:</b> Asthma <b>Start Date:</b> Jan/23/2018 <b>Ongoing:</b> YES	Initial Entry

**I.b Line/MH Number:**

Date	Location	User	Value	Reason
Aug-26-2020 11:24:59 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 2	Initial Entry

**I.b Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:**

Date	Location	User	Value	Reason
Aug-26-2020 11:24:59 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Asthma	Initial Entry

**I.b Start Date:**

Date	Location	User	Value	Reason
Aug-26-2020 11:24:59 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Jan/23/2018	Initial Entry

**I.b Ongoing:**

Date	Location	User	Value	Reason
Aug-26-2020 11:24:59 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

090177e196ae2f0e\Final\Final On: 01-Apr-2021 03:32 (GMT)

Header Text: C4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 21-Aug-2020 02:51

Site No: 1231

Subject No: 12314091

Generated By: (b) (4)

Form: VITAL SIGNS - BASELINE - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 20:34

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**1. Date:**

Date	Location	User	Value	Reason
Aug-26-2020 11:25:20 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Aug/26/2020	Initial Entry

**2. Weight:**

Date	Location	User	Value	Reason
Aug-26-2020 11:25:20 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 112.0	Initial Entry

**3. Unit:**

Date	Location	User	Value	Reason
Aug-26-2020 11:25:20 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> kg	Initial Entry

**4. Height:**

Date	Location	User	Value	Reason
Aug-26-2020 11:25:20 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 174.0	Initial Entry

**5. Unit:**

Date	Location	User	Value	Reason
Aug-26-2020 11:25:20 (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
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090177e196ae2f0e\Final\Final On: 01-Apr-2021 03:32 (GMT)

Header Text: C4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 21-Aug-2020 02:51

Site No: 1231

Subject No: 12314091

Generated By: (b) (4)

Form: VITAL SIGNS - BASELINE - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 20:34

Aug-26-2020 11:25:20 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 37.0	Initial Entry
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7.a

Date	Location	User	Value	Reason
Aug-26-2020 11:25:20 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Record Identifier 1</b> :: <b>Temperature: 37.2</b> <b>Temperature Unit:</b> <b>Temperature Location:</b> ORAL CAVITY	Initial Entry

7.a Record Identifier:

Date	Location	User	Value	Reason
Aug-26-2020 11:25:20 (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-26-2020 11:25:20 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 37.2	Initial Entry

7.a Unit:

Date	Location	User	Value	Reason
Aug-26-2020 11:25:20 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> C	Initial Entry

7.a Temperature Location:

Date	Location	User	Value	Reason
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090177e196ae2f0e\Final\Final On: 01-Apr-2021 03:32 (GMT)

**Header Text:** C4591001

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

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

**Site No:** 1231

**Subject No:** 12314091

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

**Form:** VITAL SIGNS - BASELINE - eCRF Audit Trail History

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

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

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 20:34

Aug-26-2020 11:25:20 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> ORAL CAVITY	Initial Entry
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090177e196ae2f0e\Final\Final On: 01-Apr-2021 03:32 (GMT)

**Header Text:** C4591001

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

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

**Site No:** 1231

**Subject No:** 12314091

**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 20:34

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**1. Randomization Date :**

Date	Location	User	Value	Reason
Aug-26-2020 11:25:29 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Aug/26/2020	Initial Entry

**2. Randomization Number:**

Date	Location	User	Value	Reason
Aug-26-2020 11:25:29 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 240847	Initial Entry

090177e196ae2f0e\Final\Final On: 01-Apr-2021 03:32 (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: 12314091

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 20:34

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**1. Data Origin**

Date	Location	User	Value	Reason
Aug-26-2020 11:25:35 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SITE	Initial Entry

**2. Sample Type**

Date	Location	User	Value	Reason
Aug-26-2020 11:25:35 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SERUM	Initial Entry

**3. Sample Collected?**

Date	Location	User	Value	Reason
Aug-27-2020 12:37:54 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Aug-26-2020 12:13:37 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Aug-26-2020 11:25:35 (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-26-2020 11:25:35 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES Date of Collection:	Initial Entry

090177e196ae2f0e\Final\Final On: 01-Apr-2021 03:32 (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: 12314091

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 20:34

Aug/26/2020

5.a

Date	Location	User	Value	Reason
Aug-27-2020 12:37:54 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample ID: BPT988</b>	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Aug-27-2020 12:37:54 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BPT988	Initial Entry

5.b

Date	Location	User	Value	Reason
Aug-27-2020 12:38:09 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample ID: BPT989</b>	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Aug-27-2020 12:38:09 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BPT989	Initial Entry

5.c

Date	Location	User	Value	Reason
Aug-27-2020 12:38:18 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample ID: BPT98B</b>	Initial Entry

090177e196ae2f0e\Final\Final On: 01-Apr-2021 03:32 (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: 12314091

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 20:34

5.c Sample ID

Date	Location	User	Value	Reason
Aug-27-2020 12:38:18 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BPT98B	Initial Entry

5.d

Date	Location	User	Value	Reason
Aug-27-2020 17:10:55 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample ID:</b> BNVRBW	Initial Entry

5.d Sample ID

Date	Location	User	Value	Reason
Aug-27-2020 17:10:55 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BNVRBW	Initial Entry

5.e

Date	Location	User	Value	Reason
Aug-27-2020 17:11:04 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample ID:</b> BNVRBX	Initial Entry

5.e Sample ID

Date	Location	User	Value	Reason
Aug-27-2020 17:11:04 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BNVRBX	Initial Entry

090177e196ae2f0e\Final\Final On: 01-Apr-2021 03:32 (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: 12314091

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 20:34

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**1. Data Origin**

Date	Location	User	Value	Reason
Aug-26-2020 11:25:44 (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-26-2020 11:25:44 (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-27-2020 15:41:20 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Aug-26-2020 12:13:37 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Aug-26-2020 11:25:44 (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-26-2020 11:25:44 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES Date of Collection:	Initial Entry

090177e196ae2f0e\Final\Final On: 01-Apr-2021 03:32 (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:** 12314091

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 20:34

			Aug/26/2020	
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**5.a**

Date	Location	User	Value	Reason
Aug-27-2020 15:41:20 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	Alan Colombo (b) (4)	<b>Data Entry:</b> <b>Sample ID:</b> BP2FC9	Initial Entry

**5.a Sample ID**

Date	Location	User	Value	Reason
Aug-27-2020 15:41:20 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	Alan Colombo (b) (4)	<b>Data Entry:</b> BP2FC9	Initial Entry

090177e196ae2f0e\Final\Final On: 01-Apr-2021 03:32 (GMT)

Header Text: C4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 22-Apr-2020 21:04

Site No: 1231

Subject No: 12314091

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 20:34

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**1. Was there a temporary delay of vaccination?**

Date	Location	User	Value	Reason
Aug-26-2020 11:26:10 (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
Aug-26-2020 11:26:10 (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
Aug-26-2020 11:26:10 (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
Aug-26-2020 11:26:10 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Aug/26/2020 10:02	Initial Entry

**5. Anatomical Location:**

Date	Location	User	Value	Reason
Aug-26-2020 11:26:10 (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
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090177e196ae2f0e\Final\Final On: 01-Apr-2021 03:32 (GMT)

**Header Text:** C4591001

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

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

**Site No:** 1231

**Subject No:** 12314091

**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 20:34

Aug-26-2020 11:26:10 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> LEFT	Initial Entry
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**7. Route:**

Date	Location	User	Value	Reason
Aug-26-2020 11:26:10 (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
Aug-26-2020 11:26:10 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> THE PROTOCOL SPECIFIED OBSERVATION PERIOD	Initial Entry

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

Date	Location	User	Value	Reason
Aug-26-2020 11:26:10 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

090177e196ae2f0e\Final\Final On: 01-Apr-2021 03:32 (GMT)

**Header Text:** C4591001

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

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

**Site No:** 1231

**Subject No:** 12314091

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

**Form:** REACTOGENICITY DIARY - eCRF Audit Trail History

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

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

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 20:34

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*1. Select appropriate response - Reactogenicity diary collection*

Date	Location	User	Value	Reason
Aug-26-2020 11:26:16 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO - REACTOGENICITY E-D IARY NOT COLLECTED FOR THIS SUBJECT	Initial Entry

**Header Text:** C4591001

**Visit:** V2\_VAX2\_L

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

**Site No:** 1231

**Subject No:** 12314091

**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 20:34

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*1. Date of Visit*

Date	Location	User	Value	Reason
Sep-17-2020 19:50:07 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Sep/14/2020	Initial Entry

Header Text: C4591001

Visit: V2\_VAX2\_L

Form Version: 15-Sep-2020 21:54

Site No: 1231

Subject No: 12314091

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 20:34

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**I. Date:**

Date	Location	User	Value	Reason
Sep-17-2020 19:50:21 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sep/14/2020	Initial Entry

**2.a**

Date	Location	User	Value	Reason
Sep-17-2020 19:50:21 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Record Identifier:</b> 1 : <b>Temperature:</b> 37.0 <b>Temperature Unit</b> C : <b>Temperature Location:</b> ORAL CAVITY	Initial Entry

**2.a Record Identifier:**

Date	Location	User	Value	Reason
Sep-17-2020 19:50:21 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 1	Initial Entry

**2.a Temperature:**

Date	Location	User	Value	Reason
Sep-17-2020 19:50:21 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 37.0	Initial Entry

**2.a Unit:**

090177e196ae2f0e\Final\Final On: 01-Apr-2021 03:32 (GMT)



**Header Text:** C4591001

**Visit:** V2\_VAX2\_L

**Form Version:** 15-Sep-2020 21:54

**Site No:** 1231

**Subject No:** 12314091

**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 20:34

Date	Location	User	Value	Reason
Sep-17-2020 19:50:21 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> C	Initial Entry

*2.a Temperature Location:*

Date	Location	User	Value	Reason
Sep-17-2020 19:50:21 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> ORAL CAVITY	Initial Entry

090177e196ae2f0e\Final\Final On: 01-Apr-2021 03:32 (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:** 12314091**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 20:34[Back to Form](#)**1. Data Origin**

Date	Location	User	Value	Reason
Sep-14-2020 19:34:31 (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-14-2020 19:34:31 (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-14-2020 19:34:37 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Sep-14-2020 19:34:31 (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-14-2020 19:34:31 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	Alan Colombo (b) (4)	<b>Data Entry:</b> YES Date of Collection: Sep/14/2020	Initial Entry

**5.a**

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

**Visit:** V2\_VAX2\_L

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

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

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

**Site No:** 1231

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

**Subject No:** 12314091

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 20:34

Sep-14-2020 19:34:37 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	Alan Colombo (b) (4)	<b>Data Entry:</b> <b>Sample ID:</b> BP2FTG	Initial Entry
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**5.a Sample ID**

Date	Location	User	Value	Reason
Sep-14-2020 19:34:37 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	Alan Colombo (b) (4)	<b>Data Entry:</b> BP2FTG	Initial Entry

Header Text: C4591001

Visit: V2\_VAX2\_L

Form Version: 22-Apr-2020 21:04

Site No: 1231

Subject No: 12314091

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 20:34

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**1. Was there a temporary delay of vaccination?**

Date	Location	User	Value	Reason
Sep-17-2020 19:50:59 (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-17-2020 19:50:59 (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-17-2020 19:50:59 (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-17-2020 19:50:59 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sep/14/2020 19:20	Initial Entry

**5. Anatomical Location:**

Date	Location	User	Value	Reason
Sep-17-2020 19:50:59 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> DELTOID MUSCLE	Initial Entry

**6. Body Side:**

090177e196ae2f0e\Final\Final On: 01-Apr-2021 03:32 (GMT)

Header Text: C4591001

Visit: V2\_VAX2\_L

Form Version: 22-Apr-2020 21:04

Site No: 1231

Subject No: 12314091

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 20:34

Date	Location	User	Value	Reason
Sep-17-2020 19:50:59 (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
Sep-17-2020 19:50:59 (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-17-2020 19:50:59 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> THE PROTOCOL SPECIFIED O BSERVATION PERIOD	Initial Entry

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

Date	Location	User	Value	Reason
Sep-17-2020 19:50:59 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

090177e196ae2f0e\Final\Final On: 01-Apr-2021 03:32 (GMT)

**Header Text:** C4591001

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

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

**Site No:** 1231

**Subject No:** 12314091

**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 20:34

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*1. Date of Visit*

Date	Location	User	Value	Reason
Oct-13-2020 19:24:35 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Oct/13/2020	Initial Entry

**Header Text:** C4591001**Visit:** V3\_MONTH1\_POSTVAX2\_L**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY  
- eCRF Audit Trail History**Form Version:** 22-Apr-2020 21:03**Form Status:** Data Complete, Locked, Frozen, Verified**Site No:** 1231**Site Name:** (1231) Hospital Militar Central Cirujano Mayor Dr. Cosme Argerich**Subject No:** 12314091**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 20:34[Back to Form](#)**1. Data Origin**

Date	Location	User	Value	Reason
Oct-13-2020 18:56:04 (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-13-2020 18:56:04 (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-13-2020 18:56:16 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Oct-13-2020 18:56:04 (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-13-2020 18:56:04 (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-13-2020 18:56:16 (UTC-03:00) City of	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>	Initial Entry

Header Text: C4591001

Visit: V3\_MONTH1\_POSTVAX2\_L

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1231

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

Subject No: 12314091

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 20:34

Buenos Aires	(b) (4), (b) (6)	Sample ID: BPT7T3
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5.a Sample ID

Date	Location	User	Value	Reason
Oct-13-2020 18:56:16 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> BPT7T3	Initial Entry

5.b

Date	Location	User	Value	Reason
Oct-14-2020 09:08:37 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Sample ID: BRXPYK	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Oct-14-2020 09:08:37 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> BRXPYK	Initial Entry

5.c

Date	Location	User	Value	Reason
Oct-14-2020 09:15:19 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Sample ID: BRXPY4	Initial Entry

5.c Sample ID

Date	Location	User	Value	Reason
Oct-14-2020 09:15:19 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> BRXPY4	Initial Entry

090177e196ae2f0e\Final\Final On: 01-Apr-2021 03:32 (GMT)



**Header Text:** C4591001

**Visit:** V4\_MONTH6\_L

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

**Site No:** 1231

**Subject No:** 12314091

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

**Form:** DATE OF VISIT - 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 20:34

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*1. Date of Visit*

Date	Location	User	Value	Reason
Mar-19-2021 12:09:39 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Mar/19/2021	Initial Entry

090177e196ae2f0e\Final\Final On: 01-Apr-2021 03:32 (GMT)

Header Text: C4591001

Visit: V4\_MONTH6\_L

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1231

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

Subject No: 12314091

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 20:34

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**1. Data Origin**

Date	Location	User	Value	Reason
Mar-19-2021 12:09:57 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SITE	Initial Entry

**2. Sample Type**

Date	Location	User	Value	Reason
Mar-19-2021 12:09:57 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SERUM	Initial Entry

**3. Sample Collected?**

Date	Location	User	Value	Reason
Mar-20-2021 11:57:18 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Mar-20-2021 06:59:57 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Mar-19-2021 12:09:57 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Mar-19-2021 12:09:57 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES Date of Collection:  Mar/19/2021	Initial Entry

090177e196ae2f0e\Final\Final On: 01-Apr-2021 03:32 (GMT)

Header Text: C4591001

Visit: V4\_MONTH6\_L

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1231

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

Subject No: 12314091

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 20:34

5.a

Date	Location	User	Value	Reason
Mar-20-2021 11:57:18 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample ID: BS1NX5</b>	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Mar-20-2021 11:57:18 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BS1NX5	Initial Entry

5.b

Date	Location	User	Value	Reason
Mar-20-2021 11:57:42 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample ID: BS1S80</b>	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Mar-20-2021 11:57:42 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BS1S80	Initial Entry

5.c

Date	Location	User	Value	Reason
Mar-20-2021 12:33:36 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample ID: BR28W6</b>	Initial Entry

090177e196ae2f0e\Final\Final On: 01-Apr-2021 03:32 (GMT)

**Header Text:** C4591001

**Visit:** V4\_MONTH6\_L

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

**Site No:** 1231

**Subject No:** 12314091

**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 20:34

*5.c Sample ID*

Date	Location	User	Value	Reason
Mar-20-2021 12:33:36 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BR28W6	Initial Entry

**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:** 12314091

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 20:34

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

Date	Location	User	Value	Reason
Oct-13-2020 19:25:15 (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-13-2020 19:25:15 (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-13-2020 19:25:15 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> COMPLETED	Initial Entry

090177e196ae2f0e\Final\Final On: 01-Apr-2021 03:32 (GMT)

**Header Text:** C4591001

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

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

**Site No:** 1231

**Subject No:** 12314091

**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 20:34

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*1. Date of Visit*

Date	Location	User	Value	Reason
Feb-10-2021 12:00:55 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Feb/10/2021	Initial Entry

**Header Text:** C4591001

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

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

**Site No:** 1231

**Subject No:** 12314091

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

**Form:** INFORMED CONSENT - ASYMPTOMATIC  
SURVEILLANCE - 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 20:34

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**I. Consent Was:**

Date	Location	User	Value	Reason
Feb-10-2021 12:01:05 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> OBTAINED Date Written Consent Obtained  Feb/10/2021	Initial Entry

**Header Text:** C4591001**Visit:** V201\_SURVEIL\_CONSENT -  
Unscheduled**Form Version:** 22-Apr-2020 21:03**Site No:** 1231**Subject No:** 12314091**Generated By:** (b) (4)**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY  
- eCRF Audit Trail History**Form Status:** Data Complete, Locked, Frozen, Verified**Site Name:** (1231) Hospital Militar Central Cirujano Mayor Dr. Cosme  
Argerich**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 20:34[Back to Form](#)**1. Data Origin**

Date	Location	User	Value	Reason
Feb-10-2021 12:01:15 (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
Feb-10-2021 12:01:15 (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
Feb-10-2021 15:48:52 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Feb-10-2021 12:01:15 (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.
Feb-10-2021 12:01:15 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES Date of Collection:  Feb/10/2021	Initial Entry

**5.a**

Date	Location	User	Value	Reason
Feb-10-2021 15:48:52 (UTC-03:00) City of	ACV0PFEINFP6000	Azul Mozzi (b) (4)	<b>Data Entry:</b>	Initial Entry



Header Text: C4591001

Visit: V201\_SURVEIL\_CONSENT -  
Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1231

Subject No: 12314091

Generated By: (b) (4)

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

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 20:34

Buenos Aires			Sample ID: BRT8T1	
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5.a Sample ID

Date	Location	User	Value	Reason
Feb-10-2021 15:48:52 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	Azul Mozzi (b) (4)	<u>Data Entry:</u> BRT8T1	Initial Entry

5.b

Date	Location	User	Value	Reason
Feb-11-2021 08:33:34 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	Agustin Morato Cabral (b) (4)	<u>Data Entry:</u> Sample ID: BR1PSN	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Feb-11-2021 08:33:34 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	Agustin Morato Cabral (b) (4)	<u>Data Entry:</u> BR1PSN	Initial Entry

5.c

Date	Location	User	Value	Reason
Feb-11-2021 09:39:56 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Sample ID: BRT8PF	Initial Entry

5.c Sample ID

Date	Location	User	Value	Reason
Feb-11-2021 09:39:56 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> BRT8PF	Initial Entry

090177e196ae2f0e\Final\Final On: 01-Apr-2021 03:32 (GMT)

**Header Text:** C4591001**Visit:** V201\_SURVEIL\_CONSENT -  
Unscheduled**Form Version:** 22-Apr-2020 21:03**Site No:** 1231**Subject No:** 12314091**Generated By:** (b) (4)**Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB -  
eCRF Audit Trail History**Form Status:** Data Complete, Locked, Frozen, Verified**Site Name:** (1231) Hospital Militar Central Cirujano Mayor Dr. Cosme  
Argerich**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 20:34[Back to Form](#)**1. Data Origin**

Date	Location	User	Value	Reason
Feb-10-2021 14:57:04 (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
Feb-10-2021 14:57:04 (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
Feb-10-2021 14:57:18 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Feb-10-2021 14:57:04 (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.
Feb-10-2021 14:57:04 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	Agustin Morato Cabral (b) (4)	<b>Data Entry:</b> YES Date of Collection: Feb/10/2021	Initial Entry

**5.a**

Date	Location	User	Value	Reason
Feb-10-2021 14:57:18 (UTC-03:00) City of	ACV0PFEINFP6000	Agustin Morato	<b>Data Entry:</b>	Initial Entry

**Header Text:** C4591001

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

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

**Site No:** 1231

**Subject No:** 12314091

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

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

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

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

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 20:34

Buenos Aires		Cabral (b) (4)	<b>Sample ID:</b> BR1WD7	
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**5.a Sample ID**

Date	Location	User	Value	Reason
Feb-10-2021 14:57:18 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	Agustin Morato Cabral (b) (4)	<b>Data Entry:</b> BR1WD7	Initial Entry

**Header Text:** C4591001

**Visit:** V202\_SURVEIL\_SWAB 1 -  
Unscheduled Visit on Feb/22/2021

**Form Version:** 14-Jan-2021 02:22

**Site No:** 1231

**Subject No:** 12314091

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

**Form:** DATE OF VISIT - ASYMPTOMATIC SURVEILLANCE -  
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 20:34

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**1. Date of Visit**

Date	Location	User	Value	Reason
Feb-24-2021 09:00:27 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Feb/22/2021	Initial Entry

**3. COVID-19 Surveillance Visit:**

Date	Location	User	Value	Reason
Feb-24-2021 09:00:27 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> SSWAB_WEEK2	Initial Entry

090177e196ae2f0e\Final\Final On: 01-Apr-2021 03:32 (GMT)

**Header Text:** C4591001**Visit:** V202\_SURVEIL\_SWAB 1 -  
Unscheduled Visit on Feb/22/2021**Form Version:** 10-Oct-2020 15:57**Site No:** 1231**Subject No:** 12314091**Generated By:** (b) (4)**Form:** ELECTRONIC SAMPLE TRACKING - REPEAT SWAB -  
eCRF Audit Trail History**Form Status:** Data Complete, Locked, Frozen, Verified**Site Name:** (1231) Hospital Militar Central Cirujano Mayor Dr. Cosme  
Argerich**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 20:34[Back to Form](#)**1. Data Origin**

Date	Location	User	Value	Reason
Feb-24-2021 09:00:41 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SITE	Initial Entry

**2. Sample Type**

Date	Location	User	Value	Reason
Feb-24-2021 09:00:41 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NASAL_SWAB	Initial Entry

**3. Sample Collected?**

Date	Location	User	Value	Reason
Feb-24-2021 09:00:54 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Feb-24-2021 09:00:41 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Feb-24-2021 09:00:41 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES Date of Collection:  Feb/22/2021	Initial Entry

**5.a**

Date	Location	User	Value	Reason
Feb-24-2021 09:00:54 (UTC-03:00) City of	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>	Initial Entry

**Header Text:** C4591001

**Visit:** V202\_SURVEIL\_SWAB 1 -  
Unscheduled Visit on Feb/22/2021

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

**Site No:** 1231

**Subject No:** 12314091

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

**Form:** ELECTRONIC SAMPLE TRACKING - REPEAT SWAB -  
eCRF Audit Trail History

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

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

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 20:34

Buenos Aires	(b) (4), (b) (6)	<b>Sample ID:</b> BRMDR5
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**5.a Sample ID**

Date	Location	User	Value	Reason
Feb-24-2021 09:00:54 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BRMDR5	Initial Entry

**Header Text:** C4591001

**Visit:** V202\_SURVEIL\_SWAB 2 -  
Unscheduled Visit on Mar/04/2021

**Form Version:** 14-Jan-2021 02:22

**Site No:** 1231

**Subject No:** 12314091

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

**Form:** DATE OF VISIT - ASYMPTOMATIC SURVEILLANCE -  
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 20:34

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**1. Date of Visit**

Date	Location	User	Value	Reason
Mar-05-2021 13:57:42 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	Agustin Morato Cabral (b) (4)	<b>Data Entry:</b> Mar/4/2021	Initial Entry

**3. COVID-19 Surveillance Visit:**

Date	Location	User	Value	Reason
Mar-05-2021 13:57:42 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	Agustin Morato Cabral (b) (4)	<b>Data Entry:</b> SSWAB_WEEK4	Initial Entry

090177e196ae2f0e\Final\Final On: 01-Apr-2021 03:32 (GMT)

**Header Text:** C4591001**Visit:** V202\_SURVEIL\_SWAB 2 -  
Unscheduled Visit on Mar/04/2021**Form Version:** 10-Oct-2020 15:57**Site No:** 1231**Subject No:** 12314091**Generated By:** (b) (4)**Form:** ELECTRONIC SAMPLE TRACKING - REPEAT SWAB -  
eCRF Audit Trail History**Form Status:** Data Complete, Locked, Frozen, Verified**Site Name:** (1231) Hospital Militar Central Cirujano Mayor Dr. Cosme  
Argerich**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 20:34[Back to Form](#)**1. Data Origin**

Date	Location	User	Value	Reason
Mar-05-2021 13:58:39 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SITE	Initial Entry

**2. Sample Type**

Date	Location	User	Value	Reason
Mar-05-2021 13:58:39 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	Agustin Morato Cabral (b) (4)	<b>Data Entry:</b> NASAL_SWAB	Initial Entry

**3. Sample Collected?**

Date	Location	User	Value	Reason
Mar-05-2021 14:00:23 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Mar-05-2021 13:58:39 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Mar-05-2021 13:58:39 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	Agustin Morato Cabral (b) (4)	<b>Data Entry:</b> YES Date of Collection: Mar/4/2021	Initial Entry

**5.a**

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

**Visit:** V202\_SURVEIL\_SWAB 2 -  
Unscheduled Visit on Mar/04/2021

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

**Site No:** 1231

**Subject No:** 12314091

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

**Form:** ELECTRONIC SAMPLE TRACKING - REPEAT SWAB -  
eCRF Audit Trail History

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

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

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 20:34

Mar-05-2021 14:00:23 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	Agustin Morato Cabral (b) (4)	<b>Data Entry:</b> <b>Sample ID:</b> BR265C	Initial Entry
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**5.a Sample ID**

Date	Location	User	Value	Reason
Mar-05-2021 14:00:23 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	Agustin Morato Cabral (b) (4)	<b>Data Entry:</b> BR265C	Initial Entry

**Header Text:** C4591001

**Visit:** V202\_SURVEIL\_SWAB 3 -  
Unscheduled Visit on Mar/19/2021

**Form Version:** 14-Jan-2021 02:22

**Site No:** 1231

**Subject No:** 12314091

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

**Form:** DATE OF VISIT - ASYMPTOMATIC SURVEILLANCE -  
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 20:34

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**1. Date of Visit**

Date	Location	User	Value	Reason
Mar-29-2021 09:16:17 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Clo sed	Site confirmed: Both visits were performed on the same date, which is a perfectly allowed procedure. Thank you.
Mar-26-2021 19:51:14 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	Santiago Corradetti (b) (4)	Query 1: An swere d	Both visits were performed on the same date, which is a perfectly allowed procedure. Thank you.
Mar-26-2021 04:37:07 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (b) (4)	Query 1: Op ened	DMW7838616;The Date of Visit at Visit at Visit 'COVID-19 Surveillance Visit = SSWAB_WEEK6' is the same as the other Date of Visit at Visit 'V4MTH6'. Please review for duplication and update as appropriate.
Mar-20-2021 13:37:38 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	Agustin Morato Cabral (b) (4)	<b>Data Entry</b> : Mar/1 9/202 1	Initial Entry

090177e196ae2f0e\Final\Final On: 01-Apr-2021 03:32 (GMT)

**Header Text:** C4591001

**Visit:** V202\_SURVEIL\_SWAB 3 -  
Unscheduled Visit on Mar/19/2021

**Form Version:** 14-Jan-2021 02:22

**Site No:** 1231

**Subject No:** 12314091

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

**Form:** DATE OF VISIT - ASYMPTOMATIC SURVEILLANCE -  
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 20:34

**3. COVID-19 Surveillance Visit:**

Date	Location	User	Value	Reason
Mar-20-2021 13:37:38 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	Agustin Morato Cabral (b) (4)	<u>Data Entry:</u> SSWAB_WEEK6	Initial Entry

**Header Text:** C4591001**Visit:** V202\_SURVEIL\_SWAB 3 -  
Unscheduled Visit on Mar/19/2021**Form Version:** 10-Oct-2020 15:57**Site No:** 1231**Subject No:** 12314091**Generated By:** (b) (4)**Form:** ELECTRONIC SAMPLE TRACKING - REPEAT 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 20:34[Back to Form](#)**1. Data Origin**

Date	Location	User	Value	Reason
Mar-20-2021 13:37:55 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SITE	Initial Entry

**2. Sample Type**

Date	Location	User	Value	Reason
Mar-20-2021 13:37:55 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	Agustin Morato Cabral (b) (4)	<b>Data Entry:</b> NASAL_SWAB	Initial Entry

**3. Sample Collected?**

Date	Location	User	Value	Reason
Mar-20-2021 13:38:13 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Mar-20-2021 13:37:55 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Mar-20-2021 13:37:55 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	Agustin Morato Cabral (b) (4)	<b>Data Entry:</b> YES Date of Collection: Mar/19/2021	Initial Entry

**5.a**

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

**Visit:** V202\_SURVEIL\_SWAB 3 -  
Unscheduled Visit on Mar/19/2021

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

**Site No:** 1231

**Subject No:** 12314091

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

**Form:** ELECTRONIC SAMPLE TRACKING - REPEAT 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 20:34

Mar-20-2021 13:38:13 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	Agustin Morato Cabral (b) (4)	<b>Data Entry:</b> <b>Sample ID:</b> BP8830	Initial Entry
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**5.a Sample ID**

Date	Location	User	Value	Reason
Mar-20-2021 13:38:13 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	Agustin Morato Cabral (b) (4)	<b>Data Entry:</b> BP8830	Initial Entry

**Header Text:** C4591001

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

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

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

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

**Site No:** 1231

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

**Subject No:** 12314091

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 20:34

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*1. Date of Visit*

Date	Location	User	Value	Reason
Mar-04-2021 16:30:27 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Mar/4/2021	Initial Entry

**Header Text:** C4591001

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

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

**Site No:** 1231

**Subject No:** 12314091

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

**Form:** FURTHER VACCINATION CONFIRMATION - 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 20:34

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

Date	Location	User	Value	Reason
Mar-04-2021 16:30:57 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Mar-04-2021 16:30:36 (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-04-2021 16:30:36 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Participant is willing to return f or Vaccination 3 Participant is:  eligible and NOT confirmed to have received only placeb o at Vaccination 1/2	Initial Entry

090177e196ae2f0e\Final\Final On: 01-Apr-2021 03:32 (GMT)

**Header Text:** C4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1231

**Subject No:** 12314091

**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 20:34

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Date	Location	User	Value	Reason
Feb-11-2021 10:25:29 (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:** 12314091

**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 20:34

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Date	Location	User	Value	Reason
Feb-11-2021 12:40:44 (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: 12314091

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - 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 20:34

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**1. Category:**

Date	Location	User	Value	Reason
Feb-11-2021 10:25:29 (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-11-2021 10:25:29 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 1	Initial Entry

**3. Adverse Event:**

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

Date	Location	User	Value	Reason
Feb-17-2021 03:45:50 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Feb-16-2021 20:07:11 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	The event is a new diagnosis. Thank you
Feb-15-2021 12:51:00 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	clinical: pls confirm this is a new diagnosis. Thanks
Feb-11-2021 10:25:29 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> TYPE 2 DIABETES	Initial Entry

**4. Start Date Time:**

Date	Location	User	Value	Reason
Feb-11-2021 10:25:29 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Jan/13/2021 08:00	Initial Entry

090177e196ae2f0e\Final\Final On: 01-Apr-2021 03:32 (GMT)

Header Text: C4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1231

Subject No: 12314091

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - 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 20:34

		(b) (4), (b) (6)	
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5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Feb-11-2021 10:25:29 (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
Feb-11-2021 10:25:29 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 1	Initial Entry

7. Is the adverse event serious?

If Yes, NOTIFY PFIZER IMMEDIATELY.

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

Date	Location	User	Value	Reason
Feb-11-2021 10:25:29 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

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

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

Date	Location	User	Value	Reason
Feb-11-2021 10:25:29 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

090177e196ae2f0e\Final\Final On: 01-Apr-2021 03:32 (GMT)

Header Text: C4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1231

Subject No: 12314091

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - 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 20:34

9. Is this event related to study treatment:

Date	Location	User	Value	Reason
Feb-11-2021 10:25:29 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NOT RELATED If Not Related to study treatment(s), this event is due to:  OTHER  If Other, specify:  Unknown	Initial Entry

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Feb-11-2021 10:25:29 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NOT APPLICABLE	Initial Entry

11. Was a Concomitant Medication given?

Date	Location	User	Value	Reason
Feb-11-2021 10:25:29 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Feb-11-2021 10:25:29 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

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

Date	Location	User	Value	Reason
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090177e196ae2f0e\Final\Final On: 01-Apr-2021 03:32 (GMT)

**Header Text:** C4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1231

**Subject No:** 12314091

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

**Form:** ADVERSE EVENT REPORT - 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 20:34

Feb-11-2021 10:25:29 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> RECOVERING/RESOLVING	Initial Entry
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**14. Did the adverse event cause the subject to be discontinued from the study?**

Date	Location	User	Value	Reason
Feb-11-2021 10:25:29 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

090177e196ae2f0e\Final\Final On: 01-Apr-2021 03:32 (GMT)

**Header Text:** C4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1231

**Subject No:** 12314091

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

**Form:** ADVERSE EVENT REPORT - 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 20:34

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**1. Category:**

Date	Location	User	Value	Reason
Feb-11-2021 12:40:44 (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-11-2021 12:40:44 (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-11-2021 12:40:44 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Accute appendictis	Initial Entry

**4. Start Date Time:**

Date	Location	User	Value	Reason
Feb-24-2021 12:24:11 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Jan/6/2021 16:00	New Information
Feb-11-2021 12:40:44 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Jan/12/2021 20:00	Initial Entry

**5. Is the adverse event still ongoing?**

Date	Location	User	Value	Reason
Feb-11-2021 12:40:44 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO End Date Time:	Initial Entry

090177e196ae2f0e\Final\Final On: 01-Apr-2021 03:32 (GMT)

Header Text: C4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1231

Subject No: 12314091

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - 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 20:34

Jan/23/2021 12:30

6. Toxicity Grade:

Date	Location	User	Value	Reason
Feb-11-2021 12:40:44 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 3	Initial Entry

7. Is the adverse event serious?

If Yes, NOTIFY PFIZER IMMEDIATELY.

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

Date	Location	User	Value	Reason
Feb-15-2021 04:44:44 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Feb-11-2021 12:40:44 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	For AE Acute appendicitis: Response to "Is the adverse event serious?" is 'Yes' but "Serious Adverse Event Number" is blank.
Feb-11-2021 12:40:44 (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?  NO  Did this serious event result in death?  NO	Initial Entry

090177e196ae2f0e\Final\Final On: 01-Apr-2021 03:32 (GMT)

**Header Text:** C4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1231

**Subject No:** 12314091

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

**Form:** ADVERSE EVENT REPORT - 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 20:34

			<p>Did this serious event require or prolong hospitalization?</p> <p>YES</p> <p>Did this serious event result in persistent or significant disability/incapacity?</p> <p>NO</p> <p>Is this serious event life threatening?</p> <p>NO</p> <p>Other medically important serious event</p> <p>NO</p>	
--	--	--	---	--

**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-11-2021 12:40:44 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**9. Is this event related to study treatment:**

Date	Location	User	Value	Reason
Feb-11-2021 12:40:44 (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>  unknown	Initial Entry

090177e196ae2f0e\Final\Final On: 01-Apr-2021 03:32 (GMT)



Header Text: C4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1231

Subject No: 12314091

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - 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 20:34

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Feb-11-2021 12:40:44 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NOT APPLICABLE	Initial Entry

11. Was a Concomitant Medication given?

Date	Location	User	Value	Reason
Feb-11-2021 12:40:44 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Feb-11-2021 12:40:44 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

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

Date	Location	User	Value	Reason
Feb-11-2021 12:40:44 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> RECOVERED/RESOLVED	Initial Entry

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

Date	Location	User	Value	Reason
Feb-11-2021 12:40:44 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

15. Serious Adverse Event Number: For Pfizer Use Only

Date	Location	User	Value	Reason
Feb-15-2021 04:44:44 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 2021148275	Initial Entry

090177e196ae2f0e\Final\Final On: 01-Apr-2021 03:32 (GMT)

**Header Text:** C4591001

**Visit:** Disposition - Unscheduled

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

**Site No:** 1231

**Subject No:** 12314091

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

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

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

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

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 20:34

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**1. Date Treatment Unblinded :**

Date	Location	User	Value	Reason
Mar-04-2021 16:30:57 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Mar/4/2021	Initial Entry

**2. Primary Reason for Unblinding:**

Date	Location	User	Value	Reason
Mar-04-2021 16:30:57 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> ASSESS ELIGIBILITY FOR ADDITIONAL VACCINATION	Initial Entry

090177e196ae2f0e\Final\Final On: 01-Apr-2021 03:32 (GMT)

**Header Text:** C4591001

**Visit:** Subject Status - Unscheduled

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

**Site No:** 1231

**Subject No:** 12314091

**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 20:34

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**1. Subject Status**

Date	Location	User	Value	Reason
Oct-13-2020 19:25:15 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> FOLLOW-UP	Initial Entry
Aug-26-2020 11:25:29 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> ENROLLED/RANDOMIZED	Initial Entry
Aug-26-2020 11:24:12 (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-13-2020 19:25:15 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> Oct/13/2020	Initial Entry
Aug-26-2020 11:25:29 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> Aug/26/2020	Initial Entry
Aug-26-2020 11:24:12 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> Aug/26/2020	Initial Entry

090177e196ae2f0e\Final\Final On: 01-Apr-2021 03:32 (GMT)

**Header Text:** C4591001

**Visit:** Investigator Signature - Unscheduled

**Form:** CASEBOOK SIGNATURE FORM - eCRF Audit Trail History

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

**Form Status:** Data Complete, Verified

**Site No:** 1231

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

**Subject No:** 12314091

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 20:34

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**1. Casebook Signature**

Date	Location	User	Value	Reason
Oct-21-2020 15:19:23 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Click Here to Enable	Initial Entry