

**Header Text:** C4591001

**Visit:** COHORT\_SELECTION

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

**Site No:** 1231

**Subject No:** 12314813

**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:** 12314813

**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/28/2020
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**Header Text:** C4591001

**Visit:** COHORT\_SELECTION

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

**Site No:** 1231

**Subject No:** 12314813

**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	[12314813]
2.	Birth Date:	(b) (6)/1973
3.	Sex:	FEMALE
4.	Ethnicity:	HISPANIC OR LATINO(A) OR OF SPANISH ORIGIN
5.	Race: (Check X all that apply):	WHITE
6.	Racial Designation:	

090177e196ae2e65\Final\Final On: 01-Apr-2021 03:12 (GMT)

**Header Text:** C4591001

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

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

**Site No:** 1231

**Subject No:** 12314813

**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/28/2020
2.	Erroneous Visit	

**Header Text:** C4591001

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

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

**Site No:** 1231

**Subject No:** 12314813

**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:** 12314813

**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/28/2020
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:** 12314813

**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

[Form Comments](#)  
[eCRF Audit Trail History](#)

**Medical History Details**

1.a	Line/MH Number:	[1]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[S1 disc extrusion and L4-L5 bulging]
	Start Date:	Oct/1/2000
	Ongoing:	YES

**Header Text:** C4591001

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

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

**Site No:** 1231

**Subject No:** 12314813

**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/28/2020
2.	Weight:	[68.0]
3.	Unit:	kg
4.	Height:	[178.0]
5.	Unit:	cm
6.	Body Mass Index:	[21.5]

**Vital Signs Details**

7.a	Record Identifier:	1
	Temperature:	[36.2]
	Unit:	C
	Temperature Location:	ORAL CAVITY

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**Header Text:** C4591001

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

**Form Version:** 21-Aug-2020 02:49

**Site No:** 1231

**Subject No:** 12314813

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

**Form:** LAB URINALYSIS - PREGNANCY TEST

**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](#)

**Lab Urinalysis**

1.	Lab Panel:	URINALYSIS
2.	Lab Sub-Panel:	PREGNANCY
3.	Collection Date:	Aug/28/2020
4.	Laboratory Name and Address (Derived)	[STUDY SITE]
5.	Specimen Type:	URINE

**Lab Result**

6.a	Sponsor ID:	[113]
	Test:	Choriogonadotropin Beta_PX113
	Result:	NEGATIVE
	Not Done:	

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**Header Text:** C4591001

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

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

**Site No:** 1231

**Subject No:** 12314813

**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/28/2020
2.	Randomization Number:	[72154]
3.	Randomization Group:	[ ]

**Header Text:** C4591001

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

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

**Site No:** 1231

**Subject No:** 12314813

**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/28/2020
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	[BJ4B3D]
5.b	Sample ID	[BJ4B3F]
5.c	Sample ID	[BJ4B3G]
5.d	Sample ID	[BPWVY9]
5.e	Sample ID	[BPWVYB]
5.f	Sample ID	[BPWVYC]

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**Header Text:** C4591001

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

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

**Site No:** 1231

**Subject No:** 12314813

**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/28/2020
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	[BPTDP5]
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090177e196ae2e65\Final\Final On: 01-Apr-2021 03:12 (GMT)

**Header Text:** C4591001

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

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

**Site No:** 1231

**Subject No:** 12314813

**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/28/2020 13:40
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:** 12314813

**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:** 12314813

**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/17/2020
2.	Erroneous Visit	

**Header Text:** C4591001

**Visit:** V2\_VAX2\_L

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

**Site No:** 1231

**Subject No:** 12314813

**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/17/2020
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**Vital Signs Details**

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



**Header Text:** C4591001

**Visit:** V2\_VAX2\_L

**Form Version:** 21-Aug-2020 02:49

**Site No:** 1231

**Subject No:** 12314813

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

**Form:** LAB URINALYSIS - PREGNANCY TEST

**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](#)

**Lab Urinalysis**

1.	Lab Panel:	URINALYSIS
2.	Lab Sub-Panel:	PREGNANCY
3.	Collection Date:	Sep/17/2020
4.	Laboratory Name and Address (Derived)	[STUDY SITE]
5.	Specimen Type:	URINE

**Lab Result**

6.a	Sponsor ID:	[113]
	Test:	Choriogonadotropin Beta_PX113
	Result:	NEGATIVE
	Not Done:	

090177e196ae2e65\Final\Final On: 01-Apr-2021 03:12 (GMT)

**Header Text:** C4591001

**Visit:** V2\_VAX2\_L

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

**Site No:** 1231

**Subject No:** 12314813

**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/17/2020
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[ ]

**Aliquot**

Please enter barcode for each aliquot.

5.a	Sample ID	[BPWB2P]
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090177e196ae2e65\Final\Final On: 01-Apr-2021 03:12 (GMT)

**Header Text:** C4591001

**Visit:** V2\_VAX2\_L

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

**Site No:** 1231

**Subject No:** 12314813

**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**

<b>Vaccination</b>		
1.	Was there a temporary delay of vaccination?	NO
2.	Treatment Name	[BLINDED THERAPY]
3.	Formulation:	INJECTION
4.	Dose Date Time:	Sep/17/2020 14:20
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

090177e196ae2e65\Final\Final On: 01-Apr-2021 03:12 (GMT)

**Header Text:** C4591001

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

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

**Site No:** 1231

**Subject No:** 12314813

**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	Nov/11/2020
2.	Erroneous Visit	

**Header Text:** C4591001

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

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

**Site No:** 1231

**Subject No:** 12314813

**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: Nov/11/2020
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	[BJ4DT5]
5.b	Sample ID	[BJ4DW3]
5.c	Sample ID	[BP1P68]

090177e196ae2e65\Final\Final On: 01-Apr-2021 03:12 (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:** 12314813

**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:	
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**Header Text:** C4591001

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

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

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

**Form Status:** Not Started

**Site No:** 1231

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

**Subject No:** 12314813

**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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090177e196ae2e65\Final\Final On: 01-Apr-2021 03:12 (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:** 12314813

**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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**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:** 12314813

**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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**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:** 12314813    **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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090177e196ae2e65\Final\Final On: 01-Apr-2021 03:12 (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:** 12314813    **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:** 12314813

**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:	
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**Header Text:** C4591001

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

**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

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

**Form Status:** Not Started

**Site No:** 1231

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

**Subject No:** 12314813

**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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090177e196ae2e65\Final\Final On: 01-Apr-2021 03:12 (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:** 12314813

**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:** 12314813

**Subject Initials:** ---

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

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

**Unplanned Assessments**

1.	Assessments	
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**Header Text:** C4591001

**Visit:** End of Treatment - Unscheduled

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

**Site No:** 1231

**Subject No:** 12314813

**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 :	Nov/11/2020
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:** 12314813

**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  
Unscheduled Visit

**Form:** DATE OF VISIT - REPEAT SWAB

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

**Form Status:** Not Started

**Site No:** 1231

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

**Subject No:** 12314813

**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:** 12314813

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

090177e196ae2e65\Final\Final On: 01-Apr-2021 03:12 (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:** 12314813

**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:** 12314813      **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:	

090177e196ae2e65\Final\Final On: 01-Apr-2021 03:12 (GMT)

**Header Text:** C4591001

**Visit:** Unplanned Vaccination - Unscheduled

**Form:** LAB URINALYSIS - PREGNANCY TEST

**Form Version:** 20-Feb-2021 02:14

**Form Status:** Not Started

**Site No:** 1231

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

**Subject No:** 12314813

**Subject Initials:** ---

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

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

**Lab Urinalysis**

1.	Lab Panel:	
2.	Lab Sub-Panel:	
3.	Collection Date:	//
4.	Laboratory Name and Address (Derived)	[ ]
5.	Specimen Type:	

**Lab Result**

6.	Sponsor ID:	[ ]
	Test:	
	Result:	
	Not Done:	

090177e196ae2e65\Final\Final On: 01-Apr-2021 03:12 (GMT)

**Header Text:** C4591001

**Visit:** Unplanned Vaccination - Unscheduled

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

**Site No:** 1231

**Subject No:** 12314813

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

**Form:** VACCINATION

**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

**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?	

090177e196ae2e65\Final\Final On: 01-Apr-2021 03:12 (GMT)

**Header Text:** C4591001

**Visit:** Unplanned Vaccination - Unscheduled

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

**Site No:** 1231

**Subject No:** 12314813

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

**Form:** CONTACT OUTCOME - MONTH 1

**Form Status:** Not Started

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

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 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:** 12314813

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

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

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

**Site No:** 1231

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

**Subject No:** 12314813

**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	Jan/18/2021
2.	Erroneous Visit	

**Header Text:** C4591001

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

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

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

**Site No:** 1231

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

**Subject No:** 12314813

**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 per local/national recommendations and confirmed to have received only placebo at Vaccination 1/2
----	---	---

**Header Text:** C4591001

**Visit:** V101\_VAX3

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

**Site No:** 1231

**Subject No:** 12314813

**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	Jan/28/2021
2.	Erroneous Visit	

**Header Text:** C4591001

**Visit:** V101\_VAX3

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

**Site No:** 1231

**Subject No:** 12314813

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

**Form:** INFORMED CONSENT - FURTHER 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](#)

**Informed Consent - Further Vaccination**

1.	Consent Was:	OBTAINED Date Written Consent Obtained Jan/28/2021
----	--------------	--

**Header Text:** C4591001

**Visit:** V101\_VAX3

**Form Version:** 10-Dec-2020 02:30

**Site No:** 1231

**Subject No:** 12314813

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

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

**Form Comments**

**Inclusion Criteria Not Met**

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

**Exclusion Criteria Met**

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

**Header Text:** C4591001

**Visit:** V101\_VAX3

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

**Site No:** 1231

**Subject No:** 12314813

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

**Form:** DISPOSITION - SCREENING FOR FURTHER 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](#)

**Disposition - Screening for Further Vaccination**

1.	Date of Completion/Discontinuation /Death :	Jan/28/2021
2.	Phase of Disposition:	REPEAT SCREENING 1
3.	Status:	COMPLETED
4.	Specify Status:	[ ]

**Header Text:** C4591001

**Visit:** V101\_VAX3

**Form Version:** 14-Jan-2021 02:21

**Site No:** 1231

**Subject No:** 12314813

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

**Form:** LAB URINALYSIS - PREGNANCY TEST

**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](#)

**Lab Urinalysis**

1.	Lab Panel:	URINALYSIS
2.	Lab Sub-Panel:	PREGNANCY
3.	Collection Date:	Jan/28/2021
4.	Laboratory Name and Address (Derived)	[STUDY SITE]
5.	Specimen Type:	URINE

**Lab Result**

6.a	Sponsor ID:	[113]
	Test:	Choriogonadotropin Beta_PX113
	Result:	NEGATIVE
	Not Done:	

090177e196ae2e65\Final\Final On: 01-Apr-2021 03:12 (GMT)



**Header Text:** C4591001

**Visit:** V101\_VAX3

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

**Site No:** 1231

**Subject No:** 12314813

**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: Jan/28/2021
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	[BS4218]
5.b	Sample ID	[BS4219]
5.c	Sample ID	[BPWFHC]
5.d	Sample ID	[BRYWHV]

090177e196ae2e65\Final\Final On: 01-Apr-2021 03:12 (GMT)

**Header Text:** C4591001

**Visit:** V101\_VAX3

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

**Site No:** 1231

**Subject No:** 12314813

**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: Jan/28/2021
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	[BPWFPM]
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090177e196ae2e65\Final\Final On: 01-Apr-2021 03:12 (GMT)

**Header Text:** C4591001

**Visit:** V101\_VAX3

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

**Site No:** 1231

**Subject No:** 12314813

**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	[BNT162b2]
3.	Formulation:	INJECTION
4.	Dose Date Time:	Jan/28/2021 15:10
5.	Anatomical Location:	DELTOID MUSCLE
6.	Body Side:	LEFT
7.	Route:	INTRAMUSCULAR
8.	Actual Dose:	[30.0]
9.	Unit:	ug
10.	Timeframe Subject Was Observed	30 MINUTES
11.	Was the subject observed for at least the protocol specified observation period after investigational product administration?	YES

090177e196ae2e65\Final\Final On: 01-Apr-2021 03:12 (GMT)

**Header Text:** C4591001

**Visit:** V102\_VAX4

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

**Site No:** 1231

**Subject No:** 12314813

**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	Feb/17/2021
2.	Erroneous Visit	

**Header Text:** C4591001

**Visit:** V102\_VAX4

**Form Version:** 14-Jan-2021 02:21

**Site No:** 1231

**Subject No:** 12314813

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

**Form:** LAB URINALYSIS - PREGNANCY TEST

**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](#)

**Lab Urinalysis**

1.	Lab Panel:	URINALYSIS
2.	Lab Sub-Panel:	PREGNANCY
3.	Collection Date:	Feb/17/2021
4.	Laboratory Name and Address (Derived)	[STUDY SITE]
5.	Specimen Type:	URINE

**Lab Result**

6.a	Sponsor ID:	[113]
	Test:	Choriogonadotropin Beta_PX113
	Result:	NEGATIVE
	Not Done:	

090177e196ae2e65\Final\Final On: 01-Apr-2021 03:12 (GMT)

**Header Text:** C4591001

**Visit:** V102\_VAX4

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

**Site No:** 1231

**Subject No:** 12314813

**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/17/2021
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	[BR286W]
-----	-----------	----------

090177e196ae2e65\Final\Final On: 01-Apr-2021 03:12 (GMT)

**Header Text:** C4591001

**Visit:** V102\_VAX4

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

**Site No:** 1231

**Subject No:** 12314813

**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	[BNT162b2]
3.	Formulation:	INJECTION
4.	Dose Date Time:	Feb/17/2021 14:03
5.	Anatomical Location:	DELTOID MUSCLE
6.	Body Side:	LEFT
7.	Route:	INTRAMUSCULAR
8.	Actual Dose:	[30.0]
9.	Unit:	ug
10.	Timeframe Subject Was Observed	30 MINUTES
11.	Was the subject observed for at least the protocol specified observation period after investigational product administration?	YES

090177e196ae2e65\Final\Final On: 01-Apr-2021 03:12 (GMT)

**Header Text:** C4591001

**Visit:** V103\_MONTH1

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

**Site No:** 1231

**Subject No:** 12314813

**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	Mar/18/2021
2.	Erroneous Visit	



**Header Text:** C4591001

**Visit:** V103\_MONTH1

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

**Site No:** 1231

**Subject No:** 12314813

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

**Form:** CONTACT OUTCOME

**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](#)

**Contact Outcome**

1.	Contact Type:	TELEPHONE VISIT
2.	Was contact made?	YES Date of Contact: Mar/18/2021
3.	Comments:	[ ]

090177e196ae2e65\Final\Final On: 01-Apr-2021 03:12 (GMT)

**Header Text:** C4591001

**Visit:** V104\_MONTH6

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

**Site No:** 1231

**Subject No:** 12314813

**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:** V104\_MONTH6

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

**Site No:** 1231

**Subject No:** 12314813

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

**Form:** CONTACT OUTCOME

**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

**Contact Outcome**

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

090177e196ae2e65\Final\Final On: 01-Apr-2021 03:12 (GMT)

**Header Text:** C4591001

**Visit:** V105\_MONTH18

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

**Site No:** 1231

**Subject No:** 12314813

**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:** V105\_MONTH18

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

**Site No:** 1231

**Subject No:** 12314813

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

**Form:** CONTACT OUTCOME

**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

**Contact Outcome**

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

090177e196ae2e65\Final\Final On: 01-Apr-2021 03:12 (GMT)

**Header Text:** C4591001

**Visit:** FURTHER\_VACCINATION\_EOT -  
Unscheduled

**Form:** DISPOSITION - TREATMENT

**Form Version:** 20-Feb-2021 02:26

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

**Site No:** 1231

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

**Subject No:** 12314813

**Subject Initials:** ---

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

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

[eCRF Audit Trail History](#)

**Disposition - Treatment**

1.	Date of Completion/Discontinuation /Death :	Mar/18/2021
2.	Phase of Disposition:	OPEN LABEL TREATMENT
3.	Status:	COMPLETED
4.	Specify Status:	[ ]

**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:** 12314813

**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 On going	Form Instance
1.	ADVERSE EVENT	1	Low back pain	Sep/21/2020 09:00	NO End Date Time:  Oct/12/2020 09:00	<a href="#">Repeating Pages</a>
2.	ADVERSE EVENT	2	Worsening of herniated disc	Sep/21/2020 09:00	NO End Date Time:  Jan/5/2021 17:00	<a href="#">Repeating Pages</a>

090177e196ae2e65\Final\Final On: 01-Apr-2021 03:12 (GMT)

**Header Text:** C4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1231

**Subject No:** 12314813

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

**Form:** ADVERSE EVENT REPORT

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

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

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 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)	[Low back pain]
4.	Start Date Time:	Sep/21/2020 09:00
5.	Is the adverse event still ongoing?	NO End Date Time: Oct/12/2020 09:00
6.	Toxicity Grade:	2
7.	Is the adverse event serious?  If Yes, NOTIFY PFIZER IMMEDIATELY.  Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).	NO
8.	Is this adverse event the result of a study Medication Error? If Yes, record the type of medication error on the Medication Error Log.	NO
9.	Is this event related to study treatment:	NOT RELATED If Not Related to study treatment(s), this event is due to: OTHER If Other, specify: [disc extrusion at S1 and bulge at L4-L5]
10.	Latest Action Taken with Study Treatment:	NOT APPLICABLE
11.	Was a Concomitant Medication given?	YES
12.	Was a Non-Drug Treatment given?	YES

090177e196ae2e65\Final\Final On: 01-Apr-2021 03:12 (GMT)



**Header Text:** C4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1231

**Subject No:** 12314813

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

**Form:** ADVERSE EVENT REPORT

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

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

**Subject Initials:** ---

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

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	[ ]

090177e196ae2e65\Final\Final On: 01-Apr-2021 03:12 (GMT)

<b>Header Text:</b> C4591001		<b>Form:</b> ADVERSE EVENT REPORT
<b>Visit:</b> Logs - Unscheduled		<b>Form Status:</b> Data Complete, Locked, Frozen
<b>Form Version:</b> 22-Apr-2020 21:02		<b>Site Name:</b> (1231) Hospital Militar Central Cirujano Mayor Dr. Cosme Argerich
<b>Site No:</b> 1231		<b>Subject Initials:</b> ---
<b>Subject No:</b> 12314813		<b>Generated Time (GMT):</b> 29-Mar-2021 20:34
<b>Generated By:</b> (b) (4)		
<a href="#">Back to Form</a> <a href="#">eCRF Audit Trail History</a> <a href="#">Form Audit Trail</a>		
<b>Adverse Event Report</b>		
1.	Category:	ADVERSE EVENT
2.	AE ID:	[2]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[Worsening of herniated disc]
4.	Start Date Time:	Sep/21/2020 09:00
5.	Is the adverse event still ongoing?	NO End Date Time: Jan/5/2021 17:00
6.	Toxicity Grade:	3
7.	Is the adverse event serious?  If Yes, NOTIFY PFIZER IMMEDIATELY.  Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).	YES  Is this serious event associated with congenital anomaly or birth defect? NO  Did this serious event result in death? NO  Did this serious event require or prolong hospitalization? YES  Did this serious event result in persistent or significant disability/incapacity? NO  Is this serious event life threatening? NO  Other medically important serious event YES
8.	Is this adverse event the result of a study Medication Error? If Yes, record the type of medication error on the Medication Error Log.	NO
9.	Is this event related to study treatment:	NOT RELATED If Not Related to study treatment(s), this event is due to: OTHER If Other, specify: [history of herniated disc]

**Header Text:** C4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1231

**Subject No:** 12314813

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

**Form:** ADVERSE EVENT REPORT

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

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

**Subject Initials:** ---

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

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	[2020512052]

090177e196ae2e65\Final\Final On: 01-Apr-2021 03:12 (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:** 12314813

**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:** 12314813

**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	[ ]

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**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:** 12314813

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

**Site No:** 1231

**Subject No:** 12314813

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

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

**Form Status:** Not Started

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

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 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:	//

090177e196ae2e65\Final\Final On: 01-Apr-2021 03:12 (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:** 12314813

**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:** 12314813

**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?	

090177e196ae2e65\Final\Final On: 01-Apr-2021 03:12 (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:** 12314813

**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:** 12314813

**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:** 12314813

**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:** 12314813

**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:	//

090177e196ae2e665\Final\Final On: 01-Apr-2021 03:12 (GMT)

**Header Text:** C4591001

**Visit:** Disposition - Unscheduled

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

**Site No:** 1231

**Subject No:** 12314813

**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 :	Jan/18/2021
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:** 12314813

**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 :	//
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090177e196ae2e65\Final\Final On: 01-Apr-2021 03:12 (GMT)

**Header Text:** C4591001

**Visit:** Disposition - Unscheduled

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

**Site No:** 1231

**Subject No:** 12314813

**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:** 12314813

**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	Nov/11/2020

090177e196ae2e65\Final\Final On: 01-Apr-2021 03:12 (GMT)

**Header Text:** C4591001

**Visit:** Investigator Signature - Unscheduled

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

**Site No:** 1231

**Subject No:** 12314813

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

**Form:** CASEBOOK SIGNATURE FORM

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

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

**Subject Initials:** ---

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

[eCRF Audit Trail History](#)

**Casebook Signature Form**

1.	Casebook Signature	<a href="#">Click Here to Enable</a>
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**Header Text:** C4591001

**Visit:** Investigator Signature - Unscheduled

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

**Site No:** 1231

**Subject No:** 12314813

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

**Form:** CASEBOOK SIGNATURE FORM

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

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

**Subject Initials:** ---

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

[Audit Trail](#)

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

- CRF\_Sign

Name	Signature Meaning	Date	Type	Action
(b) (6)	Approved	Mar-19-2021 13:53:47 (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.

090177e196ae2e65\Final\Final On: 01-Apr-2021 03:12 (GMT)

**Header Text:** C4591001

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

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

**Site No:** 1231

**Subject No:** 12314813

**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-28-2020 16:07:42 (UTC-03:00) City of Buenos Aires	(b) (4), (b) (6)	Not Applicable

**Header Text:** C4591001

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

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

**Site No:** 1231

**Subject No:** 12314813

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

**Form:** GENERAL MEDICAL HISTORY - Comments

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

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

**Subject Initials:** ---

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

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Item	Date	User	Comment
Form	Nov-12-2020 08:24:11 (UTC-03:00) City of Buenos Aires	(b) (4), (b) (6)	
Form	Aug-28-2020 16:08:06 (UTC-03:00) City of Buenos Aires	(b) (4), (b) (6)	Not Applicable

090177e196ae2e65\Final\Final On: 01-Apr-2021 03:12 (GMT)

**Header Text:** C4591001

**Visit:** V101\_VAX3

**Form Version:** 10-Dec-2020 02:30

**Site No:** 1231

**Subject No:** 12314813

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

**Form:** INCLUSION/EXCLUSION CRITERIA - FURTHER VACCINATION -  
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	Jan-28-2021 15:48:44 (UTC-03:00) City of Buenos Aires	(b) (4), (b) (6)	Not Applicable

**Header Text:** C4591001

**Visit:** Investigator Signature - Unscheduled

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

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

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

**Site No:** 1231

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

**Subject No:** 12314813

**Subject Initials:** ---

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

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

[Back to Form](#)

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

- CRF\_Sign

Name	Signature Meaning	Date	Type	Action
(b) (6)	Approved	Mar-19-2021 13:53:47 (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-18-2021 10:48:59 (UTC-03:00) City of Buenos Aires		Edit - All signatures invalidated
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**Affidavit:**

N/A

Tatiana Estrada	Approved	Feb-19-2021 18:58:13 (UTC-03:00) City of Buenos Aires	BOOK	Signed
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**Affidavit:**

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

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

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

(b) (6)	N/A	Feb-18-2021 09:58:13 (UTC-03:00) City of Buenos Aires		Edit - All signatures invalidated
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**Affidavit:**

N/A

(b) (6)	Approved	Feb-17-2021 21:50:22 (UTC-03:00) City of Buenos Aires	BOOK	Signed
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090177e196ae2e65\Final\Final On: 01-Apr-2021 03:12 (GMT)

**Header Text:** C4591001

**Visit:** Investigator Signature - Unscheduled

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

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

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

**Site No:** 1231

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

**Subject No:** 12314813

**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.

Martina Davalli	N/A	Feb-17-2021 15:38:46 (UTC-03:00) City of Buenos Aires		Edit - All signatures invalidated
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**Affidavit:**

N/A

(b) (6)	Approved	Jan-29-2021 15:25:11 (UTC-03:00) City of Buenos Aires	BOOK	Signed
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**Affidavit:**

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

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

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

(b) (6)	N/A	Jan-28-2021 15:46:57 (UTC-03:00) City of Buenos Aires		Edit - All signatures invalidated
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**Affidavit:**

N/A

(b) (6)	Approved	Jan-21-2021 08:29:06 (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.

090177e196ae2e65\Final\Final On: 01-Apr-2021 03:12 (GMT)



**Header Text:** C4591001

**Visit:** Investigator Signature - Unscheduled

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

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

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

**Site No:** 1231

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

**Subject No:** 12314813

**Subject Initials:** ---

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

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

(b) (6)	N/A	Jan-02-2021 10:33:38 (UTC-03:00) City of Buenos Aires		Edit - All signatures invalidated
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**Affidavit:**

N/A

(b) (6)	Approved	Nov-12-2020 12:26:51 (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	Nov-12-2020 11:08:17 (UTC-03:00) City of Buenos Aires		Edit - All signatures invalidated
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**Affidavit:**

N/A

(b) (6)	Approved	Nov-12-2020 09:33:48 (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.

Martina Davalli	N/A	Nov-11-2020 16:11:28 (UTC-03:00) City of Buenos Aires		Edit - All signatures invalidated
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**Affidavit:**

N/A

(b) (6)	Approved	Nov-06-2020 14:36:49 (UTC-03:00) City of Buenos Aires	BOOK	Signed
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090177e196ae2e65\Final\Final On: 01-Apr-2021 03:12 (GMT)

**Header Text:** C4591001

**Visit:** Investigator Signature - Unscheduled

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

**Site No:** 1231

**Subject No:** 12314813

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

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

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

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

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 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 Version:** 30-Jul-2020 21:29

**Site No:** 1231

**Subject No:** 12314813

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

**Form:** COHORT\_SELECTION - eCRF Audit Trail History

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

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

**Subject Initials:** ---

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

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*1. Select appropriate response - Protocol version*

Date	Location	User	Value	Reason
Aug-28-2020 16:07:08 (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-28-2020 16:07:08 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> STAGE 3 COHORTS	Initial Entry

**Header Text:** C4591001

**Visit:** COHORT\_SELECTION

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

**Site No:** 1231

**Subject No:** 12314813

**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-28-2020 16:07:14 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> OBTAINED Date Written Consent Obtained  Aug/28/2020	Initial Entry

Header Text: C4591001

Visit: COHORT\_SELECTION

Form Version: 06-Jul-2020 21:55

Site No: 1231

Subject No: 12314813

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-28-2020 14:45:06 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 12314813	Item copied from previous form

**2. Birth Date:**

Date	Location	User	Value	Reason
Aug-28-2020 14:45:00 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> (b) (6)/1973	Enrollment Entry

**3. Sex:**

Date	Location	User	Value	Reason
Aug-28-2020 16:07:27 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> FEMALE	Initial Entry

**4. Ethnicity:**

Date	Location	User	Value	Reason
Aug-28-2020 16:07:27 (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-28-2020 16:07:27 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> WHITE	Initial Entry

090177e196ae2e65\Final\Final On: 01-Apr-2021 03:12 (GMT)

**Header Text:** C4591001

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

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

**Site No:** 1231

**Subject No:** 12314813

**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-28-2020 16:07:33 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Aug/28/2020	Initial Entry

**Header Text:** C4591001

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

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

**Site No:** 1231

**Subject No:** 12314813

**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-28-2020 16:07:56 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Aug/28/2020	Initial Entry

**2. Phase of Disposition:**

Date	Location	User	Value	Reason
Aug-28-2020 16:07:56 (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-28-2020 16:07:56 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> COMPLETED	Initial Entry

090177e196ae2e65\Final\Final On: 01-Apr-2021 03:12 (GMT)

Header Text: C4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 22-Apr-2020 21:03

Site No: 1231

Subject No: 12314813

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
Nov-12-2020 08:24:55 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> Line/MH Number: 1 <b>Medical History Term:</b> S1 disc extrusion and L4-L5 bulging <b>Start Date:</b> Oct/1/2000 <b>Ongoing:</b> YES	Initial Entry

*I.a Line/MH Number:*

Date	Location	User	Value	Reason
Nov-12-2020 08:24:55 (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
Nov-12-2020 08:24:55 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> S1 disc extrusion and L4-L5 bulging	Initial Entry

*I.a Start Date:*

Date	Location	User	Value	Reason
Nov-12-2020 08:24:55 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Oct/1/2000	Initial Entry

*I.a Ongoing:*

Date	Location	User	Value	Reason
Nov-12-2020 08:24:55 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

090177e196ae2e65\Final\Final On: 01-Apr-2021 03:12 (GMT)



Header Text: C4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 21-Aug-2020 02:51

Site No: 1231

Subject No: 12314813

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-28-2020 16:08:25 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Aug/28/2020	Initial Entry

**2. Weight:**

Date	Location	User	Value	Reason
Aug-28-2020 16:08:25 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> 68.0	Initial Entry

**3. Unit:**

Date	Location	User	Value	Reason
Aug-28-2020 16:08:25 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> kg	Initial Entry

**4. Height:**

Date	Location	User	Value	Reason
Aug-28-2020 16:08:25 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> 178.0	Initial Entry

**5. Unit:**

Date	Location	User	Value	Reason
Aug-28-2020 16:08:25 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> cm	Initial Entry

**6. Body Mass Index:**

Date	Location	User	Value	Reason
Aug-28-2020 16:08:25 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> 21.5	Initial Entry

**7.a**

090177e196ae2e65\Final\Final On: 01-Apr-2021 03:12 (GMT)

Header Text: C4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 21-Aug-2020 02:51

Site No: 1231

Subject No: 12314813

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

Date	Location	User	Value	Reason
Aug-28-2020 16:08:25 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Record Identifier::</b> 1 <b>Temperature:</b> 36.2 <b>Temperature Unit:</b> C <b>Temperature Location:</b> ORAL CAVITY	Initial Entry

**7.a Record Identifier:**

Date	Location	User	Value	Reason
Aug-28-2020 16:08:25 (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-28-2020 16:08:25 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 36.2	Initial Entry

**7.a Unit:**

Date	Location	User	Value	Reason
Aug-28-2020 16:08:25 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> C	Initial Entry

**7.a Temperature Location:**

Date	Location	User	Value	Reason
Aug-28-2020 16:08:25 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> ORAL CAVITY	Initial Entry

090177e196ae2e65\Final\Final On: 01-Apr-2021 03:12 (GMT)

Header Text: C4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 21-Aug-2020 02:49

Site No: 1231

Subject No: 12314813

Generated By: (b) (4)

Form: LAB URINALYSIS - PREGNANCY TEST - 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. Lab Panel:**

Date	Location	User	Value	Reason
Aug-28-2020 16:08:32 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> URINALYSIS	Initial Entry

**2. Lab Sub-Panel:**

Date	Location	User	Value	Reason
Aug-28-2020 16:08:32 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> PREGNANCY	Initial Entry

**3. Collection Date:**

Date	Location	User	Value	Reason
Aug-28-2020 16:08:32 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Aug/28/2020	Initial Entry

**4. Laboratory Name and Address (Derived)**

Date	Location	User	Value	Reason
Aug-28-2020 16:08:32 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> STUDY SITE	Initial Entry

**5. Specimen Type:**

Date	Location	User	Value	Reason
Aug-28-2020 16:08:32 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> URINE	Initial Entry

**6.a**

Date	Location	User	Value	Reason
Aug-28-2020 16:08:32 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> Sponsor-Defined 113 <b>Identifier:</b> <b>Test::</b> Choriogonadotropin Beta_PX113	Initial Entry

090177e196ae2e65\Final\Final On: 01-Apr-2021 03:12 (GMT)

**Header Text:** C4591001

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

**Form Version:** 21-Aug-2020 02:49

**Site No:** 1231

**Subject No:** 12314813

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

**Form:** LAB URINALYSIS - PREGNANCY TEST - 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

			<b>Result::</b> NEGATIVE	
			<b>Not Done::</b>	

**6.a Sponsor ID:**

Date	Location	User	Value	Reason
Aug-28-2020 16:08:32 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 113	Initial Entry

**6.a Test:**

Date	Location	User	Value	Reason
Aug-28-2020 16:08:32 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Choriogonadotropin Beta_PX113	Initial Entry

**6.a Result:**

Date	Location	User	Value	Reason
Aug-28-2020 16:08:32 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NEGATIVE	Initial Entry

090177e196ae2e65\Final\Final On: 01-Apr-2021 03:12 (GMT)

**Header Text:** C4591001

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

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

**Site No:** 1231

**Subject No:** 12314813

**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-28-2020 16:08:38 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Aug/28/2020	Initial Entry

**2. Randomization Number:**

Date	Location	User	Value	Reason
Aug-28-2020 16:08:38 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> 72154	Initial Entry

090177e196ae2e65\Final\Final On: 01-Apr-2021 03:12 (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: 12314813

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-28-2020 16:08:43 (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-28-2020 16:08:43 (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-29-2020 16:37:08 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Aug-28-2020 16:08:43 (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-28-2020 16:08:43 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES Date of Collection:  Aug/28/2020	Initial Entry

**5.a**

Date	Location	User	Value	Reason
Aug-29-2020 16:37:08 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	Alan Colombo (b) (4)	<b>Data Entry:</b> <b>Sample ID:</b> BJ4B3D	Initial Entry

**5.a Sample ID**

Date	Location	User	Value	Reason
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090177e196ae2e65\Final\Final On: 01-Apr-2021 03:12 (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: 12314813

Subject Initials: ---

Generated By: (b) (4)

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

Aug-29-2020 16:37:08 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	Alan Colombo (b) (4)	<b>Data Entry:</b> BJ4B3D	Initial Entry
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5.b

Date	Location	User	Value	Reason
Aug-29-2020 16:37:13 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	Alan Colombo (b) (4)	<b>Data Entry:</b> <b>Sample ID:</b> BJ4B3F	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Aug-29-2020 16:37:13 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	Alan Colombo (b) (4)	<b>Data Entry:</b> BJ4B3F	Initial Entry

5.c

Date	Location	User	Value	Reason
Aug-29-2020 16:37:17 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	Alan Colombo (b) (4)	<b>Data Entry:</b> <b>Sample ID:</b> BJ4B3G	Initial Entry

5.c Sample ID

Date	Location	User	Value	Reason
Aug-29-2020 16:37:17 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	Alan Colombo (b) (4)	<b>Data Entry:</b> BJ4B3G	Initial Entry

5.d

Date	Location	User	Value	Reason
Aug-30-2020 11:31:06 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	Maria del Pilar Pereyra (b) (4)	<b>Data Entry:</b> <b>Sample ID:</b> BPWVY9	Initial Entry

5.d Sample ID

Date	Location	User	Value	Reason
Aug-30-2020 11:31:06 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	Maria del Pilar Pereyra (b) (4)	<b>Data Entry:</b> BPWVY9	Initial Entry

090177e196ae2e65\Final\Final On: 01-Apr-2021 03:12 (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: 12314813

Subject Initials: ---

Generated By: (b) (4)

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

5.e

Date	Location	User	Value	Reason
Aug-30-2020 11:31:15 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	Maria del Pilar Pereyra (b) (4)	<b>Data Entry:</b> <b>Sample ID:</b> BPWVYB	Initial Entry

5.e Sample ID

Date	Location	User	Value	Reason
Aug-30-2020 11:31:15 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	Maria del Pilar Pereyra (b) (4)	<b>Data Entry:</b> BPWVYB	Initial Entry

5.f

Date	Location	User	Value	Reason
Aug-30-2020 11:31:29 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	Maria del Pilar Pereyra (b) (4)	<b>Data Entry:</b> <b>Sample ID:</b> BPWVYC	Initial Entry

5.f Sample ID

Date	Location	User	Value	Reason
Aug-30-2020 11:31:29 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	Maria del Pilar Pereyra (b) (4)	<b>Data Entry:</b> BPWVYC	Initial Entry

090177e196ae2e65\Final\Final On: 01-Apr-2021 03:12 (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: 12314813

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-28-2020 16:08:51 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SITE	Initial Entry

**2. Sample Type**

Date	Location	User	Value	Reason
Aug-28-2020 16:08:51 (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-30-2020 08:59:44 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Aug-28-2020 16:08:51 (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-28-2020 16:08:51 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES Date of Collection:  Aug/28/2020	Initial Entry

**5.a**

Date	Location	User	Value	Reason
Aug-30-2020 08:59:44 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sample ID: BPTDP5	Initial Entry

**5.a Sample ID**

Date	Location	User	Value	Reason
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090177e196ae2e65\Final\Final On: 01-Apr-2021 03:12 (GMT)

**Header Text:** C4591001

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

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

**Site No:** 1231

**Subject No:** 12314813

**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

Aug-30-2020 08:59:44 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BPTDP5	Initial Entry
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Header Text: C4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 22-Apr-2020 21:04

Site No: 1231

Subject No: 12314813

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-28-2020 16:09:02 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NO	Initial Entry

**2. Treatment Name**

Date	Location	User	Value	Reason
Aug-28-2020 16:09:02 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> BLINDED THERAPY	Initial Entry

**3. Formulation:**

Date	Location	User	Value	Reason
Aug-28-2020 16:09:02 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> INJECTION	Initial Entry

**4. Dose Date Time:**

Date	Location	User	Value	Reason
Aug-28-2020 16:09:02 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Aug/28/2020 13:40	Initial Entry

**5. Anatomical Location:**

Date	Location	User	Value	Reason
Aug-28-2020 16:09:02 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> DELTOID MUSCLE	Initial Entry

**6. Body Side:**

Date	Location	User	Value	Reason
Aug-28-2020 16:09:02 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> LEFT	Initial Entry

**7. Route:**

090177e196ae2e65\Final\Final On: 01-Apr-2021 03:12 (GMT)

**Header Text:** C4591001

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

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

**Site No:** 1231

**Subject No:** 12314813

**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
Aug-28-2020 16:09:02 (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-28-2020 16:09:02 (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-28-2020 16:09:02 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

090177e196ae2e65\Final\Final On: 01-Apr-2021 03:12 (GMT)

**Header Text:** C4591001

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

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

**Site No:** 1231

**Subject No:** 12314813

**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-28-2020 16:09:13 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO - REACTOGENICITY E-DIARY NOT COLLECTED FOR THIS SUBJECT	Initial Entry

**Header Text:** C4591001

**Visit:** V2\_VAX2\_L

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

**Site No:** 1231

**Subject No:** 12314813

**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 15:47:24 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sep/17/2020	Initial Entry

Header Text: C4591001

Visit: V2\_VAX2\_L

Form Version: 15-Sep-2020 21:54

Site No: 1231

Subject No: 12314813

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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**1. Date:**

Date	Location	User	Value	Reason
Sep-17-2020 15:47:45 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Sep/17/2020	Initial Entry

**2.a**

Date	Location	User	Value	Reason
Sep-17-2020 15:47:45 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> <b>Record Identifier::</b> 1 <b>Temperature:</b> 36.9 <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 15:47:45 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> 1	Initial Entry

**2.a Temperature:**

Date	Location	User	Value	Reason
Sep-17-2020 15:47:45 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> 36.9	Initial Entry

**2.a Unit:**

Date	Location	User	Value	Reason
Sep-17-2020 15:47:45 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> C	Initial Entry

**2.a Temperature Location:**

090177e196ae2e65\Final\Final On: 01-Apr-2021 03:12 (GMT)

**Header Text:** C4591001

**Visit:** V2\_VAX2\_L

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

**Site No:** 1231

**Subject No:** 12314813

**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 15:47:45 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> ORAL CAVITY	Initial Entry



Header Text: C4591001

Visit: V2\_VAX2\_L

Form Version: 21-Aug-2020 02:49

Site No: 1231

Subject No: 12314813

Generated By: (b) (4)

Form: LAB URINALYSIS - PREGNANCY TEST - 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. Lab Panel:**

Date	Location	User	Value	Reason
Sep-17-2020 15:47:54 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> URINALYSIS	Initial Entry

**2. Lab Sub-Panel:**

Date	Location	User	Value	Reason
Sep-17-2020 15:47:54 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> PREGNANCY	Initial Entry

**3. Collection Date:**

Date	Location	User	Value	Reason
Sep-17-2020 15:47:54 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sep/17/2020	Initial Entry

**4. Laboratory Name and Address (Derived)**

Date	Location	User	Value	Reason
Sep-17-2020 15:47:54 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> STUDY SITE	Initial Entry

**5. Specimen Type:**

Date	Location	User	Value	Reason
Sep-17-2020 15:47:54 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> URINE	Initial Entry

**6.a**

Date	Location	User	Value	Reason
Sep-17-2020 15:47:54 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> Sponsor-Defined 113 Identifier:	Initial Entry

090177e196ae2e65\Final\Final On: 01-Apr-2021 03:12 (GMT)

Header Text: C4591001

Visit: V2\_VAX2\_L

Form Version: 21-Aug-2020 02:49

Site No: 1231

Subject No: 12314813

Generated By: (b) (4)

Form: LAB URINALYSIS - PREGNANCY TEST - 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

			Test::	Choriogonadotropin Beta_PX113
			Result::	NEGATIVE
			Not Done::	

6.a Sponsor ID:

Date	Location	User	Value	Reason
Sep-17-2020 15:47:54 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> 113	Initial Entry

6.a Test:

Date	Location	User	Value	Reason
Sep-17-2020 15:47:54 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) [redacted] (4), [redacted] (b) [redacted] (6) [redacted]	<u>Data Entry:</u> Choriogonadotropin Beta_PX113	Initial Entry

6.a Result:

Date	Location	User	Value	Reason
Sep-17-2020 15:47:54 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) [redacted] (4), [redacted] (b) [redacted] (6) [redacted]	<u>Data Entry:</u> NEGATIVE	Initial Entry

090177e196ae2e65\Final\Final On: 01-Apr-2021 03:12 (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:** 12314813**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-17-2020 15:48:07 (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-17-2020 15:48:07 (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-17-2020 18:12:17 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Sep-17-2020 15:48:07 (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-17-2020 15:48:07 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES Date of Collection: Sep/17/2020	Initial Entry

**5.a**

Date	Location	User	Value	Reason
Sep-17-2020 18:12:17 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	Alan Colombo (b) (4)	<b>Data Entry:</b> Sample ID: BPWB2P	Initial Entry

**5.a Sample ID**

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:** 12314813

**Subject Initials:** ---

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

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

Sep-17-2020 18:12:17 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	Alan Colombo (b) (4)	<u>Data Entry:</u> BPWB2P	Initial Entry
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Header Text: C4591001

Visit: V2\_VAX2\_L

Form Version: 22-Apr-2020 21:04

Site No: 1231

Subject No: 12314813

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 15:48:23 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NO	Initial Entry

**2. Treatment Name**

Date	Location	User	Value	Reason
Sep-17-2020 15:48:23 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> BLINDED THERAPY	Initial Entry

**3. Formulation:**

Date	Location	User	Value	Reason
Sep-17-2020 15:48:23 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> INJECTION	Initial Entry

**4. Dose Date Time:**

Date	Location	User	Value	Reason
Sep-17-2020 15:48:23 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Sep/17/2020 14:20	Initial Entry

**5. Anatomical Location:**

Date	Location	User	Value	Reason
Sep-17-2020 15:48:23 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> DELTOID MUSCLE	Initial Entry

**6. Body Side:**

Date	Location	User	Value	Reason
Sep-17-2020 15:48:23 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> LEFT	Initial Entry

090177e196ae2e65\Final\Final On: 01-Apr-2021 03:12 (GMT)

**Header Text:** C4591001

**Visit:** V2\_VAX2\_L

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

**Site No:** 1231

**Subject No:** 12314813

**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

**7. Route:**

Date	Location	User	Value	Reason
Sep-17-2020 15:48:23 (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 15:48:23 (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
Sep-17-2020 15:48:23 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

090177e196ae2e65\Final\Final On: 01-Apr-2021 03:12 (GMT)

Header Text: C4591001

Visit: V3\_MONTH1\_POSTVAX2\_L

Form Version: 22-Apr-2020 21:02

Site No: 1231

Subject No: 12314813

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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*I. Date of Visit*

Date	Location	User	Value	Reason
Nov-12-2020 13:29:41 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Nov-12-2020 09:00:47 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	The visit was not carried out in the corresponding time for personal reasons of the volunteer.
Nov-12-2020 06:34:23 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000.InFormAdapter.Discrepancy	PFE SDQ PROD (b) (4)	Query 1: Opened	PDQ: Date of visit at V3_MONTH1_POSTVAX2_L is out of window for 20 days from V2_VAX2_L DOV or V2 Vaccination date. Please verify and update. Else, confirm in query response appropriately. (b) (4),
Nov-11-2020 17:58:07 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry</b> : Nov/11/2020	Initial Entry

090177e196ae2e65\Final\Final On: 01-Apr-2021 03:12 (GMT)

**Header Text:** C4591001**Visit:** V3\_MONTH1\_POSTVAX2\_L**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - eCRF  
Audit Trail History**Form Version:** 22-Apr-2020 21:03**Form Status:** Data Complete, Locked, Frozen, Verified**Site No:** 1231**Site Name:** (1231) Hospital Militar Central Cirujano Mayor Dr. Cosme Argerich**Subject No:** 12314813**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
Nov-11-2020 17:58:16 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SITE	Initial Entry

**2. Sample Type**

Date	Location	User	Value	Reason
Nov-11-2020 17:58:16 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SERUM	Initial Entry

**3. Sample Collected?**

Date	Location	User	Value	Reason
Nov-11-2020 19:10:10 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Nov-11-2020 17:58:16 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Nov-11-2020 17:58:16 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES Date of Collection:  Nov/11/2020	Initial Entry

**5.a**

Date	Location	User	Value	Reason
Nov-11-2020 19:10:10 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	Alan Colombo (b) (4)	<b>Data Entry:</b> <b>Sample ID:</b> BJ4DT5	Initial Entry

**5.a Sample ID**

Date	Location	User	Value	Reason
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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: 12314813

Subject Initials: ---

Generated By: (b) (4)

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

Nov-11-2020 19:10:10 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	Alan Colombo (b) (4)	<b>Data Entry:</b> BJ4DT5	Initial Entry
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5.b

Date	Location	User	Value	Reason
Nov-12-2020 11:08:17 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample ID:</b> BJ4DW3	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Nov-12-2020 11:08:17 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BJ4DW3	Initial Entry

5.c

Date	Location	User	Value	Reason
Nov-12-2020 12:05:07 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample ID:</b> BP1P68	Initial Entry

5.c Sample ID

Date	Location	User	Value	Reason
Nov-12-2020 12:05:07 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BP1P68	Initial Entry

090177e196ae2e65\Final\Final On: 01-Apr-2021 03:12 (GMT)

**Header Text:** C4591001

**Visit:** End of Treatment - Unscheduled

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

**Site No:** 1231

**Subject No:** 12314813

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

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

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

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

**Subject Initials:** ---

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

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

Date	Location	User	Value	Reason
Nov-11-2020 17:58:38 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Nov/11/2020	Initial Entry

**2. Phase of Disposition:**

Date	Location	User	Value	Reason
Nov-11-2020 17:58:38 (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
Nov-11-2020 17:58:38 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> COMPLETED	Initial Entry

090177e196ae2e65\Final\Final On: 01-Apr-2021 03:12 (GMT)

**Header Text:** C4591001

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

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

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

**Site No:** 1231

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

**Subject No:** 12314813

**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
Jan-19-2021 12:30:17 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	Martina Davalli (b) (4)	<b>Data Entry:</b> Jan/18/2021	Initial Entry

**Header Text:** C4591001

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

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

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

**Site No:** 1231

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

**Subject No:** 12314813

**Subject Initials:** ---

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

**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
Jan-19-2021 12:30:35 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Jan-19-2021 12:30:26 (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.
Jan-19-2021 12:30:26 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	Martina Davalli (b) (4)	<b>Data Entry:</b> Participant is willing to return for Vaccination 3 Participant is:  eligible per local/national recommendations and confirmed to have received only placebo at Vaccination 1/2	Initial Entry

090177e196ae2e65\Final\Final On: 01-Apr-2021 03:12 (GMT)

**Header Text:** C4591001

**Visit:** V101\_VAX3

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

**Site No:** 1231

**Subject No:** 12314813

**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
Jan-28-2021 15:46:57 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Jan/28/2021	Initial Entry

**Header Text:** C4591001

**Visit:** V101\_VAX3

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

**Site No:** 1231

**Subject No:** 12314813

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

**Form:** INFORMED CONSENT - FURTHER 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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**I. Consent Was:**

Date	Location	User	Value	Reason
Jan-28-2021 15:47:08 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> OBTAINED Date Written Consent Obtained  Jan/28/2021	Initial Entry

**Header Text:** C4591001

**Visit:** V101\_VAX3

**Form:** DISPOSITION - SCREENING FOR FURTHER VACCINATION - eCRF Audit Trail History

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

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

**Site No:** 1231

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

**Subject No:** 12314813

**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
Jan-28-2021 15:49:04 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Jan/28/2021	Initial Entry

**2. Phase of Disposition:**

Date	Location	User	Value	Reason
Jan-28-2021 15:49:04 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> REPEAT SCREENING 1	Initial Entry

**3. Status:**

Date	Location	User	Value	Reason
Jan-28-2021 15:49:04 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> COMPLETED	Initial Entry

090177e196ae2e65\Final\Final On: 01-Apr-2021 03:12 (GMT)

Header Text: C4591001

Visit: V101\_VAX3

Form Version: 14-Jan-2021 02:21

Site No: 1231

Subject No: 12314813

Generated By: (b) (4)

Form: LAB URINALYSIS - PREGNANCY TEST - 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. Lab Panel:**

Date	Location	User	Value	Reason
Jan-28-2021 15:49:21 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> URINALYSIS	Initial Entry

**2. Lab Sub-Panel:**

Date	Location	User	Value	Reason
Jan-28-2021 15:49:21 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> PREGNANCY	Initial Entry

**3. Collection Date:**

Date	Location	User	Value	Reason
Jan-28-2021 15:49:21 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Jan/28/2021	Initial Entry

**4. Laboratory Name and Address (Derived)**

Date	Location	User	Value	Reason
Jan-28-2021 15:49:21 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> STUDY SITE	Initial Entry

**5. Specimen Type:**

Date	Location	User	Value	Reason
Jan-28-2021 15:49:21 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> URINE	Initial Entry

**6.a**

Date	Location	User	Value	Reason
Jan-28-2021 15:49:21 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> Sponsor-Defined 113 Identifier: Test:: Choriogonadotropin Beta_PX113	Initial Entry

090177e196ae2e65\Final\Final On: 01-Apr-2021 03:12 (GMT)



Header Text: C4591001

Visit: V101\_VAX3

Form Version: 14-Jan-2021 02:21

Site No: 1231

Subject No: 12314813

Generated By: (b) (4)

Form: LAB URINALYSIS - PREGNANCY TEST - 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

			<b>Result::</b> NEGATIVE	
			<b>Not Done::</b>	

**6.a Sponsor ID:**

Date	Location	User	Value	Reason
Jan-28-2021 15:49:21 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 113	Initial Entry

**6.a Test:**

Date	Location	User	Value	Reason
Jan-28-2021 15:49:21 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) [redacted] (4), [redacted] (b) (6) [redacted]	<b>Data Entry:</b> Choriogonadotropin Beta_PX113	Initial Entry

**6.a Result:**

Date	Location	User	Value	Reason
Jan-28-2021 15:49:21 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) [redacted] (4), [redacted] (b) (6) [redacted]	<b>Data Entry:</b> NEGATIVE	Initial Entry

090177e196ae2e65\Final\Final On: 01-Apr-2021 03:12 (GMT)

Header Text: C4591001

Visit: V101\_VAX3

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: 12314813

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
Jan-28-2021 15:49:42 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> SITE	Initial Entry

**2. Sample Type**

Date	Location	User	Value	Reason
Jan-28-2021 15:49:42 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> SERUM	Initial Entry

**3. Sample Collected?**

Date	Location	User	Value	Reason
Jan-29-2021 09:47:16 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Jan-29-2021 05:15:15 (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.
Jan-28-2021 15:49:42 (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.
Jan-28-2021 15:49:42 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> YES Date of Collection:  Jan/28/2021	Initial Entry

**5.a**

Date	Location	User	Value	Reason
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090177e196ae2e65\Final\Final On: 01-Apr-2021 03:12 (GMT)

Header Text: C4591001

Visit: V101\_VAX3

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: 12314813

Subject Initials: ---

Generated By: (b) (4)

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

Jan-29-2021 09:47:16 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample ID:</b> BS4218	Initial Entry
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5.a Sample ID

Date	Location	User	Value	Reason
Jan-29-2021 09:47:16 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BS4218	Initial Entry

5.b

Date	Location	User	Value	Reason
Jan-29-2021 09:47:25 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample ID:</b> BS4219	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Jan-29-2021 09:47:25 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BS4219	Initial Entry

5.c

Date	Location	User	Value	Reason
Jan-29-2021 13:07:40 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample ID:</b> BPWFHC	Initial Entry

5.c Sample ID

Date	Location	User	Value	Reason
Jan-29-2021 13:07:40 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BPWFHC	Initial Entry

5.d

Date	Location	User	Value	Reason
Jan-29-2021 13:48:48 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample ID:</b> BRYWHV	Initial Entry

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**Header Text:** C4591001

**Visit:** V101\_VAX3

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

**Site No:** 1231

**Subject No:** 12314813

**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

**5.d Sample ID**

Date	Location	User	Value	Reason
Jan-29-2021 13:48:48 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BRYWHV	Initial Entry

Header Text: C4591001

Visit: V101\_VAX3

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: 12314813

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
Jan-28-2021 15:50:14 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> SITE	Initial Entry

**2. Sample Type**

Date	Location	User	Value	Reason
Jan-28-2021 15:50:14 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> NASAL_SWAB	Initial Entry

**3. Sample Collected?**

Date	Location	User	Value	Reason
Jan-29-2021 11:37:15 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Jan-29-2021 05:15:15 (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.
Jan-28-2021 15:50:14 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Jan-28-2021 15:50:14 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> YES Date of Collection:  Jan/28/2021	Initial Entry

**5.a**

Date	Location	User	Value	Reason
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090177e196ae2e65\Final\Final On: 01-Apr-2021 03:12 (GMT)

**Header Text:** C4591001

**Visit:** V101\_VAX3

**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:** 12314813

**Subject Initials:** ---

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

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

Jan-29-2021 11:37:15 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample ID:</b> BPWFPM	Initial Entry
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**5.a Sample ID**

Date	Location	User	Value	Reason
Jan-29-2021 11:37:15 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BPWFPM	Initial Entry

Header Text: C4591001

Visit: V101\_VAX3

Form Version: 10-Dec-2020 02:26

Site No: 1231

Subject No: 12314813

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
Jan-28-2021 15:55:46 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NO	Initial Entry

**2. Treatment Name**

Date	Location	User	Value	Reason
Jan-28-2021 15:55:46 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> BNT162b2	Initial Entry

**3. Formulation:**

Date	Location	User	Value	Reason
Jan-28-2021 15:55:46 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> INJECTION	Initial Entry

**4. Dose Date Time:**

Date	Location	User	Value	Reason
Jan-28-2021 15:55:46 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Jan/28/2021 15:10	Initial Entry

**5. Anatomical Location:**

Date	Location	User	Value	Reason
Jan-28-2021 15:55:46 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> DELTOID MUSCLE	Initial Entry

**6. Body Side:**

Date	Location	User	Value	Reason
Jan-28-2021 15:55:46 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> LEFT	Initial Entry

**7. Route:**

090177e196ae2e65\Final\Final On: 01-Apr-2021 03:12 (GMT)

Header Text: C4591001

Visit: V101\_VAX3

Form Version: 10-Dec-2020 02:26

Site No: 1231

Subject No: 12314813

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
Jan-28-2021 15:55:46 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> INTRAMUSCULAR	Initial Entry

**8. Actual Dose:**

Date	Location	User	Value	Reason
Jan-28-2021 15:55:46 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> 30.0	Initial Entry

**9. Unit:**

Date	Location	User	Value	Reason
Jan-28-2021 15:55:46 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> ug	Initial Entry

**10. Timeframe Subject Was Observed**

Date	Location	User	Value	Reason
Jan-28-2021 15:55:46 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> 30 MINUTES	Initial Entry

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

Date	Location	User	Value	Reason
Jan-28-2021 15:55:46 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> YES	Initial Entry

090177e196ae2e65\Final\Final On: 01-Apr-2021 03:12 (GMT)



**Header Text:** C4591001

**Visit:** V102\_VAX4

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

**Site No:** 1231

**Subject No:** 12314813

**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-17-2021 15:38:46 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	Martina Davalli (b) (4)	<b>Data Entry:</b> Feb/17/2021	Initial Entry

Header Text: C4591001

Visit: V102\_VAX4

Form Version: 14-Jan-2021 02:21

Site No: 1231

Subject No: 12314813

Generated By: (b) (4)

Form: LAB URINALYSIS - PREGNANCY TEST - 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. Lab Panel:**

Date	Location	User	Value	Reason
Feb-17-2021 15:39:14 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> URINALYSIS	Initial Entry

**2. Lab Sub-Panel:**

Date	Location	User	Value	Reason
Feb-17-2021 15:39:14 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> PREGNANCY	Initial Entry

**3. Collection Date:**

Date	Location	User	Value	Reason
Feb-17-2021 15:39:14 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	Martina Davalli (b) (4)	<b>Data Entry:</b> Feb/17/2021	Initial Entry

**4. Laboratory Name and Address (Derived)**

Date	Location	User	Value	Reason
Feb-17-2021 15:39:14 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> STUDY SITE	Initial Entry

**5. Specimen Type:**

Date	Location	User	Value	Reason
Feb-17-2021 15:39:14 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> URINE	Initial Entry

**6.a**

Date	Location	User	Value	Reason
Feb-17-2021 15:39:14 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> Sponsor-Defined 113 <b>Identifier:</b> <b>Test::</b> Choriogonadotropin Beta_PX113	Initial Entry

090177e196ae2e65\Final\Final On: 01-Apr-2021 03:12 (GMT)

**Header Text:** C4591001

**Visit:** V102\_VAX4

**Form Version:** 14-Jan-2021 02:21

**Site No:** 1231

**Subject No:** 12314813

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

**Form:** LAB URINALYSIS - PREGNANCY TEST - 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

			<b>Result::</b> NEGATIVE	
			<b>Not Done::</b>	

**6.a Sponsor ID:**

Date	Location	User	Value	Reason
Feb-17-2021 15:39:14 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 113	Initial Entry

**6.a Test:**

Date	Location	User	Value	Reason
Feb-17-2021 15:39:14 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	Martina Davalli (b) (4)	<b>Data Entry:</b> Choriogonadotropin Beta_PX113	Initial Entry

**6.a Result:**

Date	Location	User	Value	Reason
Feb-17-2021 15:39:14 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	Martina Davalli (b) (4)	<b>Data Entry:</b> NEGATIVE	Initial Entry

090177e196ae2e65\Final\Final On: 01-Apr-2021 03:12 (GMT)

Header Text: C4591001

Visit: V102\_VAX4

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: 12314813

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
Feb-17-2021 15:39:24 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SITE	Initial Entry

**2. Sample Type**

Date	Location	User	Value	Reason
Feb-17-2021 15:39:24 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> NASAL_SWAB	Initial Entry

**3. Sample Collected?**

Date	Location	User	Value	Reason
Feb-18-2021 09:58:13 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Feb-18-2021 09:47:27 (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.
Feb-17-2021 15:39:24 (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-17-2021 15:39:24 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	Martina Davalli (b) (4)	<b>Data Entry:</b> YES Date of Collection:  Feb/17/2021	Initial Entry

**5.a**

Date	Location	User	Value	Reason
Feb-18-2021 09:58:13 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample ID:</b> BR286W	Initial Entry

090177e196ae2e65\Final\Final On: 01-Apr-2021 03:12 (GMT)

**Header Text:** C4591001

**Visit:** V102\_VAX4

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

**Site No:** 1231

**Subject No:** 12314813

**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

*5.a Sample ID*

Date	Location	User	Value	Reason
Feb-18-2021 09:58:13 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> BR286W	Initial Entry

Header Text: C4591001

Visit: V102\_VAX4

Form Version: 10-Dec-2020 02:26

Site No: 1231

Subject No: 12314813

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
Feb-17-2021 15:39:52 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	Martina Davalli (b) (4)	<u>Data Entry:</u> NO	Initial Entry

**2. Treatment Name**

Date	Location	User	Value	Reason
Feb-17-2021 15:39:52 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> BNT162b2	Initial Entry

**3. Formulation:**

Date	Location	User	Value	Reason
Feb-17-2021 15:39:52 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> INJECTION	Initial Entry

**4. Dose Date Time:**

Date	Location	User	Value	Reason
Feb-17-2021 15:39:52 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	Martina Davalli (b) (4)	<u>Data Entry:</u> Feb/17/2021 14:03	Initial Entry

**5. Anatomical Location:**

Date	Location	User	Value	Reason
Feb-17-2021 15:39:52 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> DELTOID MUSCLE	Initial Entry

**6. Body Side:**

Date	Location	User	Value	Reason
Feb-17-2021 15:39:52 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	Martina Davalli (b) (4)	<u>Data Entry:</u> LEFT	Initial Entry

**7. Route:**

090177e196ae2e65\Final\Final On: 01-Apr-2021 03:12 (GMT)

Header Text: C4591001

Visit: V102\_VAX4

Form Version: 10-Dec-2020 02:26

Site No: 1231

Subject No: 12314813

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
Feb-17-2021 15:39:52 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> INTRAMUSCULAR	Initial Entry

**8. Actual Dose:**

Date	Location	User	Value	Reason
Feb-17-2021 15:39:52 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> 30.0	Initial Entry

**9. Unit:**

Date	Location	User	Value	Reason
Feb-17-2021 15:39:52 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> ug	Initial Entry

**10. Timeframe Subject Was Observed**

Date	Location	User	Value	Reason
Feb-17-2021 15:39:52 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> 30 MINUTES	Initial Entry

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

Date	Location	User	Value	Reason
Feb-17-2021 15:39:52 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	Martina Davalli (b) (4)	<u>Data Entry:</u> YES	Initial Entry

090177e196ae2e65\Final\Final On: 01-Apr-2021 03:12 (GMT)

**Header Text:** C4591001

**Visit:** V103\_MONTH1

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

**Site No:** 1231

**Subject No:** 12314813

**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
Mar-18-2021 10:48:59 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Mar/18/2021	Initial Entry



**Header Text:** C4591001

**Visit:** V103\_MONTH1

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

**Site No:** 1231

**Subject No:** 12314813

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

**Form:** CONTACT OUTCOME - 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. Contact Type:**

Date	Location	User	Value	Reason
Mar-18-2021 10:49:10 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> TELEPHONE VISIT	Initial Entry

**2. Was contact made?**

Date	Location	User	Value	Reason
Mar-18-2021 10:49:10 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES Date of Contact:  Mar/18/2021	Initial Entry

090177e196ae2e65\Final\Final On: 01-Apr-2021 03:12 (GMT)

**Header Text:** C4591001

**Visit:** FURTHER\_VACCINATION\_EOT -  
Unscheduled

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

**Form Version:** 20-Feb-2021 02:26

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

**Site No:** 1231

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

**Subject No:** 12314813

**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
Mar-18-2021 12:51:50 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Mar/18/2021	Initial Entry

**2. Phase of Disposition:**

Date	Location	User	Value	Reason
Mar-18-2021 12:51:50 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> OPEN LABEL TREATMENT	Initial Entry

**3. Status:**

Date	Location	User	Value	Reason
Mar-18-2021 12:51:50 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> COMPLETED	Initial Entry

090177e196ae2e65\Final\Final On: 01-Apr-2021 03:12 (GMT)

**Header Text:** C4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1231

**Subject No:** 12314813

**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
Nov-11-2020 16:11:28 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	Martina Davalli (b) (4)	Form Created	

**Header Text:** C4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1231

**Subject No:** 12314813

**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
Jan-02-2021 10:33:38 (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: 12314813

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen

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

Subject Initials: ---

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

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**1. Category:**

Date	Location	User	Value	Reason
Nov-11-2020 16:11:28 (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
Nov-11-2020 16:11:28 (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
Nov-11-2020 16:11:28 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	Martina Davalli (b) (4)	<b>Data Entry:</b> Low back pain	Initial Entry

**4. Start Date Time:**

Date	Location	User	Value	Reason
Nov-11-2020 16:11:28 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	Martina Davalli (b) (4)	<b>Data Entry:</b> Sep/21/2020 09:00	Initial Entry

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

Date	Location	User	Value	Reason
Nov-11-2020 16:11:28 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	Martina Davalli (b) (4)	<b>Data Entry:</b> NO End Date Time: Oct/12/2020 09:00	Initial Entry

**6. Toxicity Grade:**

Date	Location	User	Value	Reason
Nov-11-2020 16:11:28 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	Martina Davalli (b) (4)	<b>Data Entry:</b> 2	Initial Entry

090177e196ae2e65\Final\Final On: 01-Apr-2021 03:12 (GMT)

Header Text: C4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1231

Subject No: 12314813

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen

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

Subject Initials: ---

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

7. Is the adverse event serious?

If Yes, NOTIFY PFIZER IMMEDIATELY.

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

Date	Location	User	Value	Reason
Nov-11-2020 16:11:28 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	Martina Davalli (b) (4)	<u>Data Entry:</u> 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
Nov-11-2020 16:11:28 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	Martina Davalli (b) (4)	<u>Data Entry:</u> NO	Initial Entry

9. Is this event related to study treatment:

Date	Location	User	Value	Reason
Nov-11-2020 16:11:28 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	Martina Davalli (b) (4)	<u>Data Entry:</u> NOT RELATED If Not Related to study treatment(s), this event is due to:  OTHER  If Other, specify:  disc extrusion at S1 and bulge at L4-L5	Initial Entry

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Nov-11-2020 16:11:28 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	Martina Davalli (b) (4)	<u>Data Entry:</u> NOT APPLICABLE	Initial Entry

11. Was a Concomitant Medication given?

Date	Location	User	Value	Reason
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090177e196ae2e65\Final\Final On: 01-Apr-2021 03:12 (GMT)

**Header Text:** C4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1231

**Subject No:** 12314813

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

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

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

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

**Subject Initials:** ---

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

Nov-11-2020 16:11:28 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	Martina Davalli (b) (4)	<b>Data Entry:</b> YES	Initial Entry
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**12. Was a Non-Drug Treatment given?**

Date	Location	User	Value	Reason
Nov-11-2020 16:11:28 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	Martina Davalli (b) (4)	<b>Data Entry:</b> YES	Initial Entry

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

Date	Location	User	Value	Reason
Nov-11-2020 16:11:28 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	Martina Davalli (b) (4)	<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
Nov-11-2020 16:11:28 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	Martina Davalli (b) (4)	<b>Data Entry:</b> NO	Initial Entry

090177e196ae2e65\Final\Final On: 01-Apr-2021 03:12 (GMT)

Header Text: C4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1231

Subject No: 12314813

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen

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

Subject Initials: ---

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

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**1. Category:**

Date	Location	User	Value	Reason
Jan-02-2021 10:33:38 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> ADVERSE EVENT	Initial Entry

**2. AE ID:**

Date	Location	User	Value	Reason
Jan-02-2021 10:33:38 (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
Jan-26-2021 01:01:32 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Jan-15-2021 17:36:40 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	A follow-up form for the serious adverse event is sent to the sponsor, clarifying that the date of knowledge of the SAE is DEC 22, 2020.
Jan-13-2021 10:47:33 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reissued:Opened	CLINICAL Thank you; however most recent SAE update (10Jan21) did not include any medications (other than VAX2) in the Product Information section of SAE report.
Jan-11-2021 10:07:39 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	SAE safety report was sent with this information.
Jan-08-2021 11:52:41 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	Clinical Please submit a SAE safety report reporting the subjects

090177e196ae2e65\Final\Final On: 01-Apr-2021 03:12 (GMT)



Header Text: C4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1231

Subject No: 12314813

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen

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

Subject Initials: ---

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

				medications at time of hosp admission in Meds section (text has tramadol, acetaminophen, pregabalin)
Jan-02-2021 10:33:38 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Worsening of herniated disc	Initial Entry

4. Start Date Time:

Date	Location	User	Value	Reason
Jan-02-2021 10:33:38 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sep/21/2020 09:00	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Jan-06-2021 11:08:47 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO End Date Time: Jan/5/2021 17:00	New Information
Jan-02-2021 10:33:38 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

6. Toxicity Grade:

Date	Location	User	Value	Reason
Jan-12-2021 17:26:50 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	Samuel Dychter (b) (4)	Query 1: Closed	Response satisfies query
Jan-08-2021 12:14:50 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Changed Information
Jan-08-2021 12:14:50 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	Martina Davalli (b) (4)	<b>Data Entry:</b> 3	Changed Information
Jan-06-2021 21:55:57 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	Samuel Dychter (b) (4)	Query 1: Opened	GPD Clin: Please confirm Grade 4 for this event.

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Header Text: C4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1231

Subject No: 12314813

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen

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

Subject Initials: ---

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

Jan-02-2021 10:33:38 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> 4	Initial Entry
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7. Is the adverse event serious?

If Yes, NOTIFY PFIZER IMMEDIATELY.

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

Date	Location	User	Value	Reason
Jan-05-2021 08:43:58 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Jan-02-2021 10:33:38 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	For AE Worsening of herniated disc: Response to "Is the adverse event serious?" is 'Yes' but "Serious Adverse Event Number" is blank.
Jan-02-2021 10:33:38 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> 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?	Initial Entry

090177e196ae2e65\Final\Final On: 01-Apr-2021 03:12 (GMT)

Header Text: C4591001

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Site No: 1231

Subject No: 12314813

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen

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

Subject Initials: ---

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

			NO	
			Other medically important serious event	
			YES	

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

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

Date	Location	User	Value	Reason
Jan-02-2021 10:33:38 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NO	Initial Entry

9. Is this event related to study treatment:

Date	Location	User	Value	Reason
Jan-02-2021 10:33:38 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NOT RELATED If Not Related to study treatment(s), this event is due to:  OTHER  If Other, specify:  history of herniated disc	Initial Entry

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Jan-02-2021 10:33:38 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NOT APPLICABLE	Initial Entry

11. Was a Concomitant Medication given?

Date	Location	User	Value	Reason
Jan-02-2021 10:33:38 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> YES	Initial Entry

12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
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090177e196ae2e65\Final\Final On: 01-Apr-2021 03:12 (GMT)

Header Text: C4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1231

Subject No: 12314813

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen

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

Subject Initials: ---

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

Jan-02-2021 10:33:38 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry
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13. What was the outcome of this adverse event?:

Date	Location	User	Value	Reason
Jan-06-2021 11:08:59 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Jan-06-2021 11:08:59 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> RECOVERED/RESOLVED	New Information
Jan-06-2021 11:08:47 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	For AE Worsening of herniated disc: Response to "What was the outcome of this adverse event?" is 'Recovering/Resolving' but AE End Date/Time is present.
Jan-02-2021 10:33:38 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> RECOVERING/RESOLVING	Initial Entry

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

Date	Location	User	Value	Reason
Jan-02-2021 10:33:38 (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
Jan-05-2021 08:43:58 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 2020512052	Initial Entry

090177e196ae2e65\Final\Final On: 01-Apr-2021 03:12 (GMT)

**Header Text:** C4591001

**Visit:** Disposition - Unscheduled

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

**Site No:** 1231

**Subject No:** 12314813

**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
Jan-19-2021 12:30:35 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	Martina Davalli (b) (4)	<b>Data Entry:</b> Jan/18/2021	Initial Entry

**2. Primary Reason for Unblinding:**

Date	Location	User	Value	Reason
Jan-19-2021 12:30:35 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	Martina Davalli (b) (4)	<b>Data Entry:</b> ASSESS ELIGIBILITY FOR ADDITIONAL VACCINATION	Initial Entry

090177e196ae2e65\Final\Final On: 01-Apr-2021 03:12 (GMT)

Header Text: C4591001

Visit: Subject Status - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1231

Subject No: 12314813

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
Nov-11-2020 17:58:38 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> FOLLOW-UP	Initial Entry
Aug-28-2020 16:08:38 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> ENROLLED/RANDOMIZED	Initial Entry
Aug-28-2020 16:07:56 (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
Jan-05-2021 08:42:35 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Jan-04-2021 16:30:31 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	SAE was loaded in AE CRF.
Jan-02-2021 07:36:14 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	SAE RECON:AER#2020512052 Disc herniation worsening(onset date:21Sep2020)was reported as serious in Safety database but missing in AE CRF. Please confirm and update CRF. If safety update is required, submit a follow-up SAE Form.
Nov-11-2020 17:58:38 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> Nov/11/2020	Initial Entry
Aug-28-2020 16:08:38 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> Aug/28/2020	Initial Entry
Aug-28-2020 16:07:56 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> Aug/28/2020	Initial Entry

090177e196ae2e65\Final\Final On: 01-Apr-2021 03:12 (GMT)

**Header Text:** C4591001

**Visit:** Subject Status - Unscheduled

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

**Site No:** 1231

**Subject No:** 12314813

**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

Buenos Aires

090177e196ae2e65\Final\Final On: 01-Apr-2021 03:12 (GMT)

**Header Text:** C4591001

**Visit:** Investigator Signature - Unscheduled

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

**Site No:** 1231

**Subject No:** 12314813

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

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

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

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

**Subject Initials:** ---

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

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*I. Casebook Signature*

Date	Location	User	Value	Reason
Nov-06-2020 14:36:39 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Click Here to Enable	Initial Entry