

**Header Text:** c4591001

**Visit:** COHORT\_SELECTION

**Form:** COHORT SELECTION

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

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

**Site No:** 1231

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

**Subject No:** 12314894

**Subject Initials:** ---

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

**Generated Time (GMT):** 19-Apr-2021 21:04

[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

090177e196d6f285\Final\Final On: 22-Apr-2021 02:12 (GMT)

**Header Text:** c4591001

**Visit:** COHORT\_SELECTION

**Form:** MAIN INFORMED CONSENT

**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:** 12314894

**Subject Initials:** ---

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

**Generated Time (GMT):** 19-Apr-2021 21:04

[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:** DEMOGRAPHY

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

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

**Site No:** 1231

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

**Subject No:** 12314894

**Subject Initials:** ---

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

**Generated Time (GMT):** 19-Apr-2021 21:04

[eCRF Audit Trail History](#)

**Demography**

1.	Subject ID	[12314894]
2.	Birth Date:	(b) (6) /1994
3.	Sex:	FEMALE
4.	Ethnicity:	HISPANIC OR LATINO(A) OR OF SPANISH ORIGIN
5.	Race: (Check X all that apply):	WHITE
6.	Racial Designation:	

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**Header Text:** c4591001

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

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

**Site No:** 1231

**Subject No:** 12314894

**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):** 19-Apr-2021 21:04

[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:** 12314894

**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):** 19-Apr-2021 21:04

**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 _____
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**Header Text:** c4591001

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

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

**Site No:** 1231

**Subject No:** 12314894

**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):** 19-Apr-2021 21:04

[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:** 12314894

**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):** 19-Apr-2021 21:04

[eCRF Audit Trail History](#)

**Medical History Details**

1.a	Line/MH Number:	[1]
	Disease/Syndrome /Surgery/Non-Drug Allergies/Drug Allergies:	[Pneumonia]
	Start Date:	Jun/1/2005
	Ongoing:	NO End Date: Jun/15/2005
1.b	Line/MH Number:	[2]
	Disease/Syndrome /Surgery/Non-Drug Allergies/Drug Allergies:	[Bronchial asthma]
	Start Date:	May/1/2005
	Ongoing:	NO End Date: Jun/1/2006

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**Header Text:** c4591001

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

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

**Site No:** 1231

**Subject No:** 12314894

**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):** 19-Apr-2021 21:04

[eCRF Audit Trail History](#)

**Vital Signs**

1.	Date:	Aug/28/2020
2.	Weight:	[78.9]
3.	Unit:	kg
4.	Height:	[167.0]
5.	Unit:	cm
6.	Body Mass Index:	[28.3]

**Vital Signs Details**

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



**Header Text:** c4591001

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

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

**Site No:** 1231

**Subject No:** 12314894

**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):** 19-Apr-2021 21:04

[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:** 12314894

**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):** 19-Apr-2021 21:04

[eCRF Audit Trail History](#)

**Disposition**

1.	Randomization Date :	Aug/28/2020
2.	Randomization Number:	[72865]
3.	Randomization Group:	[ ]

**Header Text:** c4591001

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

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

**Site No:** 1231

**Subject No:** 12314894

**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):** 19-Apr-2021 21:04

[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	[BPWW4P]
5.b	Sample ID	[BPWW4R]
5.c	Sample ID	[BPWW4S]
5.d	Sample ID	[BJ4B8D]
5.e	Sample ID	[BJ4B8F]

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**Header Text:** c4591001**Visit:** V1\_DAY1\_VAX1\_L**Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB**Form Version:** 22-Apr-2020 21:03**Form Status:** Data Complete, Locked, Frozen, Verified**Site No:** 1231**Site Name:** (1231) Hospital Militar Central Cirujano Mayor Dr. Cosme Argerich**Subject No:** 12314894**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 19-Apr-2021 21:04[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	[BPTDSS]
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**Header Text:** c4591001

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

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

**Site No:** 1231

**Subject No:** 12314894

**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):** 19-Apr-2021 21:04

[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 17:15
5.	Anatomical Location:	DELTOID MUSCLE
6.	Body Side:	RIGHT
7.	Route:	INTRAMUSCULAR
8.	Actual Dose:	[ ]
9.	Unit:	
10.	Timeframe Subject Was Observed	THE PROTOCOL SPECIFIED OBSERVATION PERIOD
11.	Was the subject observed for at least the protocol specified observation period after investigational product administration?	YES

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**Header Text:** c4591001

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

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

**Site No:** 1231

**Subject No:** 12314894

**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):** 19-Apr-2021 21:04

[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:** 12314894

**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):** 19-Apr-2021 21:04

[eCRF Audit Trail History](#)

**Date of Visit**

1.	Date of Visit	Sep/16/2020
2.	Erroneous Visit	

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

**Site No:** 1231

**Subject No:** 12314894

**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):** 19-Apr-2021 21:04

[eCRF Audit Trail History](#)

**Vital Signs**

1.	Date:	Sep/16/2020
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**Vital Signs Details**

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

090177e196d6f285\Final\Final On: 22-Apr-2021 02:12 (GMT)



**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

**Site No:** 1231

**Subject No:** 12314894

**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):** 19-Apr-2021 21:04

[eCRF Audit Trail History](#)

**Lab Urinalysis**

1.	Lab Panel:	URINALYSIS
2.	Lab Sub-Panel:	PREGNANCY
3.	Collection Date:	Sep/16/2020
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:	

090177e196d6f285\Final\Final On: 22-Apr-2021 02:12 (GMT)

**Header Text:** c4591001**Visit:** V2\_VAX2\_L**Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB**Form Version:** 22-Apr-2020 21:03**Form Status:** Data Complete, Locked, Frozen, Verified**Site No:** 1231**Site Name:** (1231) Hospital Militar Central Cirujano Mayor Dr. Cosme Argerich**Subject No:** 12314894**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 19-Apr-2021 21:04[eCRF Audit Trail History](#)**Electronic Sample Tracking**

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB
3.	Sample Collected?	YES Date of Collection: Sep/16/2020
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	[BP2BLF]
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**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

**Site No:** 1231

**Subject No:** 12314894

**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):** 19-Apr-2021 21:04

[eCRF Audit Trail History](#)

**Vaccination**

1.	Was there a temporary delay of vaccination?	NO
2.	Treatment Name	[BLINDED THERAPY]
3.	Formulation:	INJECTION
4.	Dose Date Time:	Sep/16/2020 18:55
5.	Anatomical Location:	DELTOID MUSCLE
6.	Body Side:	RIGHT
7.	Route:	INTRAMUSCULAR
8.	Actual Dose:	[ ]
9.	Unit:	
10.	Timeframe Subject Was Observed	THE PROTOCOL SPECIFIED OBSERVATION PERIOD
11.	Was the subject observed for at least the protocol specified observation period after investigational product administration?	YES

090177e196d6f285\Final\Final On: 22-Apr-2021 02:12 (GMT)

**Header Text:** c4591001

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

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

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

**Subject No:** 12314894 **Subject Initials:** ---

**Generated By:** (b) (4) **Generated Time (GMT):** 19-Apr-2021 21:04

[eCRF Audit Trail History](#)

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

**Header Text:** c4591001**Visit:** V3\_MONTH1\_POSTVAX2\_L **Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY**Form Version:** 22-Apr-2020 21:03 **Form Status:** Data Complete, Locked, Frozen, Verified**Site No:** 1231**Site Name:** (1231) Hospital Militar Central Cirujano Mayor Dr. Cosme Argerich**Subject No:** 12314894**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 19-Apr-2021 21:04[eCRF Audit Trail History](#)**Electronic Sample Tracking**

1.	Data Origin	SITE
2.	Sample Type	SERUM
3.	Sample Collected?	YES Date of Collection: Oct/19/2020
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[ ]

**Aliquot**

Please enter barcode for each aliquot.

5.a	Sample ID	[BLBH1K]
5.b	Sample ID	[BLBH0X]
5.c	Sample ID	[BPWDHK]

**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:** 12314894

**Subject Initials:** ---

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

**Generated Time (GMT):** 19-Apr-2021 21:04

**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 Version:** 20-Feb-2021 02:17

**Site No:** 1231

**Subject No:** 12314894

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

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

**Form Status:** Not Started

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

**Subject Initials:** ---

**Generated Time (GMT):** 19-Apr-2021 21:04

### 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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**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:** 12314894**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 19-Apr-2021 21:04**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 Version:** 22-Apr-2020 21:03

**Site No:** 1231

**Subject No:** 12314894

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

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

**Form Status:** Not Started

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

**Subject Initials:** ---

**Generated Time (GMT):** 19-Apr-2021 21:04

**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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090177e196d6f285\Final\Final On: 22-Apr-2021 02:12 (GMT)

**Header Text:** c4591001

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

**Form:** HEALTH CARE UTILIZATION

**Form Version:** 20-Feb-2021 02:19

**Form Status:** Not Started

**Site No:** 1231

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

**Subject No:** 12314894

**Subject Initials:** ---

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

**Generated Time (GMT):** 19-Apr-2021 21:04

**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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**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:** 12314894

**Subject Initials:** ---

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

**Generated Time (GMT):** 19-Apr-2021 21:04

**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:** 12314894

**Subject Initials:** ---

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

**Generated Time (GMT):** 19-Apr-2021 21:04

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

**Header Text:** c4591001**Visit:** POT\_COVID\_CONVA - New  
Unscheduled Visit**Form:** 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:** 12314894**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 19-Apr-2021 21:04**Electronic Sample Tracking**

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

**Aliquot**

Please enter barcode for each aliquot.

5.	Sample ID	[ ]
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**Header Text:** c4591001

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

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

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

**Subject No:** 12314894 **Subject Initials:** ---

**Generated By:** (b) (4) **Generated Time (GMT):** 19-Apr-2021 21:04

**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:** 12314894    **Subject Initials:** ---

**Generated By:** (b) (4)    **Generated Time (GMT):** 19-Apr-2021 21:04

**Unplanned Assessments**

1.	Assessments	
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090177e196d6f285\Final\Final On: 22-Apr-2021 02:12 (GMT)

**Header Text:** c4591001

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

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

**Site No:** 1231

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

**Subject No:** 12314894

**Subject Initials:** ---

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

**Generated Time (GMT):** 19-Apr-2021 21:04

[eCRF Audit Trail History](#)

**Disposition - Treatment**

1.	Date of Completion/Discontinuation /Death :	Oct/19/2020
2.	Phase of Disposition:	VACCINATION
3.	Status:	COMPLETED
4.	Specify Status:	[ ]



**Header Text:** c4591001

**Visit:** Follow-Up - Unscheduled

**Form:** DISPOSITION - FOLLOW-UP

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

**Form Status:** Not Started

**Site No:** 1231

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

**Subject No:** 12314894

**Subject Initials:** ---

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

**Generated Time (GMT):** 19-Apr-2021 21:04

**Disposition - Follow-Up**

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

090177e196d6f285\Final\Final On: 22-Apr-2021 02:12 (GMT)

**Header Text:** c4591001

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

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

**Site No:** 1231

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

**Subject No:** 12314894

**Subject Initials:** ---

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

**Generated Time (GMT):** 19-Apr-2021 21:04

**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:** 12314894 **Subject Initials:** ---

**Generated By:** (b) (4) **Generated Time (GMT):** 19-Apr-2021 21:04

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

090177e196d6f285\Final\Final On: 22-Apr-2021 02:12 (GMT)

**Header Text:** c4591001

**Visit:** Logs

**Form:** ADVERSE EVENT REPORT

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

**Site No:** 1231

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

**Subject No:** 12314894

**Subject Initials:** ---

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

**Generated Time (GMT):** 19-Apr-2021 21:04

#	Category	AE Identifier	Adverse Event	Start Date	Is the Adverse Event Still Ongoing	Form Instance
1.	ADVERSE EVENT	1	right retroatrial inflammation	Sep/21/2020 08:00	NO End Date Time:  Sep/21/2020 20:00	<a href="#">Repeating Pages</a>

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1231

**Subject No:** 12314894

**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):** 19-Apr-2021 21:04

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[Form Audit Trail](#)

**Adverse Event Report**

1.	Category:	ADVERSE EVENT
2.	AE ID:	[1]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[right retroatrial inflammation]
4.	Start Date Time:	Sep/21/2020 08:00
5.	Is the adverse event still ongoing?	NO End Date Time: Sep/21/2020 20:00
6.	Toxicity Grade:	1

090177e196d6f285\Final\Final On: 22-Apr-2021 02:12 (GMT)

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1231

**Subject No:** 12314894

**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):** 19-Apr-2021 21:04

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: [Unkonwn]
10.	Latest Action Taken with Study Treatment:	NOT APPLICABLE

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**Header Text:** c4591001

**Visit:** Logs - Unscheduled

**Form:** ADVERSE EVENT REPORT

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

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

**Site No:** 1231

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

**Subject No:** 12314894

**Subject Initials:** ---

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

**Generated Time (GMT):** 19-Apr-2021 21:04

11.	Was a Concomitant Medication given?	YES
12.	Was a Non-Drug Treatment given?	NO
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	[ ]

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**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:** 12314894

**Subject Initials:** ---

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

**Generated Time (GMT):** 19-Apr-2021 21:04

#	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:** 12314894

**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):** 19-Apr-2021 21:04

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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	[ ]

090177e196d6f285\Final\Final On: 22-Apr-2021 02:12 (GMT)

**Header Text:** c4591001

**Visit:** Logs

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

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

**Site No:** 1231

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

**Subject No:** 12314894

**Subject Initials:** ---

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

**Generated Time (GMT):** 19-Apr-2021 21:04

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

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

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

**Form Status:** Not Started

**Site No:** 1231

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

**Subject No:** 12314894

**Subject Initials:** ---

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

**Generated Time (GMT):** 19-Apr-2021 21:04

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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:	//

090177e196d6f285\Final\Final On: 22-Apr-2021 02:12 (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:** 12314894

**Subject Initials:** ---

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

**Generated Time (GMT):** 19-Apr-2021 21:04

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

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

**Form:** CONCOMITANT MEDICATIONS - PROHIBITED

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

**Form Status:** Not Started

**Site No:** 1231

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

**Subject No:** 12314894

**Subject Initials:** ---

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

**Generated Time (GMT):** 19-Apr-2021 21:04

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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?	

090177e196d6f285\Final\Final On: 22-Apr-2021 02:12 (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:** 12314894

**Subject Initials:** ---

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

**Generated Time (GMT):** 19-Apr-2021 21:04

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

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

**Form:** RADIATION TREATMENT

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

**Form Status:** Not Started

**Site No:** 1231

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

**Subject No:** 12314894

**Subject Initials:** ---

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

**Generated Time (GMT):** 19-Apr-2021 21:04

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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?	

090177e196d6f285\Final\Final On: 22-Apr-2021 02:12 (GMT)

**Header Text:** c4591001

**Visit:** Logs

**Form:** TRANSFUSIONS

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

**Site No:** 1231

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

**Subject No:** 12314894

**Subject Initials:** ---

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

**Generated Time (GMT):** 19-Apr-2021 21:04

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



**Header Text:** c4591001

**Visit:** Logs - Unscheduled

**Form:** TRANSFUSIONS

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

**Form Status:** Not Started

**Site No:** 1231

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

**Subject No:** 12314894

**Subject Initials:** ---

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

**Generated Time (GMT):** 19-Apr-2021 21:04

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

**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:** 12314894

**Subject Initials:** ---

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

**Generated Time (GMT):** 19-Apr-2021 21:04

**Date of Visit**

1.	Date of Visit	//
2.	Erroneous Visit	

**Header Text:** c4591001

**Visit:** Unplanned Vaccination -  
Unscheduled

**Form:** VITAL SIGNS - TEMP

**Form Version:** 20-Feb-2021 02:16

**Form Status:** Not Started

**Site No:** 1231

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

**Subject No:** 12314894

**Subject Initials:** ---

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

**Generated Time (GMT):** 19-Apr-2021 21:04

**Vital Signs**

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

**Vital Signs Details**

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

090177e196d6f285\Final\Final On: 22-Apr-2021 02:12 (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:** 12314894**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 19-Apr-2021 21:04**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:	

**Header Text:** c4591001

**Visit:** Unplanned Vaccination -  
Unscheduled

**Form:** VACCINATION

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

**Form Status:** Not Started

**Site No:** 1231

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

**Subject No:** 12314894

**Subject Initials:** ---

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

**Generated Time (GMT):** 19-Apr-2021 21:04

**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?	

090177e196d6f285\Final\Final On: 22-Apr-2021 02:12 (GMT)

**Header Text:** c4591001

**Visit:** Unplanned Vaccination -  
Unscheduled

**Form:** CONTACT OUTCOME - MONTH 1

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

**Form Status:** Not Started

**Site No:** 1231

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

**Subject No:** 12314894

**Subject Initials:** ---

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

**Generated Time (GMT):** 19-Apr-2021 21:04

**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:** 12314894

**Subject Initials:** ---

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

**Generated Time (GMT):** 19-Apr-2021 21:04

**Contact Outcome**

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

**Header Text:** c4591001

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

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

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

**Subject No:** 12314894 **Subject Initials:** ---

**Generated By:** (b) (4) **Generated Time (GMT):** 19-Apr-2021 21:04

[eCRF Audit Trail History](#)

**Date of Visit**

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



**Header Text:** c4591001

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

**Form:** INFORMED CONSENT - ASYMPTOMATIC  
SURVEILLANCE

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

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

**Site No:** 1231

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

**Subject No:** 12314894

**Subject Initials:** ---

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

**Generated Time (GMT):** 19-Apr-2021 21:04

[eCRF Audit Trail History](#)

**Informed Consent - Asymptomatic Surveillance**

1.	Consent Was:	OBTAINED Date Written Consent Obtained Feb/5/2021
----	--------------	---

**Header Text:** c4591001**Visit:** V201\_SURVEIL\_CONSENT - **Form:** ELECTRONIC SAMPLE TRACKING -  
Unscheduled IMMUNOGENICITY**Form Version:** 22-Apr-2020 21:03 **Form Status:** Data Complete, Frozen, Verified**Site No:** 1231**Site Name:** (1231) Hospital Militar Central Cirujano  
Mayor Dr. Cosme Argerich**Subject No:** 12314894**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 19-Apr-2021 21:04[eCRF Audit Trail History](#)**Electronic Sample Tracking**

1.	Data Origin	SITE
2.	Sample Type	SERUM
3.	Sample Collected?	YES Date of Collection: Feb/5/2021
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	[BNTRT7]
5.b	Sample ID	[BHXH11]
5.c	Sample ID	[BPTH4F]
5.d	Sample ID	[BNTRSG]

**Header Text:** c4591001**Visit:** V201\_SURVEIL\_CONSENT -  
Unscheduled**Form:** ELECTRONIC SAMPLE TRACKING - NASAL  
SWAB**Form Version:** 22-Apr-2020 21:03**Form Status:** Data Complete, Frozen, Verified**Site No:** 1231**Site Name:** (1231) Hospital Militar Central Cirujano  
Mayor Dr. Cosme Argerich**Subject No:** 12314894**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 19-Apr-2021 21:04[eCRF Audit Trail History](#)**Electronic Sample Tracking**

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB
3.	Sample Collected?	YES Date of Collection: Feb/5/2021
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	[BPTH4F]
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**Header Text:** c4591001

**Visit:** V202\_SURVEIL\_SWAB 1 -  
Unscheduled Visit on Feb/17/2021

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

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

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

**Site No:** 1231

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

**Subject No:** 12314894

**Subject Initials:** ---

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

**Generated Time (GMT):** 19-Apr-2021 21:04

[eCRF Audit Trail History](#)

**Date of Visit**

1.	Date of Visit	Feb/17/2021
2.	Erroneous Visit	

**COVID-19 Surveillance Visit**

3.	COVID-19 Surveillance Visit:	SSWAB_WEEK2
----	---------------------------------	-------------

**Header Text:** c4591001**Visit:** V202\_SURVEIL\_SWAB 1 -  
Unscheduled Visit on Feb/17/2021**Form:** ELECTRONIC SAMPLE TRACKING - REPEAT  
SWAB**Form Version:** 10-Oct-2020 15:57**Form Status:** Data Complete, Frozen, Verified**Site No:** 1231**Site Name:** (1231) Hospital Militar Central Cirujano  
Mayor Dr. Cosme Argerich**Subject No:** 12314894**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 19-Apr-2021 21:04[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	[BRMD8Y]
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**Header Text:** c4591001

**Visit:** V202\_SURVEIL\_SWAB 2 -  
Unscheduled Visit on Mar/05/2021

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

**Site No:** 1231

**Subject No:** 12314894

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

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

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

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

**Subject Initials:** ---

**Generated Time (GMT):** 19-Apr-2021 21:04

[eCRF Audit Trail History](#)

**Date of Visit**

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

**COVID-19 Surveillance Visit**

3.	COVID-19 Surveillance Visit:	SSWAB_WEEK4
----	---------------------------------	-------------

**Header Text:** c4591001**Visit:** V202\_SURVEIL\_SWAB 2 -  
Unscheduled Visit on Mar/05/2021**Form Version:** 10-Oct-2020 15:57**Site No:** 1231**Subject No:** 12314894**Generated By:** (b) (4)**Form:** ELECTRONIC SAMPLE TRACKING - REPEAT  
SWAB**Form Status:** Data Complete, Frozen, Verified**Site Name:** (1231) Hospital Militar Central Cirujano  
Mayor Dr. Cosme Argerich**Subject Initials:** ---**Generated Time (GMT):** 19-Apr-2021 21:04[eCRF Audit Trail History](#)**Electronic Sample Tracking**

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB
3.	Sample Collected?	YES Date of Collection: Mar/5/2021
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	[BR1LZ3]
-----	-----------	----------

**Header Text:** c4591001

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

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

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

**Subject No:** 12314894      **Subject Initials:** ---

**Generated By:** (b) (4)      **Generated Time (GMT):** 19-Apr-2021 21:04

[eCRF Audit Trail History](#)

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



**Header Text:** c4591001

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

**Form Version:** 10-Dec-2020 02:25      **Form Status:** Data Complete, Frozen

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

**Subject No:** 12314894      **Subject Initials:** ---

**Generated By:** (b) (4)      **Generated Time (GMT):** 19-Apr-2021 21:04

[eCRF Audit Trail History](#)

**Further Vaccination Confirmation**

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

**Header Text:** c4591001

**Visit:** Disposition - Unscheduled

**Form:** TREATMENT UNBLINDED

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

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

**Site No:** 1231

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

**Subject No:** 12314894

**Subject Initials:** ---

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

**Generated Time (GMT):** 19-Apr-2021 21:04

[eCRF Audit Trail History](#)

**Treatment Unblinded**

1.	Date Treatment Unblinded :	Mar/5/2021
2.	Primary Reason for Unblinding:	ASSESS ELIGIBILITY FOR ADDITIONAL VACCINATION

**Header Text:** c4591001

**Visit:** Disposition - Unscheduled

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

**Site No:** 1231

**Subject No:** 12314894

**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):** 19-Apr-2021 21:04

**Withdrawal Of Consent**

1.	Withdrawal of Consent Date :	//
----	---------------------------------	----

**Header Text:** c4591001

**Visit:** Disposition - Unscheduled

**Form:** DEATH DETAILS CODED

**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:** 12314894

**Subject Initials:** ---

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

**Generated Time (GMT):** 19-Apr-2021 21:04

**Death Details**

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

**Cause of Death**

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

**Header Text:** c4591001

**Visit:** V101\_VAX3

**Form:** DATE OF VISIT

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

**Form Status:** Data Complete, Verified

**Site No:** 1231

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

**Subject No:** 12314894

**Subject Initials:** ---

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

**Generated Time (GMT):** 19-Apr-2021 21:04

[eCRF Audit Trail History](#)

Date of Visit		
1.	Date of Visit	Mar/9/2021
2.	Erroneous Visit	

**Header Text:** c4591001

**Visit:** V101\_VAX3

**Form:** INFORMED CONSENT - FURTHER VACCINATION

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

**Form Status:** Data Complete, Verified

**Site No:** 1231

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

**Subject No:** 12314894

**Subject Initials:** ---

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

**Generated Time (GMT):** 19-Apr-2021 21:04

[eCRF Audit Trail History](#)

**Informed Consent - Further Vaccination**

1.	Consent Was:	OBTAINED Date Written Consent Obtained Mar/9/2021
----	--------------	---

**Header Text:** c4591001

**Visit:** V101\_VAX3

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

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

**Form Status:** Data Complete, Verified

**Site No:** 1231

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

**Subject No:** 12314894

**Subject Initials:** ---

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

**Generated Time (GMT):** 19-Apr-2021 21:04

**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
----	--	----------------

090177e196d6f285\Final\Final On: 22-Apr-2021 02:12 (GMT)

**Header Text:** c4591001

**Visit:** V101\_VAX3

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

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

**Form Status:** Data Complete, Verified

**Site No:** 1231

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

**Subject No:** 12314894

**Subject Initials:** ---

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

**Generated Time (GMT):** 19-Apr-2021 21:04

[eCRF Audit Trail History](#)

**Disposition - Screening for Further Vaccination**

1.	Date of Completion/Discontinuation /Death :	Mar/9/2021
2.	Phase of Disposition:	REPEAT SCREENING 1
3.	Status:	COMPLETED
4.	Specify Status:	[ ]

090177e196d6f285\Final\Final On: 22-Apr-2021 02:12 (GMT)



**Header Text:** c4591001

**Visit:** V101\_VAX3

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

**Site No:** 1231

**Subject No:** 12314894

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

**Form:** LAB URINALYSIS - PREGNANCY TEST

**Form Status:** Data Complete, Verified

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

**Subject Initials:** ---

**Generated Time (GMT):** 19-Apr-2021 21:04

[eCRF Audit Trail History](#)

**Lab Urinalysis**

1.	Lab Panel:	URINALYSIS
2.	Lab Sub-Panel:	PREGNANCY
3.	Collection Date:	Mar/9/2021
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:	

090177e196d6f285\Final\Final On: 22-Apr-2021 02:12 (GMT)

**Header Text:** c4591001**Visit:** V101\_VAX3**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY**Form Version:** 22-Apr-2020 21:03**Form Status:** Data Complete, Verified**Site No:** 1231**Site Name:** (1231) Hospital Militar Central Cirujano Mayor Dr. Cosme Argerich**Subject No:** 12314894**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 19-Apr-2021 21:04[eCRF Audit Trail History](#)**Electronic Sample Tracking**

1.	Data Origin	SITE
2.	Sample Type	SERUM
3.	Sample Collected?	YES Date of Collection: Mar/9/2021
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	[BRYXBD]
5.b	Sample ID	[BR1PKP]
5.c	Sample ID	[BRYXB6]

**Header Text:** c4591001

**Visit:** V101\_VAX3

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

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

**Form Status:** Data Complete, Verified

**Site No:** 1231

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

**Subject No:** 12314894

**Subject Initials:** ---

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

**Generated Time (GMT):** 19-Apr-2021 21:04

[eCRF Audit Trail History](#)

**Electronic Sample Tracking**

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB
3.	Sample Collected?	YES Date of Collection: Mar/9/2021
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	[BR22V1]
-----	-----------	----------

**Header Text:** c4591001

**Visit:** V101\_VAX3

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

**Site No:** 1231

**Subject No:** 12314894

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

**Form:** VACCINATION

**Form Status:** Data Complete, Verified

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

**Subject Initials:** ---

**Generated Time (GMT):** 19-Apr-2021 21:04

[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:	Mar/9/2021 17:41
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

090177e196d6f285\Final\Final On: 22-Apr-2021 02:12 (GMT)

**Header Text:** c4591001

**Visit:** V102\_VAX4

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

**Site No:** 1231

**Subject No:** 12314894

**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):** 19-Apr-2021 21:04

**Date of Visit**

1.	Date of Visit	//
2.	Erroneous Visit	

**Header Text:** c4591001

**Visit:** V102\_VAX4

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

**Site No:** 1231

**Subject No:** 12314894

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

**Form:** LAB URINALYSIS - PREGNANCY TEST

**Form Status:** Not Started

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

**Subject Initials:** ---

**Generated Time (GMT):** 19-Apr-2021 21:04

**Lab Urinalysis**

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

**Lab Result**

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

090177e196d6f285\Final\Final On: 22-Apr-2021 02:12 (GMT)

**Header Text:** c4591001

**Visit:** V102\_VAX4

**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:** 12314894

**Subject Initials:** ---

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

**Generated Time (GMT):** 19-Apr-2021 21:04

**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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090177e196d6f285\Final\Final On: 22-Apr-2021 02:12 (GMT)

**Header Text:** c4591001

**Visit:** V102\_VAX4

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

**Site No:** 1231

**Subject No:** 12314894

**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):** 19-Apr-2021 21:04

**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?	

090177e196d6f285\Final\Final On: 22-Apr-2021 02:12 (GMT)



**Header Text:** c4591001

**Visit:** V103\_MONTH1

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

**Site No:** 1231

**Subject No:** 12314894

**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):** 19-Apr-2021 21:04

**Date of Visit**

1.	Date of Visit	//
2.	Erroneous Visit	

**Header Text:** c4591001

**Visit:** V103\_MONTH1

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

**Site No:** 1231

**Subject No:** 12314894

**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):** 19-Apr-2021 21:04

**Contact Outcome**

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

**Header Text:** c4591001

**Visit:** V104\_MONTH6

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

**Site No:** 1231

**Subject No:** 12314894

**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):** 19-Apr-2021 21:04

**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:** 12314894

**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):** 19-Apr-2021 21:04

**Contact Outcome**

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

**Header Text:** c4591001

**Visit:** V105\_MONTH18

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

**Site No:** 1231

**Subject No:** 12314894

**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):** 19-Apr-2021 21:04

**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:** 12314894

**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):** 19-Apr-2021 21:04

**Contact Outcome**

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

**Header Text:** c4591001

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

**Form:** DISPOSITION - TREATMENT

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

**Form Status:** Not Started

**Site No:** 1231

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

**Subject No:** 12314894

**Subject Initials:** ---

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

**Generated Time (GMT):** 19-Apr-2021 21:04

**Disposition - Treatment**

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

090177e196d6f285\Final\Final On: 22-Apr-2021 02:12 (GMT)

**Header Text:** c4591001

**Visit:** Subject Status - Unscheduled

**Form:** SUBJECT STATUS

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

**Form Status:** Data Complete, Verified

**Site No:** 1231

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

**Subject No:** 12314894

**Subject Initials:** ---

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

**Generated Time (GMT):** 19-Apr-2021 21:04

[eCRF Audit Trail History](#)

**Subject Status**

1.	Subject Status	FOLLOW-UP
2.	Subject Status Date	Oct/19/2020



**Header Text:** c4591001

**Visit:** Investigator Signature -  
Unscheduled

**Form:** CASEBOOK SIGNATURE FORM

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

**Form Status:** Data Complete, Verified

**Site No:** 1231

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

**Subject No:** 12314894

**Subject Initials:** ---

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

**Generated Time (GMT):** 19-Apr-2021 21:04

[eCRF Audit Trail History](#)

**Casebook Signature Form**

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

**Header Text:** c4591001

**Visit:** Investigator Signature -  
Unscheduled

**Form:** CASEBOOK SIGNATURE FORM

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

**Form Status:** Data Complete, Verified

**Site No:** 1231

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

**Subject No:** 12314894

**Subject Initials:** ---

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

**Generated Time (GMT):** 19-Apr-2021 21:04

[Audit Trail](#)

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

- CRF\_Sign
- CRF\_Sign\_1

Name	Signature Meaning	Date	Type	Action
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**Header Text:** c4591001

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

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

**Site No:** 1231

**Subject No:** 12314894

**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):** 19-Apr-2021 21:04

[Back to Form](#)

Item	Date	User	Comment
Form	Aug-28-2020 18:35:00 (UTC-03:00) City of Buenos Aires	(b) (4), (b) (6)	Not Applicable

**Header Text:** c4591001

**Visit:** V101\_VAX3

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

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

**Form Status:** Data Complete, Verified

**Site No:** 1231

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

**Subject No:** 12314894

**Subject Initials:** ---

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

**Generated Time (GMT):** 19-Apr-2021 21:04

[Back to Form](#)

Item	Date	User	Comment
Form	Mar-10-2021 11:13:43 (UTC-03:00) City of Buenos Aires	(b) (4), (b) (6) [Redacted]	Not Applicable

**Header Text:** c4591001

**Visit:** Investigator Signature -  
Unscheduled

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

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

**Form Status:** Data Complete, Verified

**Site No:** 1231

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

**Subject No:** 12314894

**Subject Initials:** ---

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

**Generated Time (GMT):** 19-Apr-2021 21:04

[Back to Form](#)

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

- CRF\_Sign
- CRF\_Sign\_1

Name	Signature Meaning	Date	Type	Action
(b) (6)	N/A	Mar-08-2021 11:39:15 (UTC-03:00) City of Buenos Aires		Edit - All signatures invalidated

**Affidavit:**  
N/A

Carola Baldoni	Approved	Mar-06-2021 16:08:48 (UTC-03:00) City of Buenos Aires	BOOK	Signed
----------------	----------	--	------	--------

**Affidavit:**

By my dated signature below, I, CarolaBaldoni, 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-06-2021 10:54:37 (UTC-03:00) City of Buenos Aires		Edit - All signatures invalidated
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090177e196d6f285\Final\Final On: 22-Apr-2021 02:12 (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, Verified

**Site No:** 1231

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

**Subject No:** 12314894

**Subject Initials:** ---

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

**Generated Time (GMT):** 19-Apr-2021 21:04

**Affidavit:**

N/A

(b) (6)	Approved	Feb-18-2021 17:11:44 (UTC-03:00) City of Buenos Aires	BOOK	Signed
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**Affidavit:**

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

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

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

(b) (6)	N/A	Feb-18-2021 17:10:02 (UTC-03:00) City of Buenos Aires		Edit - All signatures invalidated
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**Affidavit:**

N/A

(b) (6)	Approved	Feb-09-2021 11:25:07 (UTC-03:00) City of Buenos Aires	BOOK	Signed
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090177e196d6f285\Final\Final On: 22-Apr-2021 02:12 (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, Verified

**Site No:** 1231

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

**Subject No:** 12314894

**Subject Initials:** ---

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

**Generated Time (GMT):** 19-Apr-2021 21:04

**Affidavit:**

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

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

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

(b) (6)	N/A	Feb-05-2021 14:56:01 (UTC-03:00) City of Buenos Aires		Edit - All signatures invalidated
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**Affidavit:**

N/A

(b) (6)	Approved	Oct-26-2020 21:33:58 (UTC-03:00) City of Buenos Aires	BOOK	Signed
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090177e196d6f285\Final\Final On: 22-Apr-2021 02:12 (GMT)

**Header Text:** c4591001

**Visit:** Investigator Signature -  
Unscheduled

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

**Site No:** 1231

**Subject No:** 12314894

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

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

**Form Status:** Data Complete, Verified

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

**Subject Initials:** ---

**Generated Time (GMT):** 19-Apr-2021 21:04

**Affidavit:**

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

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

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



**Header Text:** c4591001

**Visit:** COHORT\_SELECTION

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

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

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

**Site No:** 1231

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

**Subject No:** 12314894

**Subject Initials:** ---

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

**Generated Time (GMT):** 19-Apr-2021 21:04

[Back to Form](#)

*1. Select appropriate response - Protocol version*

Date	Location	User	Value	Reason
Aug-28-2020 18:34:28 (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 18:34:28 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> STAGE 3 COHOR TS	Initial Entry

090177e196d6f285\Final\Final On: 22-Apr-2021 02:12 (GMT)

**Header Text:** c4591001

**Visit:** COHORT\_SELECTION

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

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

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

**Site No:** 1231

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

**Subject No:** 12314894

**Subject Initials:** ---

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

**Generated Time (GMT):** 19-Apr-2021 21:04

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*1. Consent Was:*

Date	Location	User	Value	Reason
Aug-28-2020 18:34:35 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> OBTAINED Date Written Con sent Obtained  Aug/28/2020	Initial Entry

**Header Text:** c4591001

**Visit:** COHORT\_SELECTION

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

**Site No:** 1231

**Subject No:** 12314894

**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):** 19-Apr-2021 21:04

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**1. Subject ID**

Date	Location	User	Value	Reason
Aug-28-2020 16:30:33 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 12314894	Item copied from previous form

**2. Birth Date:**

Date	Location	User	Value	Reason
Aug-28-2020 16:30:29 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> (b) (6)/1994	Enrollment Entry

**3. Sex:**

Date	Location	User	Value	Reason
Aug-28-2020 18:34:45 (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 18:34:45	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> HISPANIC OR LA	Initial Entry

090177e196d6f285\Final\Final On: 22-Apr-2021 02:12 (GMT)

**Header Text:** c4591001

**Visit:** COHORT\_SELECTION

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

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

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

**Site No:** 1231

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

**Subject No:** 12314894

**Subject Initials:** ---

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

**Generated Time (GMT):** 19-Apr-2021 21:04

(UTC-03:00) City of Buenos Aires			TINO(A) OR OF SPANISH ORIGIN	
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**5. Race: (Check X all that apply):**

Date	Location	User	Value	Reason
Aug-28-2020 18:34:45 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> WHITE	Initial Entry

**Header Text:** c4591001

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

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

**Site No:** 1231

**Subject No:** 12314894

**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):** 19-Apr-2021 21:04

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*1. Date of Visit*

Date	Location	User	Value	Reason
Aug-28-2020 18:34:52 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Aug/28/2020	Initial Entry

090177e196d6f285\Final\Final On: 22-Apr-2021 02:12 (GMT)

**Header Text:** c4591001

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

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

**Site No:** 1231

**Subject No:** 12314894

**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):** 19-Apr-2021 21:04

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

Date	Location	User	Value	Reason
Aug-28-2020 18:35:11 (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 18:35:11 (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 18:35:11 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> COMPLETED	Initial Entry

090177e196d6f285\Final\Final On: 22-Apr-2021 02:12 (GMT)

**Header Text:** c4591001

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

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

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

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

**Site No:** 1231

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

**Subject No:** 12314894

**Subject Initials:** ---

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

**Generated Time (GMT):** 19-Apr-2021 21:04

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*1.a*

Date	Location	User	Value	Reason
Aug-28-2020 18:35:44 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Line/MH Number:</b> 1 <b>Medical History Term:</b> Pneumonia <b>Start Date:</b> Jun/1/2005 <b>Ongoing:</b> NO End Date:  Jun/15/2005	Initial Entry

*1.a Line/MH Number:*

Date	Location	User	Value	Reason
Aug-28-2020 18:35:44 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 1	Initial Entry

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

Date	Location	User	Value	Reason
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090177e196d6f285\Final\Final On: 22-Apr-2021 02:12 (GMT)

**Header Text:** c4591001

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

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

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

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

**Site No:** 1231

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

**Subject No:** 12314894

**Subject Initials:** ---

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

**Generated Time (GMT):** 19-Apr-2021 21:04

Aug-28-2020 18:35:44 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Pneumonia	Initial Entry
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**1.a Start Date:**

Date	Location	User	Value	Reason
Aug-28-2020 18:35:44 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Jun/1/2005	Initial Entry

**1.a Ongoing:**

Date	Location	User	Value	Reason
Aug-28-2020 18:35:44 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO End Date: Jun/15/2005	Initial Entry

**1.b**

Date	Location	User	Value	Reason
Aug-28-2020 18:36:06 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Line/MH</b> 2 <b>Number:</b> <b>Medical Hi</b> Bronchial <b>story Term</b> asthma :	Initial Entry

090177e196d6f285\Final\Final On: 22-Apr-2021 02:12 (GMT)



**Header Text:** c4591001

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

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

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

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

**Site No:** 1231

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

**Subject No:** 12314894

**Subject Initials:** ---

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

**Generated Time (GMT):** 19-Apr-2021 21:04

			<b>Start Date:</b> May/1/20 05 <b>Ongoing:</b> NO End Date:  Jun/1/ 2006	
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090177e196d6f285\Final\Final On: 22-Apr-2021 02:12 (GMT)

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1231

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

Subject No: 12314894

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 19-Apr-2021 21:04

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

Date	Location	User	Value	Reason
Aug-28-2020 18:36:06 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 2	Initial Entry

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

Date	Location	User	Value	Reason
Aug-28-2020 18:36:06 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Bronchial asthma	Initial Entry

**1.b Start Date:**

Date	Location	User	Value	Reason
Aug-28-2020 18:36:06 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> May/1/2005	Initial Entry

**1.b Ongoing:**

Date	Location	User	Value	Reason
Aug-28-2020 18:36:06 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO End Date:	Initial Entry

090177e196d6f285\Final\Final On: 22-Apr-2021 02:12 (GMT)

**Header Text:** c4591001

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

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

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

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

**Site No:** 1231

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

**Subject No:** 12314894

**Subject Initials:** ---

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

**Generated Time (GMT):** 19-Apr-2021 21:04

Jun/1/2006

090177e196d6f285\Final\Final On: 22-Apr-2021 02:12 (GMT)

**Header Text:** c4591001

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

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

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

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

**Site No:** 1231

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

**Subject No:** 12314894

**Subject Initials:** ---

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

**Generated Time (GMT):** 19-Apr-2021 21:04

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**1. Date:**

Date	Location	User	Value	Reason
Aug-28-2020 18:36:29 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Aug/28/2020	Initial Entry

**2. Weight:**

Date	Location	User	Value	Reason
Aug-28-2020 18:36:29 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 78.9	Initial Entry

**3. Unit:**

Date	Location	User	Value	Reason
Aug-28-2020 18:36:29 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> kg	Initial Entry

**4. Height:**

Date	Location	User	Value	Reason
Aug-28-2020	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>	Initial Entry

090177e196d6f285\Final\Final On: 22-Apr-2021 02:12 (GMT)

**Header Text:** c4591001

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

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

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

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

**Site No:** 1231

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

**Subject No:** 12314894

**Subject Initials:** ---

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

**Generated Time (GMT):** 19-Apr-2021 21:04

18:36:29 (UTC-03:00) City of Buenos Aires		(b) (4), (b) (6)	167.0	
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**5. Unit:**

Date	Location	User	Value	Reason
Aug-28-2020 18:36:29 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> cm	Initial Entry

**6. Body Mass Index:**

Date	Location	User	Value	Reason
Aug-28-2020 18:36:29 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 28.3	Initial Entry

**7.a**

Date	Location	User	Value	Reason
Aug-28-2020 18:36:29 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Record Identifier:</b> : <b>Temperature:</b> <b>Temperature Unit:</b>	Initial Entry

090177e196d6f285\Final\Final On: 22-Apr-2021 02:12 (GMT)

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form: VITAL SIGNS - BASELINE - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:51

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1231

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

Subject No: 12314894

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 19-Apr-2021 21:04

			Temperat ure Locat ion:: TY	
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7.a Record Identifier:

Date	Location	User	Value	Reason
Aug-28-2020 18:36:29 (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 18:36:29 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 37.0	Initial Entry

7.a Unit:

Date	Location	User	Value	Reason
Aug-28-2020 18:36:29 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> C	Initial Entry

7.a Temperature Location:

Date	Location	User	Value	Reason
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090177e196d6f285\Final\Final On: 22-Apr-2021 02:12 (GMT)

**Header Text:** c4591001

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

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

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

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

**Site No:** 1231

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

**Subject No:** 12314894

**Subject Initials:** ---

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

**Generated Time (GMT):** 19-Apr-2021 21:04

Aug-28-2020 18:36:29 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> ORAL CAVITY	Initial Entry
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**Header Text:** c4591001

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

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

**Site No:** 1231

**Subject No:** 12314894

**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):** 19-Apr-2021 21:04

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**1. Lab Panel:**

Date	Location	User	Value	Reason
Aug-28-2020 18:36:39 (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 18:36:39 (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 18:36:39 (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	ACV0PFEINFP6000	auto calc	<b>Data Entry:</b>	Initial Entry

090177e196d6f285\Final\Final On: 22-Apr-2021 02:12 (GMT)



**Header Text:** c4591001

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

**Form:** LAB URINALYSIS - PREGNANCY TEST - eCRF Audit Trail History

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

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

**Site No:** 1231

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

**Subject No:** 12314894

**Subject Initials:** ---

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

**Generated Time (GMT):** 19-Apr-2021 21:04

18:36:39  
(UTC-03:00) City  
of Buenos Aires

(autocalc)

STUDY SITE

**5. Specimen Type:**

Date	Location	User	Value	Reason
Aug-28-2020 18:36:39 (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 18:36:39 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Sponsor-</b> 113 <b>Defined I</b> <b>dentifier:</b> <b>Test::</b> Choriogon adotropin Beta_PX11 3 <b>Result::</b> NEGATIV E <b>Not Done</b> ::	Initial Entry

**6.a Sponsor ID:**

Date	Location	User	Value	Reason
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090177e196d6f285\Final\Final On: 22-Apr-2021 02:12 (GMT)

**Header Text:** c4591001

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

**Form:** LAB URINALYSIS - PREGNANCY TEST - eCRF Audit Trail History

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

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

**Site No:** 1231

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

**Subject No:** 12314894

**Subject Initials:** ---

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

**Generated Time (GMT):** 19-Apr-2021 21:04

Aug-28-2020 18:36:39 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 113	Initial Entry
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**6.a Test:**

Date	Location	User	Value	Reason
Aug-28-2020 18:36:39 (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 18:36:39 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NEGATIVE	Initial Entry

090177e196d6f285\Final\Final On: 22-Apr-2021 02:12 (GMT)

**Header Text:** c4591001

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

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

**Site No:** 1231

**Subject No:** 12314894

**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):** 19-Apr-2021 21:04

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**1. Randomization Date :**

Date	Location	User	Value	Reason
Aug-28-2020 18:36:45 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Aug/28/2020	Initial Entry

**2. Randomization Number:**

Date	Location	User	Value	Reason
Aug-28-2020 18:36:45 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 72865	Initial Entry

090177e196d6f285\Final\Final On: 22-Apr-2021 02:12 (GMT)

**Header Text:** c4591001

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

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

**Site No:** 1231

**Subject No:** 12314894

**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):** 19-Apr-2021 21:04

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**1. Data Origin**

Date	Location	User	Value	Reason
Aug-28-2020 18:37:09 (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 18:37:09 (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 15:40:44 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Aug-28-2020 18:37:09 (UTC-03:00) City of Buenos	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candida te	'Sample Collected?' is Yes, however no barcodes

090177e196d6f285\Final\Final On: 22-Apr-2021 02:12 (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:** 12314894

**Subject Initials:** ---

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

**Generated Time (GMT):** 19-Apr-2021 21:04

Aires				are entered. Please review and correct as appropriate.
Aug-28-2020 18:37:09 (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 15:40:44 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	Maria del Pilar Pereyra (b) (4)	<b>Data Entry:</b> Sample I BPWW D: 4P	Initial Entry

**5.a Sample ID**

Date	Location	User	Value	Reason
Aug-29-2020 15:40:44 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	Maria del Pilar Pereyra (b) (4)	<b>Data Entry:</b> BPWW4P	Initial Entry

**5.b**

Date	Location	User	Value	Reason
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090177e196d6f285\Final\Final On: 22-Apr-2021 02:12 (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:** 12314894

**Subject Initials:** ---

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

**Generated Time (GMT):** 19-Apr-2021 21:04

Aug-29-2020 15:40:54 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	Maria del Pilar Pereyra (b) (4)	<b>Data Entry:</b> <b>Sample I</b> BPWW4 <b>D:</b> R	Initial Entry
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**5.b Sample ID**

Date	Location	User	Value	Reason
Aug-29-2020 15:40:54 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	Maria del Pilar Pereyra (b) (4)	<b>Data Entry:</b> BPWW4R	Initial Entry

**5.c**

Date	Location	User	Value	Reason
Aug-29-2020 15:41:13 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	Maria del Pilar Pereyra (b) (4)	<b>Data Entry:</b> <b>Sample I</b> BPWW <b>D:</b> 4S	Initial Entry

**5.c Sample ID**

Date	Location	User	Value	Reason
Aug-29-2020 15:41:13 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	Maria del Pilar Pereyra (b) (4)	<b>Data Entry:</b> BPWW4S	Initial Entry

**5.d**

090177e196d6f285\Final\Final On: 22-Apr-2021 02:12 (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: 12314894

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 19-Apr-2021 21:04

Date	Location	User	Value	Reason
Aug-29-2020 16:03:43 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	Alan Colombo (b) (4)	<b>Data Entry:</b> Sample I BJ4B8 D: D	Initial Entry

*5.d Sample ID*

Date	Location	User	Value	Reason
Aug-29-2020 16:03:43 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	Alan Colombo (b) (4)	<b>Data Entry:</b> BJ4B8D	Initial Entry

*5.e*

Date	Location	User	Value	Reason
Aug-29-2020 16:03:47 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	Alan Colombo (b) (4)	<b>Data Entry:</b> Sample ID BJ4B8 : F	Initial Entry

*5.e Sample ID*

Date	Location	User	Value	Reason
Aug-29-2020 16:03:47 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	Alan Colombo (b) (4)	<b>Data Entry:</b> BJ4B8F	Initial Entry

090177e196d6f285\Final\Final On: 22-Apr-2021 02:12 (GMT)

**Header Text:** c4591001

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

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

**Site No:** 1231

**Subject No:** 12314894

**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):** 19-Apr-2021 21:04

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**1. Data Origin**

Date	Location	User	Value	Reason
Aug-28-2020 18:37:15 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SITE	Initial Entry

**2. Sample Type**

Date	Location	User	Value	Reason
Aug-28-2020 18:37:15 (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 10:37:19 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Aug-28-2020 18:37:15 (UTC-03:00) City of Buenos	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candida te	'Sample Collected?' is Yes, however no barcodes

090177e196d6f285\Final\Final On: 22-Apr-2021 02:12 (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:** 12314894

**Subject Initials:** ---

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

**Generated Time (GMT):** 19-Apr-2021 21:04

Aires				are entered. Please review and correct as appropriate.
Aug-28-2020 18:37:15 (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 10:37:19 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample ID BPTDS</b> : S	Initial Entry

**5.a Sample ID**

Date	Location	User	Value	Reason
Aug-30-2020 10:37:19 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BPTDSS	Initial Entry

090177e196d6f285\Final\Final On: 22-Apr-2021 02:12 (GMT)

**Header Text:** c4591001

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

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

**Site No:** 1231

**Subject No:** 12314894

**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):** 19-Apr-2021 21:04

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

Date	Location	User	Value	Reason
Aug-28-2020 18:37:28 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**2. Treatment Name**

Date	Location	User	Value	Reason
Aug-28-2020 18:37:28 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> BLINDED THERAPY	Initial Entry

**3. Formulation:**

Date	Location	User	Value	Reason
Aug-28-2020 18:37:28 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> INJECTION	Initial Entry

**4. Dose Date Time:**

Date	Location	User	Value	Reason
Aug-28-2020 18:37:28	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Aug/28/2020 17:1	Initial Entry

090177e196d6f285\Final\Final On: 22-Apr-2021 02:12 (GMT)

**Header Text:** c4591001

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

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

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

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

**Site No:** 1231

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

**Subject No:** 12314894

**Subject Initials:** ---

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

**Generated Time (GMT):** 19-Apr-2021 21:04

(UTC-03:00) City of Buenos Aires			5	
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**5. Anatomical Location:**

Date	Location	User	Value	Reason
Aug-28-2020 18:37:28 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> DELTOID MUSCLE	Initial Entry

**6. Body Side:**

Date	Location	User	Value	Reason
Aug-28-2020 18:37:28 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> RIGHT	Initial Entry

**7. Route:**

Date	Location	User	Value	Reason
Aug-28-2020 18:37:28 (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 18:37:28	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> THE PROTOCOL SPE	Initial Entry

090177e196d6f285\Final\Final On: 22-Apr-2021 02:12 (GMT)

**Header Text:** c4591001

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

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

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

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

**Site No:** 1231

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

**Subject No:** 12314894

**Subject Initials:** ---

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

**Generated Time (GMT):** 19-Apr-2021 21:04

(UTC-03:00) City of Buenos Aires

CIFIED OBSERVATION PERIOD

***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 18:37:28 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

**Header Text:** c4591001

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

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

**Site No:** 1231

**Subject No:** 12314894

**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):** 19-Apr-2021 21:04

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*1. Select appropriate response - Reactogenicity diary collection*

Date	Location	User	Value	Reason
Aug-28-2020 18:38:03 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO - REACTOGE NICITY E-DIARY NOT COLLECTE D FOR THIS SUB JECT	Initial Entry

090177e196d6f285\Final\Final On: 22-Apr-2021 02:12 (GMT)

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

**Site No:** 1231

**Subject No:** 12314894

**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):** 19-Apr-2021 21:04

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*1. Date of Visit*

Date	Location	User	Value	Reason
Sep-19-2020 08:34:59 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sep/16/2020	Initial Entry

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

**Site No:** 1231

**Subject No:** 12314894

**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):** 19-Apr-2021 21:04

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**1. Date:**

Date	Location	User	Value	Reason
Sep-19-2020 08:35:09 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sep/16/2020	Initial Entry

**2.a**

Date	Location	User	Value	Reason
Sep-19-2020 08:35:09 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Record Identifier::</b> <b>Temperature:</b> 37.0 <b>Temperature Unit:</b> C <b>Temperature Location:</b> ORAL CAVIT <b>Y</b>	Initial Entry

**2.a Record Identifier:**

Date	Location	User	Value	Reason
Sep-19-2020 08:35:09 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 1	Initial Entry

090177e196d6f285\Final\Final On: 22-Apr-2021 02:12 (GMT)

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

**Site No:** 1231

**Subject No:** 12314894

**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):** 19-Apr-2021 21:04

**2.a Temperature:**

Date	Location	User	Value	Reason
Sep-19-2020 08:35:09 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 37.0	Initial Entry

**2.a Unit:**

Date	Location	User	Value	Reason
Sep-19-2020 08:35:09 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> C	Initial Entry

**2.a Temperature Location:**

Date	Location	User	Value	Reason
Sep-19-2020 08:35:09 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> ORAL CAVITY	Initial Entry

090177e196d6f285\Final\Final On: 22-Apr-2021 02:12 (GMT)



**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

**Form:** LAB URINALYSIS - PREGNANCY TEST - eCRF Audit Trail History

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

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

**Site No:** 1231

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

**Subject No:** 12314894

**Subject Initials:** ---

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

**Generated Time (GMT):** 19-Apr-2021 21:04

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**1. Lab Panel:**

Date	Location	User	Value	Reason
Sep-19-2020 08:35:22 (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-19-2020 08:35:22 (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-19-2020 08:35:22 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sep/16/2020	Initial Entry

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

Date	Location	User	Value	Reason
Sep-19-2020	ACV0PFEINFP6000	auto calc	<b>Data Entry:</b>	Initial Entry

090177e196d6f285\Final\Final On: 22-Apr-2021 02:12 (GMT)

Header Text: c4591001

Visit: V2\_VAX2\_L

Form: LAB URINALYSIS - PREGNANCY TEST - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:49

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1231

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

Subject No: 12314894

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 19-Apr-2021 21:04

08:35:22  
(UTC-03:00) City  
of Buenos Aires

(autocalc) STUDY SITE

5. Specimen Type:

Date	Location	User	Value	Reason
Sep-19-2020 08:35:22 (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-19-2020 08:35:22 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Sponsor-</b> 113 <b>Defined I</b> <b>dentifier:</b> <b>Test::</b> Choriogon adotropin Beta_PX11 3 <b>Result::</b> NEGATIV E <b>Not Done</b> ::	Initial Entry

6.a Sponsor ID:

Date	Location	User	Value	Reason
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090177e196d6f285\Final\Final On: 22-Apr-2021 02:12 (GMT)

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

**Form:** LAB URINALYSIS - PREGNANCY TEST - eCRF Audit Trail History

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

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

**Site No:** 1231

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

**Subject No:** 12314894

**Subject Initials:** ---

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

**Generated Time (GMT):** 19-Apr-2021 21:04

Sep-19-2020 08:35:22 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 113	Initial Entry
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**6.a Test:**

Date	Location	User	Value	Reason
Sep-19-2020 08:35:22 (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
Sep-19-2020 08:35:22 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NEGATIVE	Initial Entry

090177e196d6f285\Final\Final On: 22-Apr-2021 02:12 (GMT)

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

**Site No:** 1231

**Subject No:** 12314894

**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):** 19-Apr-2021 21:04

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**1. Data Origin**

Date	Location	User	Value	Reason
Sep-17-2020 08:35:04 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SITE	Initial Entry

**2. Sample Type**

Date	Location	User	Value	Reason
Sep-17-2020 08:35:04 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> NASAL_SWAB	Initial Entry

**3. Sample Collected?**

Date	Location	User	Value	Reason
Sep-17-2020 08:35:22 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Sep-17-2020 08:35:04 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered.

090177e196d6f285\Final\Final On: 22-Apr-2021 02:12 (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:** 12314894

**Subject Initials:** ---

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

**Generated Time (GMT):** 19-Apr-2021 21:04

				Please review and correct as appropriate.
Sep-17-2020 08:35:04 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES Date of Collection :  Sep/16/2020	Initial Entry

**5.a**

Date	Location	User	Value	Reason
Sep-17-2020 08:35:22 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample ID</b> BP2BL : F	Initial Entry

**5.a Sample ID**

Date	Location	User	Value	Reason
Sep-17-2020 08:35:22 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BP2BLF	Initial Entry

090177e196d6f285\Final\Final On: 22-Apr-2021 02:12 (GMT)

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

**Site No:** 1231

**Subject No:** 12314894

**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):** 19-Apr-2021 21:04

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

Date	Location	User	Value	Reason
Sep-19-2020 08:35:42 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**2. Treatment Name**

Date	Location	User	Value	Reason
Sep-19-2020 08:35:42 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> BLINDED THERAPY	Initial Entry

**3. Formulation:**

Date	Location	User	Value	Reason
Sep-19-2020 08:35:42 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> INJECTION	Initial Entry

**4. Dose Date Time:**

Date	Location	User	Value	Reason
Sep-19-2020 08:35:42	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sep/16/2020 18:55	Initial Entry

090177e196d6f285\Final\Final On: 22-Apr-2021 02:12 (GMT)

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

**Site No:** 1231

**Subject No:** 12314894

**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):** 19-Apr-2021 21:04

(UTC-03:00) City of Buenos Aires

**5. Anatomical Location:**

Date	Location	User	Value	Reason
Sep-19-2020 08:35:42 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> DELTOID MUSCLE	Initial Entry

**6. Body Side:**

Date	Location	User	Value	Reason
Sep-19-2020 08:35:42 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> RIGHT	Initial Entry

**7. Route:**

Date	Location	User	Value	Reason
Sep-19-2020 08:35:42 (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-19-2020 08:35:42	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> THE PROTOCOL SPE	Initial Entry

090177e196d6f285\Final\Final On: 22-Apr-2021 02:12 (GMT)

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

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

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

**Site No:** 1231

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

**Subject No:** 12314894

**Subject Initials:** ---

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

**Generated Time (GMT):** 19-Apr-2021 21:04

(UTC-03:00) City of Buenos Aires			CIFIED OBSERVATIO N PERIOD	
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***11. Was the subject observed for at least the protocol specified observation period after investigational product administration?***

Date	Location	User	Value	Reason
Sep-19-2020 08:35:42 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

090177e196d6f285\Final\Final On: 22-Apr-2021 02:12 (GMT)



**Header Text:** c4591001

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

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

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

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

**Site No:** 1231

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

**Subject No:** 12314894

**Subject Initials:** ---

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

**Generated Time (GMT):** 19-Apr-2021 21:04

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*1. Date of Visit*

Date	Location	User	Value	Reason
Oct-19-2020 15:45:38 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Oct/19/2020	Initial Entry

090177e196d6f285\Final\Final On: 22-Apr-2021 02:12 (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:** 12314894 **Subject Initials:** ---

**Generated By:** (b) (4) **Generated Time (GMT):** 19-Apr-2021 21:04

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**1. Data Origin**

Date	Location	User	Value	Reason
Oct-19-2020 15:45:49 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SITE	Initial Entry

**2. Sample Type**

Date	Location	User	Value	Reason
Oct-19-2020 15:45:49 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SERUM	Initial Entry

**3. Sample Collected?**

Date	Location	User	Value	Reason
Oct-19-2020 16:14:03 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Oct-19-2020 15:45:49 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered.

090177e196d6f285\Final\Final On: 22-Apr-2021 02:12 (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: 12314894 Subject Initials: ---

Generated By: (b) (4) Generated Time (GMT): 19-Apr-2021 21:04

				Please review and correct as appropriate.
Oct-19-2020 15:45:49 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES Date of Collection:  Oct/19/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Oct-19-2020 16:14:03 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample ID</b> BLBH1 : K	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Oct-19-2020 16:14:03 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BLBH1K	Initial Entry

5.b

Date	Location	User	Value	Reason
Oct-19-2020 17:08:02 (UTC-03:00) City	ACV0PFEINFP6000	Alan Colombo (b) (4)	<b>Data Entry:</b> <b>Sample I</b> BLBH0	Initial Entry

090177e196d6f285\Final\Final On: 22-Apr-2021 02:12 (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:** 12314894 **Subject Initials:** ---

**Generated By:** (b) (4) **Generated Time (GMT):** 19-Apr-2021 21:04

of Buenos Aires			<b>D:</b>	X	
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**5.b Sample ID**

Date	Location	User	Value	Reason
Oct-19-2020 17:08:02 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	Alan Colombo (b) (4)	<b>Data Entry:</b> BLBH0X	Initial Entry

**5.c**

Date	Location	User	Value	Reason
Oct-19-2020 18:03:51 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample I</b> BPWDH <b>D:</b> K	Initial Entry

**5.c Sample ID**

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

090177e196d6f285\Final\Final On: 22-Apr-2021 02:12 (GMT)

**Header Text:** c4591001

**Visit:** End of Treatment - Unscheduled **Form:** DISPOSITION - TREATMENT - eCRF Audit Trail History

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

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

**Subject No:** 12314894 **Subject Initials:** ---

**Generated By:** (b) (4) **Generated Time (GMT):** 19-Apr-2021 21:04

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

Date	Location	User	Value	Reason
Oct-19-2020 15:46:35 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Oct/19/2020	Initial Entry

**2. Phase of Disposition:**

Date	Location	User	Value	Reason
Oct-19-2020 15:46:35 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> VACCINATION	Initial Entry

**3. Status:**

Date	Location	User	Value	Reason
Oct-19-2020 15:46:35 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> COMPLETED	Initial Entry

090177e196d6f285\Final\Final On: 22-Apr-2021 02:12 (GMT)

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1231

**Subject No:** 12314894

**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):** 19-Apr-2021 21:04

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Date	Location	User	Value	Reason
Oct-09-2020 13:39:53 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Created	

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

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

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

**Site No:** 1231

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

**Subject No:** 12314894

**Subject Initials:** ---

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

**Generated Time (GMT):** 19-Apr-2021 21:04

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**1. Category:**

Date	Location	User	Value	Reason
Oct-09-2020 13:39:53 (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
Oct-09-2020 13:39:53 (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
Oct-09-2020 13:39:53 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> right retroatrial inflammation	Initial Entry

**4. Start Date Time:**

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

090177e196d6f285\Final\Final On: 22-Apr-2021 02:12 (GMT)

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

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

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

**Site No:** 1231

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

**Subject No:** 12314894

**Subject Initials:** ---

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

**Generated Time (GMT):** 19-Apr-2021 21:04

13:39:53  
(UTC-03:00) City  
of Buenos Aires

(b) (4),  
(b) (6)

Sep/21/2020 08:00

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

Date	Location	User	Value	Reason
Oct-09-2020 13:39:53 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (4), (b) (6)	<b>Data Entry:</b> NO End Date Time:  Sep/21/2020 20:00	Initial Entry

**6. Toxicity Grade:**

Date	Location	User	Value	Reason
Oct-09-2020 13:39:53 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (4), (b) (6)	<b>Data Entry:</b> 1	Initial Entry

**7. Is the adverse event serious?**

**If Yes, NOTIFY PFIZER IMMEDIATELY.**

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

Date	Location	User	Value	Reason
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090177e196d6f285\Final\Final On: 22-Apr-2021 02:12 (GMT)



**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

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

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

**Site No:** 1231

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

**Subject No:** 12314894

**Subject Initials:** ---

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

**Generated Time (GMT):** 19-Apr-2021 21:04

Oct-09-2020 13:39:53 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry
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**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
Oct-09-2020 13:39:53 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

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

Date	Location	User	Value	Reason
Oct-09-2020 13:39:53 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NOT RELATED If Not Related to study treatment(s), this event is due to:  OTHER  <i>If Other, specify:</i>  Unkonwn	Initial Entry

**10. Latest Action Taken with Study Treatment:**

Date	Location	User	Value	Reason
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090177e196d6f285\Final\Final On: 22-Apr-2021 02:12 (GMT)

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

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

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

**Site No:** 1231

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

**Subject No:** 12314894

**Subject Initials:** ---

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

**Generated Time (GMT):** 19-Apr-2021 21:04

Oct-09-2020 13:39:53 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NOT APPLICABLE	Initial Entry
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**11. Was a Concomitant Medication given?**

Date	Location	User	Value	Reason
Oct-09-2020 13:39:53 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

**12. Was a Non-Drug Treatment given?**

Date	Location	User	Value	Reason
Oct-09-2020 13:39:53 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

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

Date	Location	User	Value	Reason
Oct-09-2020 13:39:53 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> RECOVERED/RESOLVED	Initial Entry

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

090177e196d6f285\Final\Final On: 22-Apr-2021 02:12 (GMT)

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

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

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

**Site No:** 1231

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

**Subject No:** 12314894

**Subject Initials:** ---

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

**Generated Time (GMT):** 19-Apr-2021 21:04

Date	Location	User	Value	Reason
Oct-09-2020 13:39:53 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**Header Text:** c4591001

**Visit:** V201\_SURVEIL\_CONSENT - **Form:** DATE OF VISIT - eCRF Audit Trail History  
Unscheduled

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

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

**Subject No:** 12314894 **Subject Initials:** ---

**Generated By:** (b) (4) **Generated Time (GMT):** 19-Apr-2021 21:04

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*1. Date of Visit*

Date	Location	User	Value	Reason
Feb-05-2021 14:56:01 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	<b>Data Entry:</b> Feb/5/2021	Initial Entry

**Header Text:** c4591001

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

**Form:** INFORMED CONSENT - ASYMPTOMATIC  
SURVEILLANCE - eCRF Audit Trail History

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

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

**Site No:** 1231

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

**Subject No:** 12314894

**Subject Initials:** ---

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

**Generated Time (GMT):** 19-Apr-2021 21:04

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*1. Consent Was:*

Date	Location	User	Value	Reason
Feb-05-2021 14:56:08 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> OBTAINED Date Written Con- sent Obtained  Feb/5/2021	Initial Entry

090177e196d6f285\Final\Final On: 22-Apr-2021 02:12 (GMT)

**Header Text:** c4591001

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

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

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

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

**Site No:** 1231

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

**Subject No:** 12314894

**Subject Initials:** ---

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

**Generated Time (GMT):** 19-Apr-2021 21:04

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**1. Data Origin**

Date	Location	User	Value	Reason
Feb-05-2021 14:56:15 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SITE	Initial Entry

**2. Sample Type**

Date	Location	User	Value	Reason
Feb-05-2021 14:56:15 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SERUM	Initial Entry

**3. Sample Collected?**

Date	Location	User	Value	Reason
Feb-06-2021 12:20:54 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Feb-05-2021 14:56:15 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered.

090177e196d6f285\Final\Final On: 22-Apr-2021 02:12 (GMT)

Header Text: c4591001

Visit: V201\_SURVEIL\_CONSENT -  
Unscheduled

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1231

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

Subject No: 12314894

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 19-Apr-2021 21:04

				Please review and correct as appropriate.
Feb-05-2021 14:56:15 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES Date of Collection:  Feb/5/2021	Initial Entry

5.a

Date	Location	User	Value	Reason
Feb-06-2021 12:20:54 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sample I BNTRT D: 7	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Feb-06-2021 12:20:54 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BNTRT7	Initial Entry

5.b

Date	Location	User	Value	Reason
Feb-08-2021 10:25:15 (UTC-03:00) City	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sample I BHXH1	Initial Entry

090177e196d6f285\Final\Final On: 22-Apr-2021 02:12 (GMT)

**Header Text:** c4591001

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

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

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

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

**Site No:** 1231

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

**Subject No:** 12314894

**Subject Initials:** ---

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

**Generated Time (GMT):** 19-Apr-2021 21:04

of Buenos Aires

**D:** 1

**5.b Sample ID**

Date	Location	User	Value	Reason
Feb-08-2021 10:25:15 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BHXH11	Initial Entry

**5.c**

Date	Location	User	Value	Reason
Feb-08-2021 12:21:47 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <del>Sample I BPTH</del> <b>D:</b> 4F	Transcription Error <b>(DELETED)</b>
Feb-08-2021 11:50:09 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sample I BPTH <b>D:</b> 4F	Initial Entry

090177e196d6f285\Final\Final On: 22-Apr-2021 02:12 (GMT)



**Header Text:** c4591001

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

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

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

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

**Site No:** 1231

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

**Subject No:** 12314894

**Subject Initials:** ---

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

**Generated Time (GMT):** 19-Apr-2021 21:04

**5.c Sample ID**

Date	Location	User	Value	Reason
Feb-08-2021 12:21:47 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BPTH4F	Transcription Error (DELETED)
Feb-08-2021 11:50:09 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BPTH4F	Initial Entry

**5.d**

Date	Location	User	Value	Reason
Feb-08-2021 14:56:49 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sample I BNTRS D: G	Initial Entry

**5.d Sample ID**

Date	Location	User	Value	Reason
Feb-08-2021 14:56:49 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BNTRSG	Initial Entry

090177e196d6f285\Final\Final On: 22-Apr-2021 02:12 (GMT)

**Header Text:** c4591001

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

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

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

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

**Site No:** 1231

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

**Subject No:** 12314894

**Subject Initials:** ---

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

**Generated Time (GMT):** 19-Apr-2021 21:04

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**1. Data Origin**

Date	Location	User	Value	Reason
Feb-05-2021 17:25:31 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SITE	Initial Entry

**2. Sample Type**

Date	Location	User	Value	Reason
Feb-05-2021 17:25:31 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> NASAL_SWAB	Initial Entry

**3. Sample Collected?**

Date	Location	User	Value	Reason
Feb-08-2021 12:38:12 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Feb-08-2021 08:59:17 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	'Sample Collected?' is Yes, however no barcodes are entered.

090177e196d6f285\Final\Final On: 22-Apr-2021 02:12 (GMT)

**Header Text:** c4591001**Visit:** V201\_SURVEIL\_CONSENT -  
Unscheduled**Form:** ELECTRONIC SAMPLE TRACKING - NASAL  
SWAB - eCRF Audit Trail History**Form Version:** 22-Apr-2020 21:03**Form Status:** Data Complete, Frozen, Verified**Site No:** 1231**Site Name:** (1231) Hospital Militar Central Cirujano  
Mayor Dr. Cosme Argerich**Subject No:** 12314894**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 19-Apr-2021 21:04

				Please review and correct as appropriate.
Feb-05-2021 17:25:31 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Feb-05-2021 17:25:31 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES Date of Collection:  Feb/5/2021	Initial Entry

**5.a**

Date	Location	User	Value	Reason
Feb-08-2021 12:38:12 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample I</b> BPTH4 <b>D:</b> F	Initial Entry

**5.a Sample ID**

Date	Location	User	Value	Reason
Feb-08-2021 12:38:12 (UTC-03:00) City	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BPTH4F	Initial Entry

**Header Text:** c4591001

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

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

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

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

**Site No:** 1231

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

**Subject No:** 12314894

**Subject Initials:** ---

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

**Generated Time (GMT):** 19-Apr-2021 21:04

of Buenos Aires				
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**Header Text:** c4591001

**Visit:** V202\_SURVEIL\_SWAB 1 -  
Unscheduled Visit on Feb/17/2021

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

**Site No:** 1231

**Subject No:** 12314894

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

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

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

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

**Subject Initials:** ---

**Generated Time (GMT):** 19-Apr-2021 21:04

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**1. Date of Visit**

Date	Location	User	Value	Reason
Feb-18-2021 17:10:01 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Feb/17/2021	Initial Entry

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

Date	Location	User	Value	Reason
Feb-18-2021 17:10:01 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> SSWAB_WEEK2	Initial Entry

090177e196d6f285\Final\Final On: 22-Apr-2021 02:12 (GMT)

**Header Text:** c4591001

**Visit:** V202\_SURVEIL\_SWAB 1 -  
Unscheduled Visit on Feb/17/2021

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

**Site No:** 1231

**Subject No:** 12314894

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

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

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

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

**Subject Initials:** ---

**Generated Time (GMT):** 19-Apr-2021 21:04

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**1. Data Origin**

Date	Location	User	Value	Reason
Feb-18-2021 17:10:23 (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-18-2021 17:10:23 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NASAL_SWAB	Initial Entry

**3. Sample Collected?**

Date	Location	User	Value	Reason
Feb-18-2021 17:10:41 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Feb-18-2021 17:10:23 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered.

090177e196d6f285\Final\Final On: 22-Apr-2021 02:12 (GMT)

**Header Text:** c4591001

**Visit:** V202\_SURVEIL\_SWAB 1 -  
Unscheduled Visit on Feb/17/2021

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

**Site No:** 1231

**Subject No:** 12314894

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

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

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

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

**Subject Initials:** ---

**Generated Time (GMT):** 19-Apr-2021 21:04

				Please review and correct as appropriate.
Feb-18-2021 17:10:23 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES Date of Collection :  Feb/17/2021	Initial Entry

**5.a**

Date	Location	User	Value	Reason
Feb-18-2021 17:10:41 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample I</b> BRMD8 <b>D:</b> Y	Initial Entry

**5.a Sample ID**

Date	Location	User	Value	Reason
Feb-18-2021 17:10:41 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BRMD8Y	Initial Entry

090177e196d6f285\Final\Final On: 22-Apr-2021 02:12 (GMT)

**Header Text:** c4591001

**Visit:** V202\_SURVEIL\_SWAB 2 -  
Unscheduled Visit on Mar/05/2021

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

**Site No:** 1231

**Subject No:** 12314894

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

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

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

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

**Subject Initials:** ---

**Generated Time (GMT):** 19-Apr-2021 21:04

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**1. Date of Visit**

Date	Location	User	Value	Reason
Mar-08-2021 11:39:15 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Mar/5/2021	Initial Entry

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

Date	Location	User	Value	Reason
Mar-08-2021 11:39:15 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> SSWAB_WEEK4	Initial Entry



**Header Text:** c4591001

**Visit:** V202\_SURVEIL\_SWAB 2 -  
Unscheduled Visit on Mar/05/2021

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

**Site No:** 1231

**Subject No:** 12314894

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

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

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

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

**Subject Initials:** ---

**Generated Time (GMT):** 19-Apr-2021 21:04

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**1. Data Origin**

Date	Location	User	Value	Reason
Mar-08-2021 11:39:28 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SITE	Initial Entry

**2. Sample Type**

Date	Location	User	Value	Reason
Mar-08-2021 11:39:28 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NASAL_SWAB	Initial Entry

**3. Sample Collected?**

Date	Location	User	Value	Reason
Mar-08-2021 11:41:13 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Mar-08-2021 11:39:28 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered.

090177e196d6f285\Final\Final On: 22-Apr-2021 02:12 (GMT)

**Header Text:** c4591001

**Visit:** V202\_SURVEIL\_SWAB 2 -  
Unscheduled Visit on Mar/05/2021

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

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

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

**Site No:** 1231

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

**Subject No:** 12314894

**Subject Initials:** ---

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

**Generated Time (GMT):** 19-Apr-2021 21:04

				Please review and correct as appropriate.
Mar-08-2021 11:39:28 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES Date of Collection : Mar/5/2021	Initial Entry

**5.a**

Date	Location	User	Value	Reason
Mar-08-2021 11:41:13 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample ID BR1LZ</b> : 3	Initial Entry

**5.a Sample ID**

Date	Location	User	Value	Reason
Mar-08-2021 11:41:13 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BR1LZ3	Initial Entry

090177e196d6f285\Final\Final On: 22-Apr-2021 02:12 (GMT)

**Header Text:** c4591001

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

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

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

**Subject No:** 12314894      **Subject Initials:** ---

**Generated By:** (b) (4)      **Generated Time (GMT):** 19-Apr-2021 21:04

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*1. Date of Visit*

Date	Location	User	Value	Reason
Mar-06-2021 10:54:37 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Mar/5/2021	Initial Entry

090177e196d6f285\Final\Final On: 22-Apr-2021 02:12 (GMT)

**Header Text:** c4591001

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

**Form Version:** 10-Dec-2020 02:25 **Form Status:** Data Complete, Frozen

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

**Subject No:** 12314894 **Subject Initials:** ---

**Generated By:** (b) (4) **Generated Time (GMT):** 19-Apr-2021 21:04

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

Date	Location	User	Value	Reason
Mar-06-2021 10:55:03 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Delete d	Close Auto Query
Mar-06-2021 10:54:49 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candid ate	The response indicates participant was unblinded, however the TREATMENT UNBLINDED date is missing in the DISP visit. Please complete this date.
Mar-06-2021 10:54:49 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Participant is wi lling to return fo r Vaccination 3 Participant is:  eligible per o ther protocol allowance(s)	Initial Entry

090177e196d6f285\Final\Final On: 22-Apr-2021 02:12 (GMT)

**Header Text:** c4591001

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

**Form Version:** 10-Dec-2020 02:25 **Form Status:** Data Complete, Frozen

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

**Subject No:** 12314894 **Subject Initials:** ---

**Generated By:** (b) (4) **Generated Time (GMT):** 19-Apr-2021 21:04

			and confirmed to have received only placebo at Vaccination 1/2	
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**Header Text:** c4591001

**Visit:** Disposition - Unscheduled

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

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

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

**Site No:** 1231

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

**Subject No:** 12314894

**Subject Initials:** ---

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

**Generated Time (GMT):** 19-Apr-2021 21:04

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**1. Date Treatment Unblinded :**

Date	Location	User	Value	Reason
Mar-06-2021 10:55:03 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Mar/5/2021	Initial Entry

**2. Primary Reason for Unblinding:**

Date	Location	User	Value	Reason
Mar-06-2021 10:55:03 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> ASSESS ELIGIBILITY FOR ADDITIONAL VACCINATION	Initial Entry

090177e196d6f285\Final\Final On: 22-Apr-2021 02:12 (GMT)

**Header Text:** c4591001

**Visit:** V101\_VAX3

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

**Site No:** 1231

**Subject No:** 12314894

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

**Form:** DATE OF VISIT - 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):** 19-Apr-2021 21:04

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*1. Date of Visit*

Date	Location	User	Value	Reason
Mar-10-2021 11:13:17 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Mar/9/2021	Initial Entry

**Header Text:** c4591001

**Visit:** V101\_VAX3

**Form:** INFORMED CONSENT - FURTHER  
VACCINATION - eCRF Audit Trail History

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

**Form Status:** Data Complete, Verified

**Site No:** 1231

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

**Subject No:** 12314894

**Subject Initials:** ---

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

**Generated Time (GMT):** 19-Apr-2021 21:04

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*1. Consent Was:*

Date	Location	User	Value	Reason
Mar-10-2021 11:13:28 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> OBTAINED Date Written Consent Obtained  Mar/9/2021	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, Verified

**Site No:** 1231

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

**Subject No:** 12314894

**Subject Initials:** ---

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

**Generated Time (GMT):** 19-Apr-2021 21:04

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

Date	Location	User	Value	Reason
Mar-10-2021 11:14:00 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Mar/9/2021	Initial Entry

**2. Phase of Disposition:**

Date	Location	User	Value	Reason
Mar-10-2021 11:14:00 (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
Mar-10-2021 11:14:00 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> COMPLETED	Initial Entry

090177e196d6f285\Final\Final On: 22-Apr-2021 02:12 (GMT)

**Header Text:** c4591001

**Visit:** V101\_VAX3

**Form:** LAB URINALYSIS - PREGNANCY TEST - eCRF Audit Trail History

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

**Form Status:** Data Complete, Verified

**Site No:** 1231

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

**Subject No:** 12314894

**Subject Initials:** ---

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

**Generated Time (GMT):** 19-Apr-2021 21:04

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**1. Lab Panel:**

Date	Location	User	Value	Reason
Mar-10-2021 11:14:13 (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
Mar-10-2021 11:14:13 (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
Mar-10-2021 11:14:13 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Mar/9/2021	Initial Entry

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

Date	Location	User	Value	Reason
Mar-10-2021	ACV0PFEINFP6000	auto calc	<b>Data Entry:</b>	Initial Entry

090177e196d6f285\Final\Final On: 22-Apr-2021 02:12 (GMT)

Header Text: c4591001

Visit: V101\_VAX3

Form: LAB URINALYSIS - PREGNANCY TEST - eCRF Audit Trail History

Form Version: 20-Feb-2021 02:14

Form Status: Data Complete, Verified

Site No: 1231

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

Subject No: 12314894

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 19-Apr-2021 21:04

11:14:13  
(UTC-03:00) City  
of Buenos Aires

(autocalc)

STUDY SITE

5. Specimen Type:

Date	Location	User	Value	Reason
Mar-10-2021 11:14:13 (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
Mar-10-2021 11:14:13 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Sponsor-</b> 113 <b>Defined I</b> <b>dentifier:</b> <b>Test::</b> Choriogon adotropin Beta_PX11 3 <b>Result::</b> NEGATIV E <b>Not Done</b> ::	Initial Entry

6.a Sponsor ID:

Date	Location	User	Value	Reason
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090177e196d6f285\Final\Final On: 22-Apr-2021 02:12 (GMT)

**Header Text:** c4591001

**Visit:** V101\_VAX3

**Form:** LAB URINALYSIS - PREGNANCY TEST -  
eCRF Audit Trail History

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

**Form Status:** Data Complete, Verified

**Site No:** 1231

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

**Subject No:** 12314894

**Subject Initials:** ---

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

**Generated Time (GMT):** 19-Apr-2021 21:04

Mar-10-2021 11:14:13 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 113	Initial Entry
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**6.a Test:**

Date	Location	User	Value	Reason
Mar-10-2021 11:14:13 (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
Mar-10-2021 11:14:13 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NEGATIVE	Initial Entry

090177e196d6f285\Final\Final On: 22-Apr-2021 02:12 (GMT)

**Header Text:** c4591001

**Visit:** V101\_VAX3

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

**Site No:** 1231

**Subject No:** 12314894

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

**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - 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):** 19-Apr-2021 21:04

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**1. Data Origin**

Date	Location	User	Value	Reason
Mar-10-2021 11:14:24 (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
Mar-10-2021 11:14:24 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SERUM	Initial Entry

**3. Sample Collected?**

Date	Location	User	Value	Reason
Mar-10-2021 11:18:05 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Mar-10-2021 11:14:24 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered.

090177e196d6f285\Final\Final On: 22-Apr-2021 02:12 (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, Verified

Site No: 1231

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

Subject No: 12314894

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 19-Apr-2021 21:04

				Please review and correct as appropriate.
Mar-10-2021 11:14:24 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES Date of Collection:  Mar/9/2021	Initial Entry

5.a

Date	Location	User	Value	Reason
Mar-10-2021 11:18:05 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample I</b> BRYXB <b>D:</b> D	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Mar-10-2021 11:18:05 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BRYXBD	Initial Entry

5.b

Date	Location	User	Value	Reason
Mar-10-2021 12:33:53 (UTC-03:00) City	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample I</b> BR1PK	Initial Entry

090177e196d6f285\Final\Final On: 22-Apr-2021 02:12 (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, Verified

**Site No:** 1231

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

**Subject No:** 12314894

**Subject Initials:** ---

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

**Generated Time (GMT):** 19-Apr-2021 21:04

of Buenos Aires			<b>D:</b>	P	
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**5.b Sample ID**

Date	Location	User	Value	Reason
Mar-10-2021 12:33:53 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BR1PKP	Initial Entry

**5.c**

Date	Location	User	Value	Reason
Mar-10-2021 12:34:02 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample I</b> BRYX <b>D:</b> B6	Initial Entry

**5.c Sample ID**

Date	Location	User	Value	Reason
Mar-10-2021 12:34:02 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BRYXB6	Initial Entry

090177e196d6f285\Final\Final On: 22-Apr-2021 02:12 (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, Verified

**Site No:** 1231

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

**Subject No:** 12314894

**Subject Initials:** ---

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

**Generated Time (GMT):** 19-Apr-2021 21:04

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**1. Data Origin**

Date	Location	User	Value	Reason
Mar-10-2021 11:14:38 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SITE	Initial Entry

**2. Sample Type**

Date	Location	User	Value	Reason
Mar-10-2021 11:14:38 (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
Mar-10-2021 12:23:25 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Mar-10-2021 11:14:38 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered.

090177e196d6f285\Final\Final On: 22-Apr-2021 02:12 (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, Verified

**Site No:** 1231

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

**Subject No:** 12314894

**Subject Initials:** ---

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

**Generated Time (GMT):** 19-Apr-2021 21:04

				Please review and correct as appropriate.
Mar-10-2021 11:14:38 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES Date of Collection:  Mar/9/2021	Initial Entry

**5.a**

Date	Location	User	Value	Reason
Mar-10-2021 12:23:25 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sample I BR22V D: 1	Initial Entry

**5.a Sample ID**

Date	Location	User	Value	Reason
Mar-10-2021 12:23:25 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BR22V1	Initial Entry

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**Header Text:** c4591001

**Visit:** V101\_VAX3

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

**Site No:** 1231

**Subject No:** 12314894

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

**Form:** VACCINATION - 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):** 19-Apr-2021 21:04

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

Date	Location	User	Value	Reason
Mar-10-2021 11:15:01 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**2. Treatment Name**

Date	Location	User	Value	Reason
Mar-10-2021 11:15:01 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> BNT162b2	Initial Entry

**3. Formulation:**

Date	Location	User	Value	Reason
Mar-10-2021 11:15:01 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> INJECTION	Initial Entry

**4. Dose Date Time:**

Date	Location	User	Value	Reason
Mar-10-2021 11:15:01	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Mar/9/2021 17:41	Initial Entry

090177e196d6f285\Final\Final On: 22-Apr-2021 02:12 (GMT)

**Header Text:** c4591001

**Visit:** V101\_VAX3

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

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

**Form Status:** Data Complete, Verified

**Site No:** 1231

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

**Subject No:** 12314894

**Subject Initials:** ---

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

**Generated Time (GMT):** 19-Apr-2021 21:04

(UTC-03:00) City of Buenos Aires

(b) (4), (b) (6)

**5. Anatomical Location:**

Date	Location	User	Value	Reason
Mar-10-2021 11:15:01 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> DELTOID MUSCLE	Initial Entry

**6. Body Side:**

Date	Location	User	Value	Reason
Mar-10-2021 11:15:01 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> LEFT	Initial Entry

**7. Route:**

Date	Location	User	Value	Reason
Mar-10-2021 11:15:01 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> INTRAMUSCULAR	Initial Entry

**8. Actual Dose:**

Date	Location	User	Value	Reason
Mar-10-2021 11:15:01	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 30.0	Initial Entry

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**Header Text:** c4591001

**Visit:** V101\_VAX3

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

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

**Form Status:** Data Complete, Verified

**Site No:** 1231

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

**Subject No:** 12314894

**Subject Initials:** ---

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

**Generated Time (GMT):** 19-Apr-2021 21:04

(UTC-03:00) City of Buenos Aires

**9. Unit:**

Date	Location	User	Value	Reason
Mar-10-2021 11:15:01 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> ug	Initial Entry

**10. Timeframe Subject Was Observed**

Date	Location	User	Value	Reason
Mar-10-2021 11:15:01 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 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
Mar-10-2021 11:15:01 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

090177e196d6f285\Final\Final On: 22-Apr-2021 02:12 (GMT)

**Header Text:** c4591001

**Visit:** Subject Status - Unscheduled

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

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

**Form Status:** Data Complete, Verified

**Site No:** 1231

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

**Subject No:** 12314894

**Subject Initials:** ---

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

**Generated Time (GMT):** 19-Apr-2021 21:04

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**1. Subject Status**

Date	Location	User	Value	Reason
Oct-19-2020 15:46:35 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> FOLLOW-UP	Initial Entry
Aug-28-2020 18:36:45 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> ENROLLED/RANDOMIZED	Initial Entry
Aug-28-2020 18:35:11 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SCREENED	Initial Entry

**2. Subject Status Date**

Date	Location	User	Value	Reason
Oct-19-2020 15:46:35 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> Oct/19/2020	Initial Entry
Aug-28-2020 18:36:45 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> Aug/28/2020	Initial Entry

090177e196d6f285\Final\Final On: 22-Apr-2021 02:12 (GMT)

**Header Text:** c4591001

**Visit:** Subject Status - Unscheduled

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

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

**Form Status:** Data Complete, Verified

**Site No:** 1231

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

**Subject No:** 12314894

**Subject Initials:** ---

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

**Generated Time (GMT):** 19-Apr-2021 21:04

Aug-28-2020 18:35:11 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> Aug/28/2020	Initial Entry
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**Header Text:** c4591001

**Visit:** Investigator Signature -  
Unscheduled

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

**Site No:** 1231

**Subject No:** 12314894

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

**Form:** CASEBOOK SIGNATURE FORM - 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):** 19-Apr-2021 21:04

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*1. Casebook Signature*

Date	Location	User	Value	Reason
Oct-26-2020 21:33:31 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Click Here to Enable	Initial Entry

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