

**Header Text:** c4591001

**Visit:** COHORT\_SELECTION

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

**Site No:** 4444

**Subject No:** 44441979

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

**Form:** COHORT\_SELECTION

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

**Site Name:** (4444) Hospital Militar Central Cirujano Mayor Dr Cosme Argerich

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 17:38

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

**Header Text:** c4591001

**Visit:** COHORT\_SELECTION

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

**Site No:** 4444

**Subject No:** 44441979

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

**Form:** MAIN INFORMED CONSENT

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

**Site Name:** (4444) Hospital Militar Central Cirujano Mayor Dr Cosme Argerich

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 17:38

[eCRF Audit Trail History](#)

**Informed Consent**

1.	Consent Was:	OBTAINED Date Written Consent Obtained Sep/25/2020
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**Header Text:** c4591001

**Visit:** COHORT\_SELECTION

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

**Site No:** 4444

**Subject No:** 44441979

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

**Form:** DEMOGRAPHY

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

**Site Name:** (4444) Hospital Militar Central Cirujano Mayor Dr Cosme Argerich

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 17:38

[eCRF Audit Trail History](#)

**Demography**

1.	Subject ID	[44441979]
2.	Birth Date:	(b) (6)/1990
3.	Sex:	FEMALE
4.	Ethnicity:	HISPANIC OR LATINO(A) OR OF SPANISH ORIGIN
5.	Race: (Check X all that apply):	WHITE
6.	Racial Designation:	

**Header Text:** c4591001

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

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

**Site No:** 4444

**Subject No:** 44441979

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

**Form:** DATE OF VISIT

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

**Site Name:** (4444) Hospital Militar Central Cirujano Mayor Dr Cosme Argerich

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 17:38

[eCRF Audit Trail History](#)

**Date of Visit**

1.	Date of Visit	Sep/25/2020
2.	Erroneous Visit	

**Header Text:** c4591001

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

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

**Site No:** 4444

**Subject No:** 44441979

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

**Form:** INCLUSION/EXCLUSION CRITERIA

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

**Site Name:** (4444) Hospital Militar Central Cirujano Mayor Dr Cosme Argerich

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 17:38

**Form Comments**

**Inclusion Criteria Not Met**

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

**Exclusion Criteria Met**

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

**Header Text:** c4591001

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

**Form Version:** 15-Sep-2020 21:52

**Site No:** 4444

**Subject No:** 44441979

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

**Form:** DISPOSITION - SCREENING

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

**Site Name:** (4444) Hospital Militar Central Cirujano Mayor Dr Cosme Argerich

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 17:38

[eCRF Audit Trail History](#)

**Disposition - Screening**

1.	Date of Completion/Discontinuation /Death	Sep/25/2020
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:** 4444

**Subject No:** 44441979

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

**Form:** GENERAL MEDICAL HISTORY

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

**Site Name:** (4444) Hospital Militar Central Cirujano Mayor Dr Cosme Argerich

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 17:38

[Form Comments](#)

**Medical History Details**

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

090177e196ae2e60\Final\Final On: 01-Apr-2021 03:11 (GMT)

**Header Text:** c4591001

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

**Form Version:** 15-Sep-2020 21:57

**Site No:** 4444

**Subject No:** 44441979

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

**Form:** HIV STATUS

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

**Site Name:** (4444) Hospital Militar Central Cirujano Mayor Dr Cosme Argerich

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 17:38

[eCRF Audit Trail History](#)

**HIV Status**

1.	Select appropriate response - What is the subject HIV status?	The subject is NOT known to be HIV POSITIVE
----	---	---



**Header Text:** c4591001

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

**Form Version:** 15-Sep-2020 21:56

**Site No:** 4444

**Subject No:** 44441979

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

**Form:** VITAL SIGNS - BASELINE

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

**Site Name:** (4444) Hospital Militar Central Cirujano Mayor Dr Cosme Argerich

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 17:38

[eCRF Audit Trail History](#)

**Vital Signs**

1.	Date:	Sep/25/2020
2.	Weight:	[77.9]
3.	Unit:	kg
4.	Height:	[167.0]
5.	Unit:	cm
6.	Body Mass Index:	[27.9]

**Vital Signs Details**

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

090177e196ae2e60\Final\Final On: 01-Apr-2021 03:11 (GMT)

**Header Text:** c4591001

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

**Form Version:** 15-Sep-2020 21:51

**Site No:** 4444

**Subject No:** 44441979

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

**Form:** LAB URINALYSIS - PREGNANCY TEST

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

**Site Name:** (4444) Hospital Militar Central Cirujano Mayor Dr Cosme Argerich

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 17:38

[eCRF Audit Trail History](#)

**Lab Urinalysis**

1.	Lab Panel:	URINALYSIS
2.	Lab Sub-Panel:	PREGNANCY
3.	Collection Date:	Sep/25/2020
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:	

090177e196ae2e60\Final\Final On: 01-Apr-2021 03:11 (GMT)

**Header Text:** c4591001

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

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

**Site No:** 4444

**Subject No:** 44441979

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

**Form:** RANDOMIZATION

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

**Site Name:** (4444) Hospital Militar Central Cirujano Mayor Dr Cosme Argerich

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 17:38

[eCRF Audit Trail History](#)

**Disposition**

1.	Randomization Date :	Sep/25/2020
2.	Randomization Number:	[100195]
3.	Randomization Group:	[ ]

**Header Text:** c4591001

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

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

**Site No:** 4444

**Subject No:** 44441979

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

**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

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

**Site Name:** (4444) Hospital Militar Central Cirujano Mayor Dr Cosme Argerich

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 17:38

[eCRF Audit Trail History](#)

**Electronic Sample Tracking**

1.	Data Origin	SITE
2.	Sample Type	SERUM
3.	Sample Collected?	YES Date of Collection: Sep/25/2020
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	[BRVRZS]
5.b	Sample ID	[BRVRZZ]
5.c	Sample ID	[BHXGJ0]

090177e196ae2e60\Final\Final On: 01-Apr-2021 03:11 (GMT)

**Header Text:** c4591001

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

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

**Site No:** 4444

**Subject No:** 44441979

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

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

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

**Site Name:** (4444) Hospital Militar Central Cirujano Mayor Dr Cosme Argerich

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 17:38

[eCRF Audit Trail History](#)

**Electronic Sample Tracking**

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB
3.	Sample Collected?	YES Date of Collection: Sep/25/2020
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	[BPWCOM]
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090177e196ae2e60\Final\Final On: 01-Apr-2021 03:11 (GMT)

**Header Text:** c4591001

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

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

**Site No:** 4444

**Subject No:** 44441979

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

**Form:** VACCINATION

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

**Site Name:** (4444) Hospital Militar Central Cirujano Mayor Dr Cosme Argerich

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 17:38

**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/25/2020 16:20
5.	Anatomical Location:	DELTOID MUSCLE
6.	Body Side:	LEFT
7.	Route:	INTRAMUSCULAR
8.	Actual Dose:	[ ]
9.	Unit:	
10.	Timeframe Subject Was Observed	THE PROTOCOL SPECIFIED OBSERVATION PERIOD
11.	Was the subject observed for at least the protocol specified observation period after investigational product administration?	YES

090177e196ae2e60\Final\Final On: 01-Apr-2021 03:11 (GMT)

**Header Text:** c4591001

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

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

**Site No:** 4444

**Subject No:** 44441979

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

**Form:** REACTOGENICITY DIARY

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

**Site Name:** (4444) Hospital Militar Central Cirujano Mayor Dr Cosme Argerich

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 17:38

[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:** 4444

**Subject No:** 44441979

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

**Form:** DATE OF VISIT

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

**Site Name:** (4444) Hospital Militar Central Cirujano Mayor Dr Cosme Argerich

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 17:38

[Form Comments](#)

[eCRF Audit Trail History](#)

**Date of Visit**

1.	Date of Visit	Not Done _____ //	<a href="#">Comments</a>
2.	Erroneous Visit	Not Done _____	<a href="#">Comments</a>



**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

**Site No:** 4444

**Subject No:** 44441979

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

**Form:** VITAL SIGNS - TEMP

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

**Site Name:** (4444) Hospital Militar Central Cirujano Mayor Dr Cosme Argerich

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 17:38

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

**Vital Signs**

1.	Date:	Not Done _____ //	<a href="#">Comments</a>
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**Vital Signs Details**

2.a	Record Identifier:	Not Done _____ 1	
	Temperature:	Not Done _____ [ ]	<a href="#">Comments</a>
	Unit:	Not Done _____	<a href="#">Comments</a>
	Temperature Location:	Not Done _____	<a href="#">Comments</a>

090177e196ae2e60\Final\Final On: 01-Apr-2021 03:11 (GMT)

Header Text: c4591001

Visit: V2\_VAX2\_L

Form Version: 15-Sep-2020 21:51

Site No: 4444

Subject No: 44441979

Generated By: (b) (4)

Form: LAB URINALYSIS - PREGNANCY TEST

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (4444) Hospital Militar Central Cirujano Mayor Dr Cosme Argerich

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 17:38

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

**Lab Urinalysis**

1.	Lab Panel:	Not Done _____	<a href="#">Comments</a>
2.	Lab Sub-Panel:	Not Done _____	<a href="#">Comments</a>
3.	Collection Date:	Not Done _____ //	<a href="#">Comments</a>
4.	Laboratory Name and Address (Derived)	Not Done _____ [ ]	<a href="#">Comments</a>
5.	Specimen Type:	Not Done _____	<a href="#">Comments</a>

**Lab Result**

6.a	Sponsor ID:	Not Done _____ [ ]	<a href="#">Comments</a>
	Test:	Not Done _____ Choriogonadotropin Beta_PX113	
	Result:	Not Done _____	<a href="#">Comments</a>
	Not Done:	Not Done _____	<a href="#">Comments</a>

090177e196ae2e60\Final\Final On: 01-Apr-2021 03:11 (GMT)

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

**Site No:** 4444

**Subject No:** 44441979

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

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

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

**Site Name:** (4444) Hospital Militar Central Cirujano Mayor Dr Cosme Argerich

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 17:38

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

**Electronic Sample Tracking**

1.	Data Origin	Not Done _____	<a href="#">Comments</a>
2.	Sample Type	Not Done _____	<a href="#">Comments</a>
3.	Sample Collected?	Not Done _____	<a href="#">Comments</a>
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	Not Done _____ [ ]	<a href="#">Comments</a>

**Aliquot**

Please enter barcode for each aliquot.

5.	Sample ID	Not Done _____ [ ]
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090177e196ae2e60\Final\Final On: 01-Apr-2021 03:11 (GMT)

Header Text: c4591001

Visit: V2\_VAX2\_L

Form Version: 22-Apr-2020 21:04

Site No: 4444

Subject No: 44441979

Generated By: (b) (4)

Form: VACCINATION

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (4444) Hospital Militar Central Cirujano Mayor Dr Cosme Argerich

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 17:38

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

**Vaccination**

1.	Was there a temporary delay of vaccination?	Not Done _____	<a href="#">Comments</a>
2.	Treatment Name	Not Done _____ [ ]	<a href="#">Comments</a>
3.	Formulation:	Not Done _____	<a href="#">Comments</a>
4.	Dose Date Time:	Not Done _____ //	<a href="#">Comments</a>
5.	Anatomical Location:	Not Done _____	<a href="#">Comments</a>
6.	Body Side:	Not Done _____	<a href="#">Comments</a>
7.	Route:	Not Done _____	<a href="#">Comments</a>
8.	Actual Dose:	Not Done _____ [ ]	<a href="#">Comments</a>
9.	Unit:	Not Done _____	<a href="#">Comments</a>
10.	Timeframe Subject Was Observed	Not Done _____	<a href="#">Comments</a>
11.	Was the subject observed for at least the protocol specified observation period after investigational product administration?	Not Done _____	<a href="#">Comments</a>

090177e196ae2e60\Final\Final On: 01-Apr-2021 03:11 (GMT)

**Header Text:** c4591001

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

**Form:** DATE OF VISIT

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

**Form Status:** Not Started

**Site No:** 4444

**Site Name:** (4444) Hospital Militar Central Cirujano Mayor Dr Cosme Argerich

**Subject No:** 44441979

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 17:38

**Date of Visit**

1.	Date of Visit	//
2.	Erroneous Visit	

**Header Text:** c4591001

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

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

**Site No:** 4444

**Subject No:** 44441979

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

**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

**Form Status:** Not Started

**Site Name:** (4444) Hospital Militar Central Cirujano Mayor Dr Cosme Argerich

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 17:38

**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:** V4\_MONTH6\_L

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

**Site No:** 4444

**Subject No:** 44441979

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

**Form:** DATE OF VISIT

**Form Status:** Not Started

**Site Name:** (4444) Hospital Militar Central Cirujano Mayor Dr Cosme Argerich

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 17:38

**Date of Visit**

1.	Date of Visit	//
2.	Erroneous Visit	

**Header Text:** c4591001

**Visit:** V4\_MONTH6\_L

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

**Site No:** 4444

**Subject No:** 44441979

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

**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

**Form Status:** Not Started

**Site Name:** (4444) Hospital Militar Central Cirujano Mayor Dr Cosme Argerich

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 17:38

**Electronic Sample Tracking**

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

**Aliquot**

Please enter barcode for each aliquot.

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

**Visit:** V5\_MONTH12\_L

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

**Site No:** 4444

**Subject No:** 44441979

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

**Form:** DATE OF VISIT

**Form Status:** Not Started

**Site Name:** (4444) Hospital Militar Central Cirujano Mayor Dr Cosme Argerich

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 17:38

**Date of Visit**

1.	Date of Visit	//
2.	Erroneous Visit	

**Header Text:** c4591001

**Visit:** V5\_MONTH12\_L

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

**Site No:** 4444

**Subject No:** 44441979

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

**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

**Form Status:** Not Started

**Site Name:** (4444) Hospital Militar Central Cirujano Mayor Dr Cosme Argerich

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 17:38

**Electronic Sample Tracking**

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

**Aliquot**

Please enter barcode for each aliquot.

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

**Visit:** V6\_MONTH24\_L

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

**Site No:** 4444

**Subject No:** 44441979

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

**Form:** DATE OF VISIT

**Form Status:** Not Started

**Site Name:** (4444) Hospital Militar Central Cirujano Mayor Dr Cosme Argerich

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 17:38

**Date of Visit**

1.	Date of Visit	//
2.	Erroneous Visit	

**Header Text:** c4591001

**Visit:** V6\_MONTH24\_L

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

**Site No:** 4444

**Subject No:** 44441979

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

**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

**Form Status:** Not Started

**Site Name:** (4444) Hospital Militar Central Cirujano Mayor Dr Cosme Argerich

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 17:38

**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:** DATE OF VISIT - ILLNESS ONSET

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

**Form Status:** Not Started

**Site No:** 4444

**Site Name:** (4444) Hospital Militar Central Cirujano Mayor Dr Cosme Argerich

**Subject No:** 44441979

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 17:38

**Date of Visit**

1.	Date of Visit	//
2.	Erroneous Visit	

**COVID-19 Illness Visit**

3.	COVID-19 Illness Visit:	
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090177e196ae2e60\Final\Final On: 01-Apr-2021 03:11 (GMT)

**Header Text:** c4591001

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

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

**Form Status:** Not Started

**Site No:** 4444

**Site Name:** (4444) Hospital Militar Central Cirujano Mayor Dr Cosme Argerich

**Subject No:** 44441979

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 17:38

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

**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:** 4444

**Site Name:** (4444) Hospital Militar Central Cirujano Mayor Dr Cosme Argerich

**Subject No:** 44441979

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 17:38

**Electronic Sample Tracking**

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

**Aliquot**

Please enter barcode for each aliquot.

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

**Header Text:** c4591001

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

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

**Form Status:** Not Started

**Site No:** 4444

**Site Name:** (4444) Hospital Militar Central Cirujano Mayor Dr Cosme Argerich

**Subject No:** 44441979

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 17:38

**Electronic Sample Tracking**

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

**Aliquot**

Please enter barcode for each aliquot.

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

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

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

**Form Status:** Not Started

**Site No:** 4444

**Site Name:** (4444) Hospital Militar Central Cirujano Mayor Dr Cosme Argerich

**Subject No:** 44441979

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 17:38

**Health Care Utilization**

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

**Health Care Utilization Other**

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

**Health Care Utilization**

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

090177e196ae2e60\Final\Final On: 01-Apr-2021 03:11 (GMT)

**Header Text:** c4591001

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

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

**Form Status:** Not Started

**Site No:** 4444

**Site Name:** (4444) Hospital Militar Central Cirujano Mayor Dr Cosme Argerich

**Subject No:** 44441979

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 17:38

**Illness Details**

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

**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:** 4444

**Site Name:** (4444) Hospital Militar Central Cirujano Mayor Dr Cosme Argerich

**Subject No:** 44441979

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 17:38

**Date of Visit**

1.	Date of Visit	//
2.	Erroneous Visit	

**COVID-19 Illness Visit**

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

090177e196ae2e60\Final\Final On: 01-Apr-2021 03:11 (GMT)

**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:** 4444

**Site Name:** (4444) Hospital Militar Central Cirujano Mayor Dr Cosme Argerich

**Subject No:** 44441979

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 17:38

**Electronic Sample Tracking**

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

**Aliquot**

Please enter barcode for each aliquot.

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

**Header Text:** c4591001

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

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

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

**Form Status:** Not Started

**Site No:** 4444

**Site Name:** (4444) Hospital Militar Central Cirujano Mayor Dr Cosme Argerich

**Subject No:** 44441979

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 17:38

**Date of Visit**

1.	Date of Visit	//
2.	Erroneous Visit	

**COVID-19 Repeat Swab**

3.	COVID-19 Repeat Swab:	
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090177e196ae2e60\Final\Final On: 01-Apr-2021 03:11 (GMT)

**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:** 4444

**Site Name:** (4444) Hospital Militar Central Cirujano Mayor Dr Cosme Argerich

**Subject No:** 44441979

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 17:38

**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 Visit

**Form:** DATE OF VISIT

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

**Form Status:** Not Started

**Site No:** 4444

**Site Name:** (4444) Hospital Militar Central Cirujano Mayor Dr Cosme Argerich

**Subject No:** 44441979

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 17:38

**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:** 4444

**Site Name:** (4444) Hospital Militar Central Cirujano Mayor Dr Cosme Argerich

**Subject No:** 44441979

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 17:38

**Unplanned Assessments**

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



**Header Text:** c4591001

**Visit:** Logs

**Form:** ADVERSE EVENT REPORT

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

**Site No:** 4444

**Site Name:** (4444) Hospital Militar Central Cirujano Mayor Dr Cosme Argerich

**Subject No:** 44441979

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 17:38

#	Category	AE Identifier	Adverse Event	Start Date	Is the Adverse Event Still Ongoing	Form Instance
1.	ADVERSE EVENT	1	EXPOSURE DURING PREG NANCY	Sep/25/2020 16:20	YES	<a href="#">Repeating Pages</a>

090177e196ae2e60\Final\Final On: 01-Apr-2021 03:11 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 4444

Subject No: 44441979

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete

Site Name: (4444) Hospital Militar Central Cirujano Mayor Dr Cosme Argerich

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 17:38

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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)	[EXPOSURE DURING PREGNANCY]	
4.	Start Date Time:	Sep/25/2020 16:20	
5.	Is the adverse event still ongoing?	YES	
6.	Toxicity Grade:	Not Applicable	<a href="#">Comments</a>
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: [not applicable]	
10.	Latest Action Taken with Study Treatment:	DRUG WITHDRAWN	
11.	Was a Concomitant Medication given?	NO	
12.	Was a Non-Drug Treatment given?	NO	

090177e196ae2e60\Final\Final On: 01-Apr-2021 03:11 (GMT)

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 4444

**Subject No:** 44441979

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

**Form:** ADVERSE EVENT REPORT

**Form Status:** Data Complete

**Site Name:** (4444) Hospital Militar Central Cirujano Mayor Dr Cosme Argerich

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 17:38

13.	What was the outcome of this adverse event?:	UNKNOWN
14.	Did the adverse event cause the subject to be discontinued from the study?	NO
15.	Serious Adverse Event Number: For Pfizer Use Only	[ ]

090177e196ae2e60\Final\Final On: 01-Apr-2021 03:11 (GMT)

**Header Text:** c4591001

**Visit:** Logs

**Form:** MEDICATION ERROR

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

**Site No:** 4444

**Site Name:** (4444) Hospital Militar Central Cirujano Mayor Dr Cosme Argerich

**Subject No:** 44441979

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 17:38

#	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:** 4444

**Subject No:** 44441979

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

**Form:** MEDICATION ERROR

**Form Status:** Not Started

**Site Name:** (4444) Hospital Militar Central Cirujano Mayor Dr Cosme Argerich

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 17:38

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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	[ ]

090177e196ae2e60\Final\Final On: 01-Apr-2021 03:11 (GMT)

**Header Text:** c4591001

**Visit:** Logs

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

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

**Site No:** 4444

**Site Name:** (4444) Hospital Militar Central Cirujano Mayor Dr Cosme Argerich

**Subject No:** 44441979

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 17:38

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

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 4444

**Subject No:** 44441979

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

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

**Form Status:** Not Started

**Site Name:** (4444) Hospital Militar Central Cirujano Mayor Dr Cosme Argerich

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 17:38

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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:	//

090177e196ae2e60\Final\Final On: 01-Apr-2021 03:11 (GMT)

**Header Text:** c4591001

**Visit:** Logs

**Form:** CONCOMITANT MEDICATIONS - PROHIBITED

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

**Site No:** 4444

**Site Name:** (4444) Hospital Militar Central Cirujano Mayor Dr Cosme Argerich

**Subject No:** 44441979

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 17:38

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



**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 4444

**Subject No:** 44441979

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

**Form:** CONCOMITANT MEDICATIONS - PROHIBITED

**Form Status:** Not Started

**Site Name:** (4444) Hospital Militar Central Cirujano Mayor Dr Cosme Argerich

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 17:38

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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?	

090177e196ae2e60\Final\Final On: 01-Apr-2021 03:11 (GMT)

**Header Text:** c4591001

**Visit:** Logs

**Form:** RADIATION TREATMENT

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

**Site No:** 4444

**Site Name:** (4444) Hospital Militar Central Cirujano Mayor Dr Cosme Argerich

**Subject No:** 44441979

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 17:38

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

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 4444

**Subject No:** 44441979

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

**Form:** RADIATION TREATMENT

**Form Status:** Not Started

**Site Name:** (4444) Hospital Militar Central Cirujano Mayor Dr Cosme Argerich

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 17:38

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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?	

090177e196ae2e60\Final\Final On: 01-Apr-2021 03:11 (GMT)

**Header Text:** c4591001

**Visit:** Logs

**Form:** TRANSFUSIONS

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

**Site No:** 4444

**Site Name:** (4444) Hospital Militar Central Cirujano Mayor Dr Cosme Argerich

**Subject No:** 44441979

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 17:38

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

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 4444

**Subject No:** 44441979

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

**Form:** TRANSFUSIONS

**Form Status:** Not Started

**Site Name:** (4444) Hospital Militar Central Cirujano Mayor Dr Cosme Argerich

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 17:38

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

**Header Text:** c4591001

**Visit:** End of Treatment - Unscheduled

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

**Site No:** 4444

**Subject No:** 44441979

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

**Form:** DISPOSITION - TREATMENT

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

**Site Name:** (4444) Hospital Militar Central Cirujano Mayor Dr Cosme Argerich

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 17:38

[eCRF Audit Trail History](#)

**Disposition - Treatment**

1.	Date of Completion/Discontinuation /Death :	Oct/15/2020
2.	Phase of Disposition:	VACCINATION
3.	Status:	PREGNANCY
4.	Specify Status:	[ ]

**Header Text:** c4591001

**Visit:** Unplanned Vaccination - Unscheduled

**Form:** DATE OF VISIT

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

**Form Status:** Not Started

**Site No:** 4444

**Site Name:** (4444) Hospital Militar Central Cirujano Mayor Dr Cosme Argerich

**Subject No:** 44441979

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 17:38

**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:** 4444

**Site Name:** (4444) Hospital Militar Central Cirujano Mayor Dr Cosme Argerich

**Subject No:** 44441979

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 17:38

**Vital Signs**

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

**Vital Signs Details**

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



**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:** 4444

**Site Name:** (4444) Hospital Militar Central Cirujano Mayor Dr Cosme Argerich

**Subject No:** 44441979

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 17:38

**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:	

090177e196ae2e60\Final\Final On: 01-Apr-2021 03:11 (GMT)

**Header Text:** c4591001

**Visit:** Unplanned Vaccination - Unscheduled

**Form:** VACCINATION

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

**Form Status:** Not Started

**Site No:** 4444

**Site Name:** (4444) Hospital Militar Central Cirujano Mayor Dr Cosme Argerich

**Subject No:** 44441979

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 17:38

**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?	

090177e196ae2e60\Final\Final On: 01-Apr-2021 03:11 (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:** 4444

**Site Name:** (4444) Hospital Militar Central Cirujano Mayor Dr Cosme Argerich

**Subject No:** 44441979

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 17:38

**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:** 4444

**Site Name:** (4444) Hospital Militar Central Cirujano Mayor Dr Cosme Argerich

**Subject No:** 44441979

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 17:38

**Contact Outcome**

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

**Header Text:** c4591001

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

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

**Form Status:** Not Started

**Site No:** 4444

**Site Name:** (4444) Hospital Militar Central Cirujano Mayor Dr Cosme Argerich

**Subject No:** 44441979

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 17:38

**Date of Visit**

1.	Date of Visit	//
2.	Erroneous Visit	

**Header Text:** c4591001

**Visit:** V201\_SURVEIL\_CONSENT - Unscheduled **Form:** INFORMED CONSENT - ASYMPTOMATIC SURVEILLANCE

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

**Form Status:** Not Started

**Site No:** 4444

**Site Name:** (4444) Hospital Militar Central Cirujano Mayor Dr Cosme Argerich

**Subject No:** 44441979

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 17:38

**Informed Consent - Asymptomatic Surveillance**

1.	Consent Was:	
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**Header Text:** c4591001

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

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

**Form Status:** Not Started

**Site No:** 4444

**Site Name:** (4444) Hospital Militar Central Cirujano Mayor Dr Cosme Argerich

**Subject No:** 44441979

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 17:38

**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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090177e196ae2e60\Final\Final On: 01-Apr-2021 03:11 (GMT)

**Header Text:** c4591001

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

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

**Form Status:** Not Started

**Site No:** 4444

**Site Name:** (4444) Hospital Militar Central Cirujano Mayor Dr Cosme Argerich

**Subject No:** 44441979

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 17:38

**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:** Follow-Up - Unscheduled

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

**Site No:** 4444

**Subject No:** 44441979

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

**Form:** DISPOSITION - FOLLOW-UP

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

**Site Name:** (4444) Hospital Militar Central Cirujano Mayor Dr Cosme Argerich

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 17:38

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

**Disposition - Follow-Up**

1.	Date of Completion/Discontinuation /Death :	Nov/11/2020	<a href="#">Comments</a>
2.	Phase of Disposition:	FOLLOW-UP	<a href="#">Comments</a>
3.	Status:	WITHDRAWAL BY SUBJECT	<a href="#">Comments</a>
4.	Specify Status:	[the decision to stop participating is due to particular reasons]	<a href="#">Comments</a>

**Header Text:** c4591001

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

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

**Form Status:** Not Started

**Site No:** 4444

**Site Name:** (4444) Hospital Militar Central Cirujano Mayor Dr Cosme Argerich

**Subject No:** 44441979

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 17:38

**Date of Visit**

1.	Date of Visit	//
2.	Erroneous Visit	

**Header Text:** c4591001

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

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

**Form Status:** Not Started

**Site No:** 4444

**Site Name:** (4444) Hospital Militar Central Cirujano Mayor Dr Cosme Argerich

**Subject No:** 44441979

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 17:38

**Further Vaccination Confirmation**

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

**Header Text:** c4591001

**Visit:** Disposition - Unscheduled

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

**Site No:** 4444

**Subject No:** 44441979

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

**Form:** TREATMENT UNBLINDED

**Form Status:** Not Started

**Site Name:** (4444) Hospital Militar Central Cirujano Mayor Dr Cosme Argerich

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 17:38

**Treatment Unblinded**

1.	Date Treatment Unblinded :	//
2.	Primary Reason for Unblinding:	

**Header Text:** c4591001

**Visit:** Disposition - Unscheduled

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

**Site No:** 4444

**Subject No:** 44441979

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

**Form:** WITHDRAWAL OF CONSENT

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

**Site Name:** (4444) Hospital Militar Central Cirujano Mayor Dr Cosme Argerich

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 17:38

[eCRF Audit Trail History](#)

**Withdrawal Of Consent**

1.	Withdrawal of Consent Date :	Nov/11/2020
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**Header Text:** c4591001

**Visit:** Disposition - Unscheduled

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

**Site No:** 4444

**Subject No:** 44441979

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

**Form:** DEATH DETAILS CODED

**Form Status:** Not Started

**Site Name:** (4444) Hospital Militar Central Cirujano Mayor Dr Cosme Argerich

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 17:38

**Death Details**

1.	Date of Collection / Notification of Death:	//
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**Cause of Death**

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

**Header Text:** c4591001

**Visit:** Subject Status - Unscheduled

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

**Site No:** 4444

**Subject No:** 44441979

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

**Form:** SUBJECT STATUS

**Form Status:** Data Complete, Verified

**Site Name:** (4444) Hospital Militar Central Cirujano Mayor Dr Cosme Argerich

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 17:38

[eCRF Audit Trail History](#)

**Subject Status**

1.	Subject Status	DISCONTINUED
2.	Subject Status Date	Nov/11/2020

**Header Text:** c4591001

**Visit:** Investigator Signature - Unscheduled

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

**Site No:** 4444

**Subject No:** 44441979

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

**Form:** CASEBOOK SIGNATURE FORM

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

**Site Name:** (4444) Hospital Militar Central Cirujano Mayor Dr Cosme Argerich

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 17:38

[eCRF Audit Trail History](#)

**Casebook Signature Form**

1.	Casebook Signature	Click Here to Enable
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**Header Text:** c4591001

**Visit:** Investigator Signature - Unscheduled

**Form:** CASEBOOK SIGNATURE FORM

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

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

**Site No:** 4444

**Site Name:** (4444) Hospital Militar Central Cirujano Mayor Dr Cosme Argerich

**Subject No:** 44441979

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 17:38

[Audit Trail](#)

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

- CRF\_Sign

Name	Signature Meaning	Date	Type	Action
Gonzalo Perez Marc	Approved	Jan-22-2021 17:20:30 (UTC-03:00) City of Buenos Aires	BOOK	Signed

**Affidavit:**

By my dated signature below, I, GonzaloPerez, 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.

090177e196ae2e60\Final\Final On: 01-Apr-2021 03:11 (GMT)

**Header Text:** c4591001

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

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

**Site No:** 4444

**Subject No:** 44441979

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

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

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

**Site Name:** (4444) Hospital Militar Central Cirujano Mayor Dr Cosme Argerich

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 17:38

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Item	Date	User	Comment
Form	Sep-25-2020 19:58:05 (UTC-03:00) City of Buenos Aires	(b) (4), (b) (6)	Not Applicable

**Header Text:** c4591001

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

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

**Site No:** 4444

**Subject No:** 44441979

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

**Form:** GENERAL MEDICAL HISTORY - Comments

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

**Site Name:** (4444) Hospital Militar Central Cirujano Mayor Dr Cosme Argerich

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 17:38

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Item	Date	User	Comment
Form	Sep-25-2020 19:58:40 (UTC-03:00) City of Buenos Aires	(b) (4), (b) (6)	Not Applicable

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

**Site No:** 4444

**Subject No:** 44441979

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

**Form:** DATE OF VISIT - Comments

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

**Site Name:** (4444) Hospital Militar Central Cirujano Mayor Dr Cosme Argerich

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 17:38

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Item	Date	User	Comment
Form	Nov-11-2020 10:53:53 (UTC-03:00) City of Buenos Aires	(b) (4), (b) (6)	NOT DONE
Form	Nov-11-2020 10:53:31 (UTC-03:00) City of Buenos Aires	(b) (4), (b) (6)	Not Done

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

**Site No:** 4444

**Subject No:** 44441979

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

**Form:** DATE OF VISIT - Comments

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

**Site Name:** (4444) Hospital Militar Central Cirujano Mayor Dr Cosme Argerich

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 17:38

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Item	Date	User	Comment
1	Nov-11-2020 10:53:31 (UTC-03:00) City of Buenos Aires	(b) (4), (b) (6)	Not Done

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

**Site No:** 4444

**Subject No:** 44441979

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

**Form:** DATE OF VISIT - Comments

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

**Site Name:** (4444) Hospital Militar Central Cirujano Mayor Dr Cosme Argerich

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 17:38

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Item	Date	User	Comment
2	Nov-11-2020 10:53:31 (UTC-03:00) City of Buenos Aires	(b) (4), (b) (6)	Not Done

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

**Site No:** 4444

**Subject No:** 44441979

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

**Form:** VITAL SIGNS - TEMP - Comments

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

**Site Name:** (4444) Hospital Militar Central Cirujano Mayor Dr Cosme Argerich

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 17:38

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Item	Date	User	Comment
Form	Nov-11-2020 12:03:48 (UTC-03:00) City of Buenos Aires	(b) (4), (b) (6)	The volunteer withdraws consent to participate in the study <hr/> Not Done

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

**Site No:** 4444

**Subject No:** 44441979

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

**Form:** VITAL SIGNS - TEMP - Comments

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

**Site Name:** (4444) Hospital Militar Central Cirujano Mayor Dr Cosme Argerich

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 17:38

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Item	Date	User	Comment
1	Nov-11-2020 12:03:48 (UTC-03:00) City of Buenos Aires	(b) (4), (b) (6)	The volunteer withdraws consent to participate in the study <hr/> Not Done



**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

**Site No:** 4444

**Subject No:** 44441979

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

**Form:** VITAL SIGNS - TEMP - Comments

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

**Site Name:** (4444) Hospital Militar Central Cirujano Mayor Dr Cosme Argerich

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 17:38

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Item	Date	User	Comment
2.a	Nov-11-2020 12:03:48 (UTC-03:00) City of Buenos Aires	(b) (4), (b) (6)	The volunteer withdraws consent to participate in the study
			Not Done

090177e196ae2e60\Final\Final On: 01-Apr-2021 03:11 (GMT)

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

**Site No:** 4444

**Subject No:** 44441979

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

**Form:** VITAL SIGNS - TEMP - Comments

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

**Site Name:** (4444) Hospital Militar Central Cirujano Mayor Dr Cosme Argerich

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 17:38

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Item	Date	User	Comment
2.a	Nov-11-2020 12:03:48 (UTC-03:00) City of Buenos Aires	(b) (4), (b) (6)	The volunteer withdraws consent to participate in the study
			Not Done

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

**Site No:** 4444

**Subject No:** 44441979

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

**Form:** VITAL SIGNS - TEMP - Comments

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

**Site Name:** (4444) Hospital Militar Central Cirujano Mayor Dr Cosme Argerich

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 17:38

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Item	Date	User	Comment
2.a	Nov-11-2020 12:03:48 (UTC-03:00) City of Buenos Aires	(b) (4), (b) (6)	The volunteer withdraws consent to participate in the study
			Not Done

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

**Form Version:** 15-Sep-2020 21:51

**Site No:** 4444

**Subject No:** 44441979

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

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

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

**Site Name:** (4444) Hospital Militar Central Cirujano Mayor Dr Cosme Argerich

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 17:38

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Item	Date	User	Comment
Form	Nov-11-2020 12:04:07 (UTC-03:00) City of Buenos Aires	(b) (4), (b) (6)	The volunteer withdraws consent to participate in the study <hr/> Not Done
Form	Nov-10-2020 10:23:17 (UTC-03:00) City of Buenos Aires	(b) (4), (b) (6)	
Form	Nov-10-2020 10:23:00 (UTC-03:00) City of Buenos Aires	(b) (4), (b) (6)	Not Done

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

**Form Version:** 15-Sep-2020 21:51

**Site No:** 4444

**Subject No:** 44441979

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

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

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

**Site Name:** (4444) Hospital Militar Central Cirujano Mayor Dr Cosme Argerich

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 17:38

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Item	Date	User	Comment
1	Nov-11-2020 12:04:07 (UTC-03:00) City of Buenos Aires	(b) (4), (b) (6)	The volunteer withdraws consent to participate in the study <hr/> Not Done
1	Nov-10-2020 10:23:17 (UTC-03:00) City of Buenos Aires	(b) (4), (b) (6)	
1	Nov-10-2020 10:23:00 (UTC-03:00) City of Buenos Aires	(b) (4), (b) (6)	Not Done

090177e196ae2e60\Final\Final On: 01-Apr-2021 03:11 (GMT)

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

**Form Version:** 15-Sep-2020 21:51

**Site No:** 4444

**Subject No:** 44441979

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

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

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

**Site Name:** (4444) Hospital Militar Central Cirujano Mayor Dr Cosme Argerich

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 17:38

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Item	Date	User	Comment
2	Nov-11-2020 12:04:07 (UTC-03:00) City of Buenos Aires	(b) (4), (b) (6)	The volunteer withdraws consent to participate in the study <hr/> Not Done
2	Nov-10-2020 10:23:17 (UTC-03:00) City of Buenos Aires	(b) (4), (b) (6)	
2	Nov-10-2020 10:23:00 (UTC-03:00) City of Buenos Aires	(b) (4), (b) (6)	Not Done

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

**Form Version:** 15-Sep-2020 21:51

**Site No:** 4444

**Subject No:** 44441979

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

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

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

**Site Name:** (4444) Hospital Militar Central Cirujano Mayor Dr Cosme Argerich

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 17:38

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Item	Date	User	Comment
3	Nov-11-2020 12:04:07 (UTC-03:00) City of Buenos Aires	(b) (4), (b) (6)	The volunteer withdraws consent to participate in the study <hr/> Not Done
3	Nov-10-2020 10:23:17 (UTC-03:00) City of Buenos Aires	(b) (4), (b) (6)	
3	Nov-10-2020 10:23:00 (UTC-03:00) City of Buenos Aires	(b) (4), (b) (6)	Not Done

090177e196ae2e60\Final\Final On: 01-Apr-2021 03:11 (GMT)

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

**Form Version:** 15-Sep-2020 21:51

**Site No:** 4444

**Subject No:** 44441979

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

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

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

**Site Name:** (4444) Hospital Militar Central Cirujano Mayor Dr Cosme Argerich

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 17:38

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Item	Date	User	Comment
4	Nov-11-2020 12:04:07 (UTC-03:00) City of Buenos Aires	(b) (4), (b) (6)	The volunteer withdraws consent to participate in the study <hr/> Not Done
4	Nov-10-2020 10:23:17 (UTC-03:00) City of Buenos Aires	(b) (4), (b) (6)	
4	Nov-10-2020 10:23:00 (UTC-03:00) City of Buenos Aires	(b) (4), (b) (6)	Not Done



**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

**Form Version:** 15-Sep-2020 21:51

**Site No:** 4444

**Subject No:** 44441979

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

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

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

**Site Name:** (4444) Hospital Militar Central Cirujano Mayor Dr Cosme Argerich

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 17:38

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Item	Date	User	Comment
5	Nov-11-2020 12:04:07 (UTC-03:00) City of Buenos Aires	(b) (4), (b) (6)	The volunteer withdraws consent to participate in the study <hr/> Not Done
5	Nov-10-2020 10:23:17 (UTC-03:00) City of Buenos Aires	(b) (4), (b) (6)	
5	Nov-10-2020 10:23:00 (UTC-03:00) City of Buenos Aires	(b) (4), (b) (6)	Not Done

090177e196ae2e60\Final\Final On: 01-Apr-2021 03:11 (GMT)

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

**Form Version:** 15-Sep-2020 21:51

**Site No:** 4444

**Subject No:** 44441979

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

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

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

**Site Name:** (4444) Hospital Militar Central Cirujano Mayor Dr Cosme Argerich

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 17:38

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Item	Date	User	Comment
6.a	Nov-11-2020 12:04:07 (UTC-03:00) City of Buenos Aires	(b) (4), (b) (6)	The volunteer withdraws consent to participate in the study <hr/> Not Done
6.a	Nov-10-2020 10:23:17 (UTC-03:00) City of Buenos Aires	(b) (4), (b) (6)	
6.a	Nov-10-2020 10:23:00 (UTC-03:00) City of Buenos Aires	(b) (4), (b) (6)	Not Done

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

**Form Version:** 15-Sep-2020 21:51

**Site No:** 4444

**Subject No:** 44441979

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

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

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

**Site Name:** (4444) Hospital Militar Central Cirujano Mayor Dr Cosme Argerich

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 17:38

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Item	Date	User	Comment
6.a	Nov-11-2020 12:04:07 (UTC-03:00) City of Buenos Aires	(b) (4), (b) (6)	The volunteer withdraws consent to participate in the study <hr/> Not Done
6.a	Nov-10-2020 10:23:17 (UTC-03:00) City of Buenos Aires	(b) (4), (b) (6)	
6.a	Nov-10-2020 10:23:00 (UTC-03:00) City of Buenos Aires	(b) (4), (b) (6)	Not Done

090177e196ae2e60\Final\Final On: 01-Apr-2021 03:11 (GMT)

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

**Form Version:** 15-Sep-2020 21:51

**Site No:** 4444

**Subject No:** 44441979

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

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

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

**Site Name:** (4444) Hospital Militar Central Cirujano Mayor Dr Cosme Argerich

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 17:38

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Item	Date	User	Comment
6.a	Nov-11-2020 12:04:07 (UTC-03:00) City of Buenos Aires	(b) (4), (b) (6)	The volunteer withdraws consent to participate in the study <hr/> Not Done
6.a	Nov-10-2020 10:23:17 (UTC-03:00) City of Buenos Aires	(b) (4), (b) (6)	
6.a	Nov-10-2020 10:23:00 (UTC-03:00) City of Buenos Aires	(b) (4), (b) (6)	Not Done

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

**Site No:** 4444

**Subject No:** 44441979

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

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

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

**Site Name:** (4444) Hospital Militar Central Cirujano Mayor Dr Cosme Argerich

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 17:38

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Item	Date	User	Comment
Form	Nov-11-2020 12:04:33 (UTC-03:00) City of Buenos Aires	(b) (4), (b) (6)	The volunteer withdraws consent to participate in the study <hr/> Not Done

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

**Site No:** 4444

**Subject No:** 44441979

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

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

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

**Site Name:** (4444) Hospital Militar Central Cirujano Mayor Dr Cosme Argerich

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 17:38

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Item	Date	User	Comment
1	Nov-11-2020 12:04:33 (UTC-03:00) City of Buenos Aires	(b) (4), (b) (6)	The volunteer withdraws consent to participate in the study
			Not Done

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

**Site No:** 4444

**Subject No:** 44441979

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

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

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

**Site Name:** (4444) Hospital Militar Central Cirujano Mayor Dr Cosme Argerich

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 17:38

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Item	Date	User	Comment
2	Nov-11-2020 12:04:33 (UTC-03:00) City of Buenos Aires	(b) (4), (b) (6)	The volunteer withdraws consent to participate in the study <hr/> Not Done

090177e196ae2e60\Final\Final On: 01-Apr-2021 03:11 (GMT)

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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**Site No:** 4444

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

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**Site Name:** (4444) Hospital Militar Central Cirujano Mayor Dr Cosme Argerich

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**Generated Time (GMT):** 29-Mar-2021 17:38

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Item	Date	User	Comment
3	Nov-11-2020 12:04:33 (UTC-03:00) City of Buenos Aires	(b) (4), (b) (6)	The volunteer withdraws consent to participate in the study
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**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

**Site No:** 4444

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

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

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

**Site Name:** (4444) Hospital Militar Central Cirujano Mayor Dr Cosme Argerich

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 17:38

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Item	Date	User	Comment
4	Nov-11-2020 12:04:33 (UTC-03:00) City of Buenos Aires	(b) (4), (b) (6)	The volunteer withdraws consent to participate in the study <hr/> Not Done

090177e196ae2e60\Final\Final On: 01-Apr-2021 03:11 (GMT)

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

**Site No:** 4444

**Subject No:** 44441979

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

**Form:** VACCINATION - Comments

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

**Site Name:** (4444) Hospital Militar Central Cirujano Mayor Dr Cosme Argerich

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 17:38

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Item	Date	User	Comment
Form	Nov-11-2020 12:04:46 (UTC-03:00) City of Buenos Aires	(b) (4), (b) (6)	The volunteer withdraws consent to participate in the study <hr/> Not Done

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

**Site No:** 4444

**Subject No:** 44441979

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

**Form:** VACCINATION - Comments

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

**Site Name:** (4444) Hospital Militar Central Cirujano Mayor Dr Cosme Argerich

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 17:38

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Item	Date	User	Comment
1	Nov-11-2020 12:04:46 (UTC-03:00) City of Buenos Aires	(b) (4), (b) (6)	The volunteer withdraws consent to participate in the study <hr/> Not Done

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

**Site No:** 4444

**Subject No:** 44441979

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

**Form:** VACCINATION - Comments

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

**Site Name:** (4444) Hospital Militar Central Cirujano Mayor Dr Cosme Argerich

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 17:38

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Item	Date	User	Comment
2	Nov-11-2020 12:04:46 (UTC-03:00) City of Buenos Aires	(b) (4), (b) (6)	The volunteer withdraws consent to participate in the study
			Not Done

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

**Site No:** 4444

**Subject No:** 44441979

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

**Form:** VACCINATION - Comments

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

**Site Name:** (4444) Hospital Militar Central Cirujano Mayor Dr Cosme Argerich

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 17:38

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Item	Date	User	Comment
3	Nov-11-2020 12:04:46 (UTC-03:00) City of Buenos Aires	(b) (4), (b) (6)	The volunteer withdraws consent to participate in the study
			Not Done

090177e196ae2e60\Final\Final On: 01-Apr-2021 03:11 (GMT)

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

**Site No:** 4444

**Subject No:** 44441979

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

**Form:** VACCINATION - Comments

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

**Site Name:** (4444) Hospital Militar Central Cirujano Mayor Dr Cosme Argerich

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 17:38

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Item	Date	User	Comment
4	Nov-11-2020 12:04:46 (UTC-03:00) City of Buenos Aires	(b) (4), (b) (6)	The volunteer withdraws consent to participate in the study <hr/> Not Done

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

**Site No:** 4444

**Subject No:** 44441979

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

**Form:** VACCINATION - Comments

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

**Site Name:** (4444) Hospital Militar Central Cirujano Mayor Dr Cosme Argerich

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 17:38

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Item	Date	User	Comment
5	Nov-11-2020 12:04:46 (UTC-03:00) City of Buenos Aires	(b) (4), (b) (6)	The volunteer withdraws consent to participate in the study
			Not Done

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

**Site No:** 4444

**Subject No:** 44441979

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

**Form:** VACCINATION - Comments

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

**Site Name:** (4444) Hospital Militar Central Cirujano Mayor Dr Cosme Argerich

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 17:38

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Item	Date	User	Comment
6	Nov-11-2020 12:04:46 (UTC-03:00) City of Buenos Aires	(b) (4), (b) (6)	The volunteer withdraws consent to participate in the study <hr/> Not Done



**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

**Site No:** 4444

**Subject No:** 44441979

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

**Form:** VACCINATION - Comments

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

**Site Name:** (4444) Hospital Militar Central Cirujano Mayor Dr Cosme Argerich

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 17:38

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Item	Date	User	Comment
7	Nov-11-2020 12:04:46 (UTC-03:00) City of Buenos Aires	(b) (4), (b) (6)	The volunteer withdraws consent to participate in the study <hr/> Not Done

090177e196ae2e60\Final\Final On: 01-Apr-2021 03:11 (GMT)

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

**Site No:** 4444

**Subject No:** 44441979

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

**Form:** VACCINATION - Comments

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

**Site Name:** (4444) Hospital Militar Central Cirujano Mayor Dr Cosme Argerich

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 17:38

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Item	Date	User	Comment
8	Nov-11-2020 12:04:46 (UTC-03:00) City of Buenos Aires	(b) (4), (b) (6)	The volunteer withdraws consent to participate in the study
			Not Done

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

**Site No:** 4444

**Subject No:** 44441979

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

**Form:** VACCINATION - Comments

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

**Site Name:** (4444) Hospital Militar Central Cirujano Mayor Dr Cosme Argerich

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 17:38

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Item	Date	User	Comment
9	Nov-11-2020 12:04:46 (UTC-03:00) City of Buenos Aires	(b) (4), (b) (6)	The volunteer withdraws consent to participate in the study <hr/> Not Done

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

**Site No:** 4444

**Subject No:** 44441979

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

**Form:** VACCINATION - Comments

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

**Site Name:** (4444) Hospital Militar Central Cirujano Mayor Dr Cosme Argerich

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 17:38

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Item	Date	User	Comment
10	Nov-11-2020 12:04:46 (UTC-03:00) City of Buenos Aires	(b) (4), (b) (6)	The volunteer withdraws consent to participate in the study <hr/> Not Done

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

**Site No:** 4444

**Subject No:** 44441979

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

**Form:** VACCINATION - Comments

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

**Site Name:** (4444) Hospital Militar Central Cirujano Mayor Dr Cosme Argerich

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 17:38

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Item	Date	User	Comment
11	Nov-11-2020 12:04:46 (UTC-03:00) City of Buenos Aires	(b) (4), (b) (6)	The volunteer withdraws consent to participate in the study <hr/> Not Done

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 4444

**Subject No:** 44441979

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

**Form:** ADVERSE EVENT REPORT - Comments

**Form Status:** Data Complete

**Site Name:** (4444) Hospital Militar Central Cirujano Mayor Dr Cosme Argerich

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 17:38

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Item	Date	User	Comment
6	Nov-12-2020 09:53:36 (UTC-03:00) City of Buenos Aires	Maria Beretta (b) (4)	Not Applicable

**Header Text:** c4591001

**Visit:** Follow-Up - Unscheduled

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

**Site No:** 4444

**Subject No:** 44441979

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

**Form:** DISPOSITION - FOLLOW-UP - Comments

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

**Site Name:** (4444) Hospital Militar Central Cirujano Mayor Dr Cosme Argerich

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 17:38

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Item	Date	User	Comment
Form	Nov-11-2020 12:01:23 (UTC-03:00) City of Buenos Aires	(b) (4), (b) (6)	
Form	Nov-10-2020 10:21:33 (UTC-03:00) City of Buenos Aires	(b) (4), (b) (6)	Not Applicable

**Header Text:** c4591001

**Visit:** Follow-Up

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

**Site No:** 4444

**Subject No:** 44441979

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

**Form:** DISPOSITION - FOLLOW-UP - Comments

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

**Site Name:** (4444) Hospital Militar Central Cirujano Mayor Dr Cosme Argerich

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 17:38

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Item	Date	User	Comment
1	Nov-11-2020 12:01:23 (UTC-03:00) City of Buenos Aires	(b) (4), (b) (6)	
1	Nov-10-2020 10:21:33 (UTC-03:00) City of Buenos Aires	(b) (4), (b) (6)	Not Applicable
1	Nov-07-2020 11:33:51 (UTC-03:00) City of Buenos Aires	(b) (4), (b) (6)	The subject will continue the follow up visits as per protocol

090177e196ae2e60\Final\Final On: 01-Apr-2021 03:11 (GMT)



**Header Text:** c4591001

**Visit:** Follow-Up

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

**Site No:** 4444

**Subject No:** 44441979

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

**Form:** DISPOSITION - FOLLOW-UP - Comments

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

**Site Name:** (4444) Hospital Militar Central Cirujano Mayor Dr Cosme Argerich

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 17:38

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Item	Date	User	Comment
2	Nov-11-2020 12:01:23 (UTC-03:00) City of Buenos Aires	(b) (4), (b) (6)	
2	Nov-10-2020 10:21:33 (UTC-03:00) City of Buenos Aires	(b) (4), (b) (6)	Not Applicable

**Header Text:** c4591001

**Visit:** Follow-Up

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

**Site No:** 4444

**Subject No:** 44441979

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

**Form:** DISPOSITION - FOLLOW-UP - Comments

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

**Site Name:** (4444) Hospital Militar Central Cirujano Mayor Dr Cosme Argerich

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 17:38

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Item	Date	User	Comment
3	Nov-11-2020 12:01:23 (UTC-03:00) City of Buenos Aires	(b) (4), (b) (6)	
3	Nov-10-2020 10:21:33 (UTC-03:00) City of Buenos Aires	(b) (4), (b) (6)	Not Applicable
3	Nov-07-2020 11:33:01 (UTC-03:00) City of Buenos Aires	(b) (4), (b) (6)	The subject will continue the follow up visits as per protocol

**Header Text:** c4591001

**Visit:** Follow-Up

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

**Site No:** 4444

**Subject No:** 44441979

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

**Form:** DISPOSITION - FOLLOW-UP - Comments

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

**Site Name:** (4444) Hospital Militar Central Cirujano Mayor Dr Cosme Argerich

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 17:38

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Item	Date	User	Comment
4	Nov-11-2020 12:01:23 (UTC-03:00) City of Buenos Aires	(b) (4), (b) (6)	
4	Nov-10-2020 10:21:33 (UTC-03:00) City of Buenos Aires	(b) (4), (b) (6)	Not Applicable

Header Text: c4591001

Visit: Investigator Signature - Unscheduled

Form: CASEBOOK SIGNATURE FORM - Signature History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Signed, Verified

Site No: 4444

Site Name: (4444) Hospital Militar Central Cirujano Mayor Dr Cosme Argerich

Subject No: 44441979

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 17:38

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

- CRF\_Sign

Name	Signature Meaning	Date	Type	Action
Gonzalo Perez Marc	Approved	Jan-22-2021 17:20:30 (UTC-03:00) City of Buenos Aires	BOOK	Signed

**Affidavit:**

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

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

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

(b) (6)	N/A	Dec-16-2020 10:28:52 (UTC-03:00) City of Buenos Aires		Edit - All signatures invalidated
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**Affidavit:**

N/A

(b) (6)	Approved	Nov-15-2020 17:47:33 (UTC-03:00) City of Buenos Aires	BOOK	Signed
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**Affidavit:**

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

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

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

(b) (6)	N/A	Nov-11-2020 10:53:31 (UTC-03:00) City of Buenos Aires		Edit - All signatures invalidated
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**Affidavit:**

N/A

Maria Beretta	Approved	Nov-10-2020 10:58:27 (UTC-03:00) City of Buenos Aires	BOOK	Signed
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090177e196ae2e60\Final\Final On: 01-Apr-2021 03:11 (GMT)

**Header Text:** c4591001

**Visit:** Investigator Signature - Unscheduled

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

**Site No:** 4444

**Subject No:** 44441979

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

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

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

**Site Name:** (4444) Hospital Militar Central Cirujano Mayor Dr Cosme Argerich

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 17:38

**Affidavit:**

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

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

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

**Header Text:** c4591001

**Visit:** COHORT\_SELECTION

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

**Site No:** 4444

**Subject No:** 44441979

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

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

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

**Site Name:** (4444) Hospital Militar Central Cirujano Mayor Dr Cosme Argerich

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 17:38

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*1. Select appropriate response - Protocol version*

Date	Location	User	Value	Reason
Sep-25-2020 19:57:13 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 08 SEP 2020	Initial Entry

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

Date	Location	User	Value	Reason
Sep-25-2020 19:57:13 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> STAGE 3 COHORTS	Initial Entry

090177e196ae2e60\Final\Final On: 01-Apr-2021 03:11 (GMT)

**Header Text:** c4591001

**Visit:** COHORT\_SELECTION

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

**Site No:** 4444

**Subject No:** 44441979

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

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

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

**Site Name:** (4444) Hospital Militar Central Cirujano Mayor Dr Cosme Argerich

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 17:38

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*I. Consent Was:*

Date	Location	User	Value	Reason
Sep-25-2020 19:57:22 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> OBTAINED Date Written Consent Obtained  Sep/25/2020	Initial Entry

Header Text: c4591001

Visit: COHORT\_SELECTION

Form Version: 15-Sep-2020 21:54

Site No: 4444

Subject No: 44441979

Generated By: (b) (4)

Form: DEMOGRAPHY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (4444) Hospital Militar Central Cirujano Mayor Dr Cosme Argerich

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 17:38

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**1. Subject ID**

Date	Location	User	Value	Reason
Sep-25-2020 15:44:14 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 44441979	Item copied from previous form

**2. Birth Date:**

Date	Location	User	Value	Reason
Sep-25-2020 15:44:10 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> (b) (6) /1990	Enrollment Entry

**3. Sex:**

Date	Location	User	Value	Reason
Sep-25-2020 19:57:37 (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
Sep-25-2020 19:57:37 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> HISPANIC OR LATINO(A) OR OF SPANISH ORIGIN	Initial Entry

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

Date	Location	User	Value	Reason
Sep-25-2020 19:57:37 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> WHITE	Initial Entry

090177e196ae2e60\Final\Final On: 01-Apr-2021 03:11 (GMT)



**Header Text:** c4591001

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

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

**Site No:** 4444

**Subject No:** 44441979

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

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

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

**Site Name:** (4444) Hospital Militar Central Cirujano Mayor Dr Cosme Argerich

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 17:38

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*I. Date of Visit*

Date	Location	User	Value	Reason
Sep-25-2020 19:57:51 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sep/25/2020	Initial Entry

090177e196ae2e60\Final\Final On: 01-Apr-2021 03:11 (GMT)

**Header Text:** c4591001

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

**Form Version:** 15-Sep-2020 21:52

**Site No:** 4444

**Subject No:** 44441979

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

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

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

**Site Name:** (4444) Hospital Militar Central Cirujano Mayor Dr Cosme Argerich

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 17:38

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

Date	Location	User	Value	Reason
Sep-25-2020 19:58:20 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sep/25/2020	Initial Entry

**2. Phase of Disposition:**

Date	Location	User	Value	Reason
Sep-25-2020 19:58:20 (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
Sep-25-2020 19:58:20 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> COMPLETED	Initial Entry

090177e196ae2e60\Final\Final On: 01-Apr-2021 03:11 (GMT)

**Header Text:** c4591001

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

**Form Version:** 15-Sep-2020 21:57

**Site No:** 4444

**Subject No:** 44441979

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

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

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

**Site Name:** (4444) Hospital Militar Central Cirujano Mayor Dr Cosme Argerich

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 17:38

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*1. Select appropriate response - What is the subject HIV status?*

Date	Location	User	Value	Reason
Sep-25-2020 19:58:52 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> The subject is NOT known to be HIV POSITIVE	Initial Entry

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 15-Sep-2020 21:56

Site No: 4444

Subject No: 44441979

Generated By: (b) (4)

Form: VITAL SIGNS - BASELINE - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (4444) Hospital Militar Central Cirujano Mayor Dr Cosme Argerich

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 17:38

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**1. Date:**

Date	Location	User	Value	Reason
Sep-25-2020 19:59:25 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sep/25/2020	Initial Entry

**2. Weight:**

Date	Location	User	Value	Reason
Sep-25-2020 19:59:25 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 77.9	Initial Entry

**3. Unit:**

Date	Location	User	Value	Reason
Sep-25-2020 19:59:25 (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
Sep-25-2020 19:59:25 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 167.0	Initial Entry

**5. Unit:**

Date	Location	User	Value	Reason
Sep-25-2020 19:59:25 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> cm	Initial Entry

**6. Body Mass Index:**

Date	Location	User	Value	Reason
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090177e196ae2e60\Final\Final On: 01-Apr-2021 03:11 (GMT)

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 15-Sep-2020 21:56

Site No: 4444

Subject No: 44441979

Generated By: (b) (4)

Form: VITAL SIGNS - BASELINE - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (4444) Hospital Militar Central Cirujano Mayor Dr Cosme Argerich

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 17:38

Sep-25-2020 19:59:25 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 27.9	Initial Entry
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7.a

Date	Location	User	Value	Reason
Sep-25-2020 19:59:25 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Record Identifier::</b> 1 <b>Temperature:</b> 37.0 <b>Temperature Unit:</b> C <b>Temperature Location:</b> ORAL CAVITY <b>n::</b> Y	Initial Entry

7.a Record Identifier:

Date	Location	User	Value	Reason
Sep-25-2020 19:59:25 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 1	Initial Entry

7.a Temperature:

Date	Location	User	Value	Reason
Sep-25-2020 19:59:25 (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
Sep-25-2020 19:59:25 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> C	Initial Entry

7.a Temperature Location:

Date	Location	User	Value	Reason
Sep-25-2020 19:59:25 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> ORAL CAVITY	Initial Entry

090177e196ae2e60\Final\Final On: 01-Apr-2021 03:11 (GMT)

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 15-Sep-2020 21:51

Site No: 4444

Subject No: 44441979

Generated By: (b) (4)

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

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (4444) Hospital Militar Central Cirujano Mayor Dr Cosme Argerich

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 17:38

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**1. Lab Panel:**

Date	Location	User	Value	Reason
Sep-25-2020 19:59:42 (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-25-2020 19:59:42 (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-25-2020 19:59:42 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sep/25/2020	Initial Entry

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

Date	Location	User	Value	Reason
Sep-25-2020 19:59:42 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> STUDY SITE	Initial Entry

**5. Specimen Type:**

Date	Location	User	Value	Reason
Sep-25-2020 19:59:42 (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-25-2020 19:59:42 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> Sponsor-Defined Identifier: 113	Initial Entry

090177e196ae2e60\Final\Final On: 01-Apr-2021 03:11 (GMT)

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 15-Sep-2020 21:51

Site No: 4444

Subject No: 44441979

Generated By: (b) (4)

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

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (4444) Hospital Militar Central Cirujano Mayor Dr Cosme Argerich

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 17:38

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

6.a Sponsor ID:

Date	Location	User	Value	Reason
Sep-25-2020 19:59:42 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> 113	Initial Entry

6.a Test:

Date	Location	User	Value	Reason
Sep-25-2020 19:59:42 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Choriogonadotropin Beta_PX113	Initial Entry

6.a Result:

Date	Location	User	Value	Reason
Sep-25-2020 19:59:42 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NEGATIVE	Initial Entry

090177e196ae2e60\Final\Final On: 01-Apr-2021 03:11 (GMT)

**Header Text:** c4591001

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

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

**Site No:** 4444

**Subject No:** 44441979

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

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

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

**Site Name:** (4444) Hospital Militar Central Cirujano Mayor Dr Cosme Argerich

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 17:38

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**1. Randomization Date :**

Date	Location	User	Value	Reason
Sep-25-2020 20:00:52 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sep/25/2020	Initial Entry

**2. Randomization Number:**

Date	Location	User	Value	Reason
Sep-25-2020 20:00:52 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 100195	Initial Entry

090177e196ae2e60\Final\Final On: 01-Apr-2021 03:11 (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: 4444

Site Name: (4444) Hospital Militar Central Cirujano Mayor Dr Cosme Argerich

Subject No: 44441979

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 17:38

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**1. Data Origin**

Date	Location	User	Value	Reason
Sep-25-2020 20:01:04 (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-25-2020 20:01:04 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SERUM	Initial Entry

**3. Sample Collected?**

Date	Location	User	Value	Reason
Sep-27-2020 08:40:21 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Sep-26-2020 06:29:24 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Sep-25-2020 20:01:04 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Sep-25-2020 20:01:04 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES Date of Collection:  Sep/25/2020	Initial Entry

**5.a**

Date	Location	User	Value	Reason
Sep-27-2020 08:40:21 (UTC-03:00) City of	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sample ID: BRVRZS	Initial Entry

090177e196ae2e60\Final\Final On: 01-Apr-2021 03:11 (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: 4444

Site Name: (4444) Hospital Militar Central Cirujano Mayor Dr Cosme Argerich

Subject No: 44441979

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 17:38

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

Date	Location	User	Value	Reason
Sep-27-2020 08:40:21 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> BRVRZS	Initial Entry

5.b

Date	Location	User	Value	Reason
Sep-27-2020 09:26:02 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Sample ID: BRVRZZ	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Sep-27-2020 09:26:02 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> BRVRZZ	Initial Entry

5.c

Date	Location	User	Value	Reason
Sep-27-2020 10:15:50 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Sample ID: BHXGJ0	Initial Entry

5.c Sample ID

Date	Location	User	Value	Reason
Sep-27-2020 10:15:50 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> BHXGJ0	Initial Entry

090177e196ae2e60\Final\Final On: 01-Apr-2021 03:11 (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: 4444

Site Name: (4444) Hospital Militar Central Cirujano Mayor Dr Cosme Argerich

Subject No: 44441979

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 17:38

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**1. Data Origin**

Date	Location	User	Value	Reason
Sep-25-2020 20:01:13 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SITE	Initial Entry

**2. Sample Type**

Date	Location	User	Value	Reason
Sep-25-2020 20:01:13 (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-27-2020 08:49:44 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Sep-26-2020 06:29:24 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Sep-25-2020 20:01:13 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Sep-25-2020 20:01:13 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES Date of Collection:  Sep/25/2020	Initial Entry

**5.a**

Date	Location	User	Value	Reason
Sep-27-2020 08:49:44 (UTC-03:00) City of	ACV0PFEINFP6000	Romina Barrera	<b>Data Entry:</b> Sample ID: BPWCOM	Initial Entry

090177e196ae2e60\Final\Final On: 01-Apr-2021 03:11 (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:** 4444

**Site Name:** (4444) Hospital Militar Central Cirujano Mayor Dr Cosme Argerich

**Subject No:** 44441979

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 17:38

Buenos Aires

(b) (4)

**5.a Sample ID**

Date	Location	User	Value	Reason
Sep-27-2020 08:49:44 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	Romina Barrera (b) (4)	<u>Data Entry:</u> BPWCOM	Initial Entry

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 22-Apr-2020 21:04

Site No: 4444

Subject No: 44441979

Generated By: (b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (4444) Hospital Militar Central Cirujano Mayor Dr Cosme Argerich

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 17:38

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

Date	Location	User	Value	Reason
Sep-25-2020 20:01:38 (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-25-2020 20:01:38 (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-25-2020 20:01:38 (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
Nov-07-2020 23:22:41 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (b) (4)	Query 1 : Closed	Auto closed by Validation Check: VC_EC001_2_12_AN
Nov-07-2020 19:05:26 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1 : Answered	The original value is correct. The subject received the treatment on 25 sept 2020. The discontinuation was 15 oct 2020. Thank you
Nov-07-2020 17:39:28 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (b) (4)	Query 1 : Opened	DMW5309918;Date is after 'Date of Completion/Discontinuation /Death' on the Disposition - Treatment eCRF. Please clarify or correct.

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Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 22-Apr-2020 21:04

Site No: 4444

Subject No: 44441979

Generated By: (b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (4444) Hospital Militar Central Cirujano Mayor Dr Cosme Argerich

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 17:38

Sep-25-2020 20:01:38 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sep/25/2020 16:20	Initial Entry
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5. Anatomical Location:

Date	Location	User	Value	Reason
Sep-25-2020 20:01:38 (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-25-2020 20:01:38 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> LEFT	Initial Entry

7. Route:

Date	Location	User	Value	Reason
Sep-25-2020 20:01:38 (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-25-2020 20:01:38 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> THE PROTOCOL SPECIFIED OBSERVATION PERIOD	Initial Entry

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

Date	Location	User	Value	Reason
Sep-25-2020 20:01:38 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

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**Header Text:** c4591001

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

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

**Site No:** 4444

**Subject No:** 44441979

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

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

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

**Site Name:** (4444) Hospital Militar Central Cirujano Mayor Dr Cosme Argerich

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 17:38

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*1. Select appropriate response - Reactogenicity diary collection*

Date	Location	User	Value	Reason
Sep-25-2020 20:01:45 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO - REACTOGENICITY E-DIARY NOT COLLECTED FOR THIS SUBJ ECT	Initial Entry

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

**Site No:** 4444

**Subject No:** 44441979

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

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

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

**Site Name:** (4444) Hospital Militar Central Cirujano Mayor Dr Cosme Argerich

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 17:38

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**1. Date of Visit**

Date	Location	User	Value	Reason
Nov-11-2020 10:53:31 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

**2. Erroneous Visit**

Date	Location	User	Value	Reason
Nov-11-2020 10:53:31 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

090177e196ae2e60\Final\Final On: 01-Apr-2021 03:11 (GMT)



Header Text: c4591001

Visit: V2\_VAX2\_L

Form Version: 10-Oct-2020 16:01

Site No: 4444

Subject No: 44441979

Generated By: (b) (4)

Form: VITAL SIGNS - TEMP - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (4444) Hospital Militar Central Cirujano Mayor Dr Cosme Argerich

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 17:38

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**1. Date:**

Date	Location	User	Value	Reason
Nov-11-2020 12:03:48 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

**2.a**

Date	Location	User	Value	Reason
Nov-11-2020 12:03:48 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Record Identifier::</b> Not Done <b>Temperature:</b> Not Done <b>Temperature Unit:</b> Not Done <b>Temperature Location::</b> Not Done	Initial Entry

**2.a Record Identifier:**

Date	Location	User	Value	Reason
Nov-11-2020 12:03:48 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

**2.a Temperature:**

Date	Location	User	Value	Reason
Nov-11-2020 12:03:48 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

**2.a Unit:**

Date	Location	User	Value	Reason
Nov-11-2020 12:03:48 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

**2.a Temperature Location:**

Date	Location	User	Value	Reason
Nov-11-2020 12:03:48 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

090177e196ae2e60\Final\Final On: 01-Apr-2021 03:11 (GMT)

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

**Site No:** 4444

**Subject No:** 44441979

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

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

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

**Site Name:** (4444) Hospital Militar Central Cirujano Mayor Dr Cosme Argerich

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 17:38

Aires

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

Header Text: c4591001

Visit: V2\_VAX2\_L

Form Version: 15-Sep-2020 21:51

Site No: 4444

Subject No: 44441979

Generated By: (b) (4)

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

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (4444) Hospital Militar Central Cirujano Mayor Dr Cosme Argerich

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 17:38

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**1. Lab Panel:**

Date	Location	User	Value	Reason
Nov-11-2020 12:04:07 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Done	Initial Entry
Nov-10-2020 10:23:17 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u>	Initial Entry
Nov-10-2020 10:23:00 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Done	Initial Entry

**2. Lab Sub-Panel:**

Date	Location	User	Value	Reason
Nov-11-2020 12:04:07 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Done	Initial Entry
Nov-10-2020 10:23:17 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u>	Initial Entry
Nov-10-2020 10:23:00 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Done	Initial Entry

**3. Collection Date:**

Date	Location	User	Value	Reason
Nov-11-2020 17:38:21 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Closed	Response satisfies query
Nov-11-2020 12:04:07 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Done	Initial Entry
Nov-11-2020 10:56:03 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Answered	COMMENT UPDATED PER QUERY
Nov-11-2020 02:59:23 (UTC-03:00) City of	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Opened	DM: Subject is discontinued hence

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Header Text: c4591001

Visit: V2\_VAX2\_L

Form Version: 15-Sep-2020 21:51

Site No: 4444

Subject No: 44441979

Generated By: (b) (4)

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

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (4444) Hospital Militar Central Cirujano Mayor Dr Cosme Argerich

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 17:38

Buenos Aires				kindly consider marking this form as DOV form as Not done by selection form level comment or else clarify. Thank you.
Nov-10-2020 10:23:17 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>	Initial Entry
Nov-10-2020 10:23:00 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry
Oct-13-2020 19:34:05 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Oct-13-2020 13:34:03 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	this visit was never opened, nor were entries at all. there is no data to load.
Oct-13-2020 10:08:34 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	CLINICAL - please add collection date for urine HCG test; also result should be entered below

4. Laboratory Name and Address (Derived)

Date	Location	User	Value	Reason
Nov-11-2020 12:04:07 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry
Nov-10-2020 10:23:17 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>	Initial Entry
Nov-10-2020 10:23:00 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

5. Specimen Type:

Date	Location	User	Value	Reason
Nov-11-2020 12:04:07	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>	Initial Entry

090177e196ae2e60\Final\Final On: 01-Apr-2021 03:11 (GMT)

Header Text: c4591001

Visit: V2\_VAX2\_L

Form Version: 15-Sep-2020 21:51

Site No: 4444

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

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (4444) Hospital Militar Central Cirujano Mayor Dr Cosme Argerich

Subject No: 44441979

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 17:38

(UTC-03:00) City of Buenos Aires		(b) (4), (b) (6)	Not Done	
Nov-10-2020 10:23:17 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>	Initial Entry
Nov-10-2020 10:23:00 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

6.a

Date	Location	User	Value	Reason
Nov-11-2020 12:04:07 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sponsor-Defined Identifier:</b> Not Done <b>Test::</b> Not Done <b>Result::</b> Not Done <b>Not Done::</b> Not Done	Initial Entry
Nov-10-2020 10:23:17 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sponsor-Defined Identifier:</b> Not Done <b>Test::</b> Not Done <b>Result::</b> <b>Not Done::</b>	Initial Entry
Nov-10-2020 10:23:00 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sponsor-Defined Identifier:</b> Not Done <b>Test::</b> Not Done <b>Result::</b> Not Done <b>Not Done::</b> Not Done	Initial Entry

6.a Sponsor ID:

Date	Location	User	Value	Reason
Nov-11-2020 12:04:07 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

090177e196ae2e60\Final\Final On: 01-Apr-2021 03:11 (GMT)

Header Text: c4591001

Visit: V2\_VAX2\_L

Form Version: 15-Sep-2020 21:51

Site No: 4444

Subject No: 44441979

Generated By: (b) (4)

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

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (4444) Hospital Militar Central Cirujano Mayor Dr Cosme Argerich

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 17:38

Buenos Aires				
Nov-10-2020 10:23:17 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>	Initial Entry
Nov-10-2020 10:23:00 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

**6.a Test:**

Date	Location	User	Value	Reason
Nov-10-2020 10:23:00 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

**6.a Result:**

Date	Location	User	Value	Reason
Nov-11-2020 12:04:07 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry
Nov-10-2020 10:23:17 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>	Initial Entry
Nov-10-2020 10:23:00 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

**6.a Not Done:**

Date	Location	User	Value	Reason
Nov-11-2020 12:04:07 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry
Nov-10-2020 10:23:17 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>	Initial Entry
Nov-10-2020 10:23:00 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

090177e196ae2e60\Final\Final On: 01-Apr-2021 03:11 (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: 4444

Site Name: (4444) Hospital Militar Central Cirujano Mayor Dr Cosme Argerich

Subject No: 44441979

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 17:38

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**1. Data Origin**

Date	Location	User	Value	Reason
Nov-11-2020 12:04:33 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

**2. Sample Type**

Date	Location	User	Value	Reason
Nov-11-2020 12:04:33 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

**3. Sample Collected?**

Date	Location	User	Value	Reason
Nov-15-2020 13:23:14 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Nov-15-2020 12:53:32 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	The requested form has already been loaded.
Nov-15-2020 08:08:27 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	DM: Please consider updating Withdrawal of consent form, Thank you.
Nov-11-2020 12:04:33 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

**4. If no sample was collected or sample was not collected according to protocol, please provide reason:**

Date	Location	User	Value	Reason
Nov-11-2020 12:04:33 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

090177e196ae2e60\Final\Final On: 01-Apr-2021 03:11 (GMT)

Header Text: c4591001

Visit: V2\_VAX2\_L

Form Version: 22-Apr-2020 21:04

Site No: 4444

Subject No: 44441979

Generated By: (b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (4444) Hospital Militar Central Cirujano Mayor Dr Cosme Argerich

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 17:38

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

Date	Location	User	Value	Reason
Nov-11-2020 12:04:46 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

**2. Treatment Name**

Date	Location	User	Value	Reason
Nov-11-2020 12:04:46 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

**3. Formulation:**

Date	Location	User	Value	Reason
Nov-11-2020 12:04:46 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

**4. Dose Date Time:**

Date	Location	User	Value	Reason
Nov-12-2020 18:14:57 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Nov-12-2020 10:02:45 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	subject is pregnant. Thus didn't receive second dose of investigation product
Nov-11-2020 20:43:06 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (b) (4)	Query 1: Opened	DMW5359694;Randomization number is recorded and the final disposition date is present on the Disposition - Follow-up eCRF, but there is no dosing date present on the Treatment eCRF. Please review and update as appropriate.

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Header Text: c4591001

Visit: V2\_VAX2\_L

Form Version: 22-Apr-2020 21:04

Site No: 4444

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (4444) Hospital Militar Central Cirujano Mayor Dr Cosme Argerich

Subject No: 44441979

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 17:38

Nov-11-2020 12:04:46 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry</b> : Not Done	Initial Entry
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5. Anatomical Location:

Date	Location	User	Value	Reason
Nov-11-2020 12:04:46 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

6. Body Side:

Date	Location	User	Value	Reason
Nov-11-2020 12:04:46 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

7. Route:

Date	Location	User	Value	Reason
Nov-11-2020 12:04:46 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

8. Actual Dose:

Date	Location	User	Value	Reason
Nov-11-2020 12:04:46 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

9. Unit:

Date	Location	User	Value	Reason
Nov-11-2020 12:04:46 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

10. Timeframe Subject Was Observed

Date	Location	User	Value	Reason
Nov-11-2020 12:04:46	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>	Initial Entry

090177e196ae2e60\Final\Final On: 01-Apr-2021 03:11 (GMT)

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

**Site No:** 4444

**Subject No:** 44441979

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

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

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

**Site Name:** (4444) Hospital Militar Central Cirujano Mayor Dr Cosme Argerich

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 17:38

(UTC-03:00) City of Buenos Aires	(b) (4), (b) (6)	Not Done
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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
Nov-11-2020 12:04:46 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 4444

**Subject No:** 44441979

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

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

**Form Status:**

**Site Name:** (4444) Hospital Militar Central Cirujano Mayor Dr Cosme Argerich

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 17:38

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Date	Location	User	Value	Reason
Oct-13-2020 09:09:01 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Created	

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 4444

Subject No: 44441979

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete

Site Name: (4444) Hospital Militar Central Cirujano Mayor Dr Cosme Argerich

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 17:38

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**1. Category:**

Date	Location	User	Value	Reason
Oct-13-2020 09:09:01 (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-13-2020 09:09:01 (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-13-2020 09:09:01 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> EXPOSURE DURING PREGNANCY	Initial Entry

**4. Start Date Time:**

Date	Location	User	Value	Reason
Dec-16-2020 15:56:58 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 11: Closed	Response satisfies query
Dec-16-2020 10:28:52 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 11: Answered	New Information
Dec-16-2020 10:28:52 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sep/25/2020 16:20	New Information
Dec-15-2020 01:29:04 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 11: Opened	Clinical - Event end date is 05Sep20; however, SAE report end date is 25Sep20. As Injection #1 occurred on 25Sep20, exposure during pregnancy begins on this date; please review and

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Header Text: c4591001

Visit: Logs - Unscheduled

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Site No: 4444

Subject No: 44441979

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete

Site Name: (4444) Hospital Militar Central Cirujano Mayor Dr Cosme Argerich

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 17:38

				update
Nov-12-2020 18:56:22 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 9: Closed	Response satisfies query
Nov-12-2020 18:56:02 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 10: Closed	Response satisfies query
Nov-12-2020 13:11:46 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 8: Closed	Response satisfies query
Nov-12-2020 09:52:44 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	Maria Beretta (b) (4)	Query 10: Answered	Subject has a negative pregnancy test during visit1, but then the diagnosis was made. As last menstruation date was 5 SEP, that is the date considered as conception.
Nov-12-2020 09:47:59 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	Maria Beretta (b) (4)	Query 9: Answered	The pregnancy start date is considered as the last menstruation date that was on 5 SEP 2020. Despite that, subject had a negative pregnancy test on first visit and therefore, received the first dose.
Nov-12-2020 09:45:31 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 10: Opened	For EXPOSURE DURING PREGNANCY: Start date 05/Sep/2020 is before VID1VX1L visit date 25/Sep/2020. Please review and update as appropriate.
Nov-12-2020 09:45:31 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 9: Opened	Start date is before Consent Date 25/Sep /2020.
Nov-12-2020 09:45:31 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	Maria Beretta (b) (4)	<b>Data Entry:</b> Sep/5/2020 UNK:UNK	Transcription Error

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**Header Text:** c4591001**Visit:** Logs - Unscheduled**Form Version:** 22-Apr-2020 21:02**Site No:** 4444**Subject No:** 44441979**Generated By:** (b) (4)**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History**Form Status:** Data Complete**Site Name:** (4444) Hospital Militar Central Cirujano Mayor Dr Cosme Argerich**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 17:38

Nov-12-2020 09:43:45 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 8: Answered	Transcription Error
Nov-12-2020 09:43:45 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	Maria Beretta (b) (4)	<b>Data Entry:</b> UNK/UNK/2020 UNK:UNK	Transcription Error
Nov-12-2020 06:54:02 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	Balaji Prabu R (b) (4)	Query 8: Opened	As per completion guidelines version 10.0, If conception occurred prior to vaccination 1, time to be recorded as UNK:UNK. Please review and update as appropriate. Else clarify.
Nov-07-2020 13:43:33 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Closed	Response satisfies query
Nov-05-2020 07:38:58 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Reissued:Candidate	SAE RECON: Pending SDB update
Nov-04-2020 19:36:08 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	Martina Davalli (b) (4)	Query 3: Answered	The onset date is correct, and the form has been sent. Thank you.
Nov-04-2020 08:12:59 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Reissued:Opened	SAE RECON 4: Thank you for the update. Please confirm if a follow up AEM form was submitted to update onset date in Safety database.
Nov-03-2020 15:00:55 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 3: Answered	Changed Information
Nov-03-2020 15:00:55 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	Santiago Corradetti (b) (4)	<b>Data Entry:</b> Sep/25/2020 16:20	Changed Information
Nov-03-2020 10:07:00 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Reissued:Opened	SAE RECON 3: Per latest EDP guideline,if conception occurred prior to vaccination 1, Date of AE Onset =

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Site No: 4444

Subject No: 44441979

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete

Site Name: (4444) Hospital Militar Central Cirujano Mayor Dr Cosme Argerich

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 17:38

				Date of vaccination. The date of vaccination 1 for this subject is 25Sep2020. Please confirm and update accordingly.
Nov-02-2020 19:55:24 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	Mabel Berrueta (b) (4)	Query 3: Answered	Last menstrual period date: 5SEP2020- Pregnancy test positive :9OCT2020. Please advise
Oct-29-2020 06:48:32 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Reissued:Opened	SAE RECON 2: As exposure to pregnancy can only occur at the time of vaccination, onset date should reflect the date of vaccination. The date of vaccination is 25Sep2020. Please confirm and update accordingly.
Oct-21-2020 03:23:02 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (4), (b) (6)	Query 7: Closed	Response satisfies query
Oct-21-2020 03:22:41 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (4), (b) (6)	Query 6: Closed	Response satisfies query
Oct-21-2020 02:19:40 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Reissued:Candidate	SAE RECON: For Clinical review
Oct-20-2020 13:16:58 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 7: Answered	On 09OCT2020 a urine pregnancy test was performed with a positive result. 05SEP2020 is the date of the last menstruation.
Oct-20-2020 13:16:45 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 6: Answered	On 09OCT2020 a urine pregnancy test was performed with a positive result. 05SEP2020 is the date of the last menstruation.
Oct-20-2020 13:14:50 (UTC-03:00) City of	ACV0PFEINFP6000	auto query (autoquery)	Query 7: Opened	For EXPOSURE DURING

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**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 4444

**Subject No:** 44441979

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

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

**Form Status:** Data Complete

**Site Name:** (4444) Hospital Militar Central Cirujano Mayor Dr Cosme Argerich

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 17:38

Buenos Aires				PREGNANCY: Start date 05/Sep/2020 is before VID1VX1L visit date 25/Sep/2020. Please review and update as appropriate.
Oct-20-2020 13:14:50 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 6: Opened	Start date is before Consent Date 25/Sep/2020.
Oct-20-2020 13:14:50 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 3: Answered	Transcription Error
Oct-20-2020 13:14:50 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sep/5/2020 22:00	Transcription Error
Oct-18-2020 22:41:52 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 5: Closed	Response satisfies query
Oct-18-2020 22:41:09 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 4: Closed	Response satisfies query
Oct-17-2020 09:56:33 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Reissued:Opened	SAE RECON 1: Onset date updated to 19Sep2020 in AE CRF. Please confirm if a follow up AEM form was submitted to also update onset date in Safety database.
Oct-16-2020 12:59:47 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 5: Answered	On 09OCT2020 a urine pregnancy test was performed with a positive result. 19SEP is the estimated date of conception. The gestation time at the initial exposure is 2 weeks and 6 days.
Oct-16-2020 12:58:37 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 4: Answered	On 09OCT2020 a urine pregnancy test was performed with a positive result. 19SEP is the estimated date of conception.

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**Visit:** Logs - Unscheduled

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**Site No:** 4444

**Subject No:** 44441979

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

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

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**Site Name:** (4444) Hospital Militar Central Cirujano Mayor Dr Cosme Argerich

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 17:38

Oct-16-2020 12:55:37 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 5: Opened	For EXPOSURE DURING PREGNANCY: Start date 19/Sep/2020 is before VID1VX1L visit date 25/Sep/2020. Please review and update as appropriate.
Oct-16-2020 12:55:37 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 4: Opened	Start date is before Consent Date 25/Sep /2020.
Oct-16-2020 12:55:37 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 3: Answered	New Information
Oct-16-2020 12:55:37 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Sep/19/2020 22:00	New Information
Oct-16-2020 07:19:02 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Opened	SAE RECON: AER#2020394406,,per Clinical review 'The subject's first day of last menstrual period was on 05Sep2020 but the estimated date of conception is reported to be 19Sep2020. Please confirm correct onset date and update accordingly.
Oct-14-2020 02:06:46 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Closed	Response satisfies query
Oct-14-2020 02:06:23 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Oct-13-2020 09:15:08 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Answered	On 09OCT2020 a urine pregnancy test was performed with a positive result. On 5SEP2020 was the last menstruation of the participant.
Oct-13-2020 09:14:02 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	On 09OCT2020 a urine pregnancy test was

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**Site No:** 4444

**Subject No:** 44441979

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

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

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**Site Name:** (4444) Hospital Militar Central Cirujano Mayor Dr Cosme Argerich

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Buenos Aires				performed with a positive result. On 5SEP2020 was the last menstruation of the participant.
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Subject No: 44441979

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Form Status: Data Complete

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**4. Start Date Time:**

Date	Location	User	Value	Reason
Oct-13-2020 09:09:01 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Opened	For EXPOSURE DURING PREGNANCY: Start date 05/Sep/2020 is before VID1VX1L visit date 25/Sep/2020. Please review and update as appropriate.
Oct-13-2020 09:09:01 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	Start date is before Consent Date 25/Sep /2020.
Oct-13-2020 09:09:01 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sep/5/2020 22:00	Initial Entry

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

Date	Location	User	Value	Reason
Nov-12-2020 18:29:09 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Closed	Response satisfies query
Nov-12-2020 09:50:10 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	Maria Beretta (b) (4)	Query 3: Answered	After the diagnosis of pregnancy the subject decided to withdraw consent from the study.
Nov-11-2020 12:02:40 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 3: Opened	'Disposition Follow-up form is completed and this Adverse Event is still ongoing. Please review and update as appropriate.
Nov-08-2020 08:57:12 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Closed	Response satisfies query
Nov-07-2020 10:23:12 (UTC-03:00) City of	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Answered	Yes, ongoing. The subject is still pregnan.

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Subject No: 44441979

Generated By: (b) (4)

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Buenos Aires				
Nov-07-2020 09:52:40 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	Sandip Namdeorao Suryawanshi (b) (4)	Query 2: Reissued:Opened	Kindly verify and confirm if AE is still ongoing. Thank you.
Nov-06-2020 18:49:08 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Answered	Original value is correct
Nov-06-2020 18:14:29 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Opened	'Disposition Follow-up form is completed and this Adverse Event is still ongoing. Please review and update as appropriate.
Oct-14-2020 09:03:23 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Oct-14-2020 09:01:24 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	'Disposition Follow-up form is completed and this Adverse Event is still ongoing. Please review and update as appropriate.
Oct-13-2020 09:09:01 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

6. Toxicity Grade:

Date	Location	User	Value	Reason
Nov-12-2020 13:13:01 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Nov-12-2020 09:53:36 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	Maria Beretta (b) (4)	<b>Data Entry:</b> Not Applicable	Initial Entry
Nov-12-2020 09:53:24 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Transcription Error

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Nov-12-2020 09:53:24 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	Maria Beretta (b) (4)	<b>Data Entry:</b>	Transcription Error
Nov-12-2020 06:57:55 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	Balaji Prabu R (b) (4)	Query 1: Opened	Toxicity grade is not expected for pregnancy related adverse events, hence please remove the toxicity and add item level comment as NOT APPLICABLE.
Oct-13-2020 09:09:01 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 1	Initial Entry

7. Is the adverse event serious?

If Yes, NOTIFY PFIZER IMMEDIATELY.

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

Date	Location	User	Value	Reason
Oct-18-2020 22:19:42 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Closed	Response satisfies query
Oct-17-2020 09:57:48 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Closed	Response satisfies query
Oct-16-2020 09:41:32 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 3: Answered	New Information
Oct-16-2020 09:41:32 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Answered	New Information
Oct-16-2020 09:41:32 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	New Information
Oct-16-2020 07:14:21 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Opened	SAE RECON:The pregnancy was appropriately reported to safety; however,

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				seriousness criteria is met only if there is an abnormal pregnancy outcome/protocol section 8.3.5.1. Please update seriousness criteria accordingly.
Oct-16-2020 07:13:43 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	recorded as non serious in SBD
Oct-14-2020 08:05:16 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	SAE RECON:EXPOSURE DURING PREGNANCY(Onset date:14Oct2020) is not reported to Safety database but marked serious on AE CRF.Confirm seriousness and report to Pfizer immediately.If this event is not serious, downgrade the event on AE CRF
Oct-13-2020 10:59:29 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Opened	CLINICAL The pregnancy was appropriately reported to safety; however, seriousness criteria is met only if there is an abnormal pregnancy outcome (see protocol section 8.3.5.1). Please update seriousness criteria accordingly.
Oct-13-2020 09:09:01 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	For AE EXPOSURE DURING PREGNANCY: Response to "Is the adverse event serious?" is 'Yes' but "Serious Adverse Event Number" is blank.
Oct-13-2020 09:09:01 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES Is this serious event associated wi	Initial Entry

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			th congenital anomaly or birth defect?  NO  Did this serious event result in death?  NO  Did this serious event require or prolong hospitalization?  NO  Did this serious event result in persistent or significant disability/incapacity?  NO  Is this serious event life threatening?  NO  Other medically important serious event  YES	
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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-13-2020 09:09:01 (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-13-2020 09:09:01 (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	Initial Entry

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If Other, specify:

not applicable

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Nov-06-2020 05:16:28 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Closed	Response satisfies query
Nov-04-2020 20:04:01 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Answered	It is clarified that as a result of the event it was necessary for the subject to be discontinued from the study due to exposure during pregnancy. An event follow-up form is sent with this clarification. Thank you.
Nov-04-2020 07:13:35 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000.InFormAdapter.Discrepancy	PFE SDQ PROD (b) (4)	Query 2: Opened	The Adverse Event Action Taken is DRUG WITHDRAWN but reason for treatment discontinuation is not reported as ADVERSE EVENT or DEATH. Please review and clarify. (b) (4)
Oct-14-2020 09:25:27 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query

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Oct-14-2020 09:02:30 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	The EOT has already been loaded
Oct-14-2020 08:47:06 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	GPD Clinical: please complete the End of Treatment CRF page, thank you.
Oct-13-2020 09:09:01 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> DRUG WITH DRAWN	Initial Entry

**11. Was a Concomitant Medication given?**

Date	Location	User	Value	Reason
Oct-13-2020 09:09:01 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

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

Date	Location	User	Value	Reason
Oct-13-2020 09:09:01 (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
Nov-04-2020 08:10:11 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Nov-04-2020 07:43:26 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Closed	Data ok as is.
Nov-03-2020 15:05:39 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	Santiago Corradetti (b) (4)	Query 2: Answered	I've changed the outcome to "Unknown" as you requested, but if I do that and autoquery is

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				opened because the AE is still ongoing. Please provide further information on what to do.
Nov-03-2020 14:58:17 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Opened	For AE EXPOSURE DURING PREGNANCY: Response to "What was the outcome of this adverse event?" is 'Unknown' but End Date/Time is provided or "Is the adverse event still ongoing?" is marked "Yes".
Nov-03-2020 14:58:17 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Changed Information
Nov-03-2020 14:58:17 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	Santiago Corradetti (b) (4)	<b>Data Entry:</b> UNKNOWN	Changed Information
Nov-03-2020 12:09:36 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	SAE RECON: AER#2020394406, the outcome in AE CRF was reported as NOT RECOVERED/NOT RESOLVED. Based on the latest EDP guidance, outcome should be recorded as UNKNOWN. Please confirm and update accordingly.
Oct-13-2020 09:09:01 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NOT RECOVERED/NOT RESOLVED	Initial Entry

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

Date	Location	User	Value	Reason
Nov-07-2020 18:02:34 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	Hayley Wyper (b) (4)	Query 1: Closed	Response satisfies query
Nov-07-2020 16:35:09 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Subject will continue in safety followup
Nov-07-2020 16:35:09 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Subject will continue in safety followup
Nov-07-2020 16:11:37 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	Hayley Wyper (b) (4)	Query 1: Reissued:Opened	CLINQUERY: Please review this entry in line with FUP tab i.e. if subject will continue in safety followup then please update this field to 'no'. Field indicates end of study not end of treatment
Nov-06-2020 18:54:41 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Changed data per query
Nov-06-2020 17:11:39 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	Hayley Wyper (b) (4)	Query 1: Opened	CLINQUERY: Entry indicates subject will no longer attend visits on the study due to pregnancy. If this is correct, then please update the FUP tab to report subject has ceased participation on the trial
Nov-04-2020 20:01:36 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	New Information
Oct-13-2020 09:09:01 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

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Site No: 4444

Subject No: 44441979

Generated By: (b) (4)

Form: DISPOSITION - TREATMENT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

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Subject Initials: ---

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

Date	Location	User	Value	Reason
Nov-07-2020 23:24:29 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (b) (4)	Query 2 : Closed	Auto closed by Validation Check: VC_DS001_19
Nov-07-2020 19:03:17 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 2 : Answered	Transcription Error
Nov-07-2020 19:03:17 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Oct/15/ 2020	Transcription Error
Nov-07-2020 17:42:23 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (b) (4)	Query 1 : Closed	Auto closed by Validation Check: VC_DS001_14_AN
Nov-07-2020 17:40:19 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (b) (4)	Query 2 : Opened	DMW5310452;Date is before 'Date Written consent Obtained' on the Consent form. Please clarify or correct.
Nov-07-2020 12:13:30 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1 : Answered	Transcription Error
Nov-07-2020 12:13:30 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sep/5/ 2020	Transcription Error
Nov-06-2020 23:58:52 (UTC-03:00)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (b) (4)	Query 1 : Opened	DMW5308130;'Treatment Date of Completion/Discontinuation

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City of Buenos Aires				/Death' is after 'Date of Completion/Discontinuation /Death' on the Disposition - Follow-up eCRF. Please clarify or correct.
Oct-14-2020 09:00:54 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Oct/9/2020	Initial Entry

**2. Phase of Disposition:**

Date	Location	User	Value	Reason
Oct-14-2020 09:00:54 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> VACCINATION	Initial Entry

**3. Status:**

Date	Location	User	Value	Reason
Nov-07-2020 12:12:03 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 5: Closed	Close Auto Query
Nov-07-2020 12:11:16 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 5: Opened	Response to "Status" is PREGNANCY but "Specify Status" is Provided.
Nov-07-2020 12:11:16 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> PREGNANCY	Transcription Error
Nov-07-2020 12:10:04 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 4: Closed	Close Auto Query
Nov-07-2020 12:08:38 (UTC-03:00)	ACV0PFEINFP6000	auto query (autoquery)	Query 4: Opened	Response to "Status" is OTHER but "Specify Status" is missing.

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City of Buenos Aires				
Nov-07-2020 12:08:38 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> OTHER	Transcription Error
Oct-19-2020 01:48:41 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query.
Oct-16-2020 18:01:54 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 3: Closed	Close Auto Query
Oct-16-2020 18:01:54 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> PREGNANCY	Transcription Error
Oct-16-2020 17:51:19 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 3: Opened	Status is reported as Adverse Event, but there is no Adverse Event with 'Did the adverse event cause the subject to be discontinued from the study' reported as YES. Please check and correct the data.
Oct-16-2020 17:51:19 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Transcription Error
Oct-16-2020 17:51:19 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> ADVERSE EVENT	Transcription Error
Oct-16-2020 10:44:03 (UTC-03:00)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Closed	Query raised

090177e196ae2e60\Final\Final On: 01-Apr-2021 03:11 (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: 4444

Site Name: (4444) Hospital Militar Central Cirujano Mayor Dr Cosme Argerich

Subject No: 44441979

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 17:38

City of Buenos Aires				
Oct-15-2020 15:14:56 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Answered	The volunteer notified the research team that she performed a pregnancy test on her own, it was positive.
Oct-15-2020 06:11:09 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (b) (4)	Query 2: Opened	DMW4975198;Response to 'Status' is PREGNANCY, but there is no pregnancy tests with a positive result with a 'Collection Date' on or before the disposition date. Please review and update as appropriate.
Oct-14-2020 13:34:10 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	DM: As per CRF CR Section 8.55.2, If there are two or more reasons for withdrawal and an adverse event is one of them, the adverse event is considered the primary reason. Kindly update data accordingly, else clarify, Thank you.
Oct-14-2020 09:00:54 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: PREGNANCY	Initial Entry

4. Specify Status:

Date	Location	User	Value	Reason
Nov-07-2020 12:12:03 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Transcription Error
Nov-07-2020 12:10:04 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: DISCONTINUED BY PREGNANCY	Initial Entry

090177e196ae2e60\Final\Final On: 01-Apr-2021 03:11 (GMT)

Header Text: c4591001

Visit: Follow-Up - Unscheduled

Form Version: 15-Sep-2020 21:53

Site No: 4444

Subject No: 44441979

Generated By: (b) (4)

Form: DISPOSITION - FOLLOW-UP - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (4444) Hospital Militar Central Cirujano Mayor Dr Cosme Argerich

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 17:38

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

Date	Location	User	Value	Reason
Nov-15-2020 07:51:44 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Nov-14-2020 10:43:48 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	The EOT date is correct, as she did not receive a second dose due to pregnancy. The follow-up date is also correct because the volunteer withdrew the consent for the follow-up.
Nov-12-2020 12:30:53 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	GPD Clinical: please consider if the date of Completion should be the same as the End of Treatment Date, thank you.
Nov-11-2020 12:02:40 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Nov/11/2020	Initial Entry
Nov-11-2020 12:01:23 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>	Initial Entry
Nov-10-2020 10:21:33 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry
Nov-07-2020 11:29:34 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>	Transcription Error
Nov-06-2020 18:48:11 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sep/25/2020	Changed Information
Nov-06-2020 18:14:29 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Oct/9/2020	Initial Entry

090177e196ae2e60\Final\Final On: 01-Apr-2021 03:11 (GMT)



**Header Text:** c4591001

**Visit:** Follow-Up - Unscheduled

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

**Site No:** 4444

**Subject No:** 44441979

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

**Form:** DISPOSITION - FOLLOW-UP - eCRF Audit Trail History

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

**Site Name:** (4444) Hospital Militar Central Cirujano Mayor Dr Cosme Argerich

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 17:38

Oct-14-2020 09:03:23 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>	Transcription Error
Oct-14-2020 09:01:24 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Oct/9/2020	Initial Entry

**2. Phase of Disposition:**

Date	Location	User	Value	Reason
Nov-11-2020 12:02:40 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> FOLLOW-UP	Initial Entry
Nov-11-2020 12:01:23 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b>	Initial Entry
Nov-10-2020 10:21:33 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> Not Applicable	Initial Entry
Nov-07-2020 11:29:34 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b>	Transcription Error
Nov-06-2020 18:14:29 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> FOLLOW-UP	Initial Entry
Oct-14-2020 09:03:23 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b>	Transcription Error
Oct-14-2020 09:01:24 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> FOLLOW-UP	Initial Entry

**3. Status:**

Date	Location	User	Value	Reason
Nov-11-2020 12:02:40 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> WITHDRAWAL BY SUBJECT	Initial Entry
Nov-11-2020 12:01:23 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>	Initial Entry

090177e196ae2e60\Final\Final On: 01-Apr-2021 03:11 (GMT)

**Header Text:** c4591001**Visit:** Follow-Up - Unscheduled**Form Version:** 15-Sep-2020 21:53**Site No:** 4444**Subject No:** 44441979**Generated By:** (b) (4)**Form:** DISPOSITION - FOLLOW-UP - eCRF Audit Trail History**Form Status:** Data Complete, Frozen, Verified**Site Name:** (4444) Hospital Militar Central Cirujano Mayor Dr Cosme Argerich**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 17:38

Nov-10-2020 10:21:33 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry
Nov-07-2020 16:12:27 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	Hayley Wyper (b) (4)	Query 1: Closed	Response satisfies query
Nov-07-2020 11:29:46 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Transcription Error
Nov-07-2020 11:29:46 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>	Transcription Error
Nov-07-2020 07:16:56 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	Hayley Wyper (b) (4)	Query 1: Opened	CLINQUERY: Please note, this page is related to end of study (not end of treatment). Please review its completion and confirm data correct i.e. that subject will no longer take part in safety follow up
Nov-06-2020 18:54:26 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> PREGNANCY	Changed Information
Nov-06-2020 18:47:37 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> ADVERSE EVENT	Changed Information
Nov-06-2020 18:14:29 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> PREGNANCY	Initial Entry
Oct-14-2020 09:03:14 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>	Transcription Error
Oct-14-2020 09:01:24 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> PREGNANCY	Initial Entry

**4. Specify Status:**

Date	Location	User	Value	Reason
Nov-11-2020 12:02:40	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>	Initial Entry

**Header Text:** c4591001

**Visit:** Follow-Up - Unscheduled

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

**Site No:** 4444

**Subject No:** 44441979

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

**Form:** DISPOSITION - FOLLOW-UP - eCRF Audit Trail History

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

**Site Name:** (4444) Hospital Militar Central Cirujano Mayor Dr Cosme Argerich

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 17:38

(UTC-03:00) City of Buenos Aires		(b) (4), (b) (6)	the decision to stop participating is due to particular reasons	
Nov-11-2020 12:01:23 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>	Initial Entry
Nov-10-2020 10:21:33 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

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**Header Text:** c4591001

**Visit:** Disposition - Unscheduled

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

**Site No:** 4444

**Subject No:** 44441979

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

**Form:** WITHDRAWAL OF CONSENT - eCRF Audit Trail History

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

**Site Name:** (4444) Hospital Militar Central Cirujano Mayor Dr Cosme Argerich

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 17:38

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***1. Withdrawal of Consent Date :***

<b>Date</b>	<b>Location</b>	<b>User</b>	<b>Value</b>	<b>Reason</b>
Nov-15-2020 12:52:49 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Nov/11/2020	Initial Entry

Header Text: c4591001

Visit: Subject Status - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 4444

Subject No: 44441979

Generated By: (b) (4)

Form: SUBJECT STATUS - eCRF Audit Trail History

Form Status: Data Complete, Verified

Site Name: (4444) Hospital Militar Central Cirujano Mayor Dr Cosme Argerich

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 17:38

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**I. Subject Status**

Date	Location	User	Value	Reason
Nov-11-2020 12:02:40 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> DISCONTINUED	Initial Entry
Nov-07-2020 12:11:16 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> DISCONTINUED	Transcription Error
Nov-07-2020 12:08:38 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> DISCONTINUED	Transcription Error
Nov-07-2020 11:29:46 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> DISCONTINUED	Transcription Error
Nov-06-2020 18:54:26 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> DISCONTINUED	Changed Information
Nov-06-2020 18:47:37 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> DISCONTINUED	Changed Information
Nov-06-2020 18:14:29 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> DISCONTINUED	Initial Entry
Oct-16-2020 18:01:54 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> DISCONTINUED	Transcription Error
Oct-16-2020 17:51:19 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> DISCONTINUED	Transcription Error
Oct-14-2020 09:03:14 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> DISCONTINUED	Transcription Error
Oct-14-2020 09:01:24 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> DISCONTINUED	Initial Entry
Oct-14-2020 09:00:54 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> DISCONTINUED	Initial Entry

090177e196ae2e60\Final\Final On: 01-Apr-2021 03:11 (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: 4444

Site Name: (4444) Hospital Militar Central Cirujano Mayor Dr Cosme Argerich

Subject No: 44441979

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 17:38

Buenos Aires				
Sep-25-2020 20:00:52 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> ENROLLED/RANDOMIZED	Initial Entry
Sep-25-2020 19:58:20 (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
Nov-11-2020 12:02:40 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> Nov/11/2020	Initial Entry
Nov-07-2020 19:03:17 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> Oct/15/2020	Transcription Error
Nov-07-2020 12:13:30 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> Sep/5/2020	Transcription Error
Nov-07-2020 12:11:16 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> Oct/9/2020	Transcription Error
Nov-07-2020 12:08:38 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> Oct/9/2020	Transcription Error
Nov-07-2020 11:29:46 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> Oct/9/2020	Transcription Error
Nov-07-2020 11:29:34 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> Oct/9/2020	Transcription Error
Nov-06-2020 18:54:26 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> Sep/25/2020	Changed Information
Nov-06-2020 18:48:11 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> Sep/25/2020	Changed Information
Nov-06-2020 18:47:37 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> Oct/9/2020	Changed Information

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**Header Text:** c4591001

**Visit:** Subject Status - Unscheduled

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

**Site No:** 4444

**Subject No:** 44441979

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

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

**Form Status:** Data Complete, Verified

**Site Name:** (4444) Hospital Militar Central Cirujano Mayor Dr Cosme Argerich

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 17:38

Nov-06-2020 18:14:29 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> Oct/9/2020	Initial Entry
Oct-16-2020 18:01:54 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> Oct/9/2020	Transcription Error
Oct-16-2020 17:51:19 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> Oct/9/2020	Transcription Error
Oct-14-2020 09:03:23 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> Oct/9/2020	Transcription Error
Oct-14-2020 09:03:14 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> Oct/9/2020	Transcription Error
Oct-14-2020 09:01:24 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> Oct/9/2020	Initial Entry
Oct-14-2020 09:00:54 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> Oct/9/2020	Initial Entry
Sep-25-2020 20:00:52 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> Sep/25/2020	Initial Entry
Sep-25-2020 19:58:20 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> Sep/25/2020	Initial Entry

090177e196ae2e60\Final\Final On: 01-Apr-2021 03:11 (GMT)

**Header Text:** c4591001

**Visit:** Investigator Signature - Unscheduled

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

**Site No:** 4444

**Subject No:** 44441979

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

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

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

**Site Name:** (4444) Hospital Militar Central Cirujano Mayor Dr Cosme Argerich

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 17:38

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*I. Casebook Signature*

Date	Location	User	Value	Reason
Nov-10-2020 10:58:17 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	Maria Beretta (b) (4)	<b>Data Entry:</b> Click Here to Enable	Initial Entry