

**Header Text:** c4591001

**Visit:** COHORT\_SELECTION

**Form:** COHORT SELECTION

**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:** 44441550

**Subject Initials:** ---

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

**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:** 44441550

**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/23/2020
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**Header Text:** c4591001

**Visit:** COHORT\_SELECTION

**Form:** DEMOGRAPHY

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

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

**Site No:** 4444

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

**Subject No:** 44441550

**Subject Initials:** ---

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

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

[eCRF Audit Trail History](#)

**Demography**

1.	Subject ID	[44441550]
2.	Birth Date:	(b) (6)/1971
3.	Sex:	FEMALE
4.	Ethnicity:	HISPANIC OR LATINO(A) OR OF SPANISH ORIGIN
5.	Race: (Check X all that apply):	WHITE
6.	Racial Designation:	

090177e196ae2ee6\Final\Final On: 01-Apr-2021 03:26 (GMT)

**Header Text:** c4591001

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

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

**Site No:** 4444

**Subject No:** 44441550

**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/23/2020
2.	Erroneous Visit	

**Header Text:** c4591001

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

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

**Site No:** 4444

**Subject No:** 44441550

**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 _____
----	--	-------------------------

090177e196ae2ee6\Final\Final On: 01-Apr-2021 03:26 (GMT)

**Header Text:** c4591001

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

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

**Site No:** 4444

**Subject No:** 44441550

**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/23/2020
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:** 44441550

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

**Form:** GENERAL MEDICAL 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

[eCRF Audit Trail History](#)

**Medical History Details**

1.a	Line/MH Number:	[1]
	Disease/Syndrome /Surgery/Non-Drug Allergies/Drug Allergies:	[Climacteric syndrome]
	Start Date:	Jan/1/2012
	Ongoing:	YES
1.b	Line/MH Number:	[2]
	Disease/Syndrome /Surgery/Non-Drug Allergies/Drug Allergies:	[bilateral breast implant placement]
	Start Date:	Feb/13/2020
	Ongoing:	NO End Date: Feb/13/2020
1.c	Line/MH Number:	[3]
	Disease/Syndrome /Surgery/Non-Drug Allergies/Drug Allergies:	[gallstones]
	Start Date:	Feb/1/2020
	Ongoing:	NO End Date: Dec/23/2020

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**Header Text:** c4591001

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

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

**Site No:** 4444

**Subject No:** 44441550

**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:** 44441550

**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/23/2020
2.	Weight:	[59.0]
3.	Unit:	kg
4.	Height:	[170.0]
5.	Unit:	cm
6.	Body Mass Index:	[20.4]

**Vital Signs Details**

7.a	Record Identifier:	1
	Temperature:	[36.5]
	Unit:	C
	Temperature Location:	ORAL CAVITY

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**Header Text:** c4591001

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

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

**Site No:** 4444

**Subject No:** 44441550

**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/23/2020
4.	Laboratory Name and Address (Derived)	[STUDY SITE]
5.	Specimen Type:	URINE

**Lab Result**

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

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**Header Text:** c4591001

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

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

**Site No:** 4444

**Subject No:** 44441550

**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/23/2020
2.	Randomization Number:	[97257]
3.	Randomization Group:	[ ]

**Header Text:** c4591001**Visit:** V1\_DAY1\_VAX1\_L**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY**Form Version:** 22-Apr-2020 21:03**Form Status:** Data Complete, Locked, Frozen, Verified**Site No:** 4444**Site Name:** (4444) Hospital Militar Central Cirujano Mayor Dr Cosme Argerich**Subject No:** 44441550**Subject Initials:** ---**Generated By:** (b) (4)**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/23/2020
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	[BRVLGS]
5.b	Sample ID	[BRVLGT]
5.c	Sample ID	[BHXG7V]
5.d	Sample ID	[BRVLHG]

**Header Text:** c4591001

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

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

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

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

**Site No:** 4444

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

**Subject No:** 44441550

**Subject Initials:** ---

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

**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/23/2020
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	[BPWBV2]
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**Header Text:** c4591001

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

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

**Site No:** 4444

**Subject No:** 44441550

**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/23/2020 10:00
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

090177e196ae2ee6\Final\Final On: 01-Apr-2021 03:26 (GMT)

**Header Text:** c4591001

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

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

**Site No:** 4444

**Subject No:** 44441550

**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:** 44441550

**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	Oct/15/2020
2.	Erroneous Visit	



**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

**Site No:** 4444

**Subject No:** 44441550

**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

[eCRF Audit Trail History](#)

**Vital Signs**

1.	Date:	Oct/15/2020
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**Vital Signs Details**

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

090177e196ae2ee6\Final\Final On: 01-Apr-2021 03:26 (GMT)

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

**Site No:** 4444

**Subject No:** 44441550

**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:	Oct/15/2020
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:	

090177e196ae2ee6\Final\Final On: 01-Apr-2021 03:26 (GMT)

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

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

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

**Site No:** 4444

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

**Subject No:** 44441550

**Subject Initials:** ---

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

**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: Oct/15/2020
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	[BKNZDP]
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090177e196ae2ee6\Final\Final On: 01-Apr-2021 03:26 (GMT)

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

**Site No:** 4444

**Subject No:** 44441550

**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:	Oct/15/2020 10:56
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

090177e196ae2ee6\Final\Final On: 01-Apr-2021 03:26 (GMT)

**Header Text:** c4591001

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

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

**Site No:** 4444

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

**Subject No:** 44441550

**Subject Initials:** ---

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

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

[eCRF Audit Trail History](#)

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

**Header Text:** c4591001**Visit:** V3\_MONTH1\_POSTVAX2\_L **Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY**Form Version:** 22-Apr-2020 21:03 **Form Status:** Data Complete, Locked, Frozen, Verified**Site No:** 4444**Site Name:** (4444) Hospital Militar Central Cirujano Mayor Dr Cosme Argerich**Subject No:** 44441550**Subject Initials:** ---**Generated By:** (b) (4)**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: Nov/12/2020
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[ ]

**Aliquot**

Please enter barcode for each aliquot.

5.a	Sample ID	[BNV0WS]
5.b	Sample ID	[BP1R1H]
5.c	Sample ID	[BNV0TW]

**Header Text:** c4591001

**Visit:** V4\_MONTH6\_L

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

**Site No:** 4444

**Subject No:** 44441550

**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:** 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:** 44441550**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:** V5\_MONTH12\_L

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

**Site No:** 4444

**Subject No:** 44441550

**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:** 44441550

**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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090177e196ae2ee6\Final\Final On: 01-Apr-2021 03:26 (GMT)

**Header Text:** c4591001

**Visit:** V6\_MONTH24\_L

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

**Site No:** 4444

**Subject No:** 44441550

**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:** 44441550

**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 1 -  
Unscheduled Visit on Jan/12/2021

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

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

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

**Site No:** 4444

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

**Subject No:** 44441550

**Subject Initials:** ---

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

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

[eCRF Audit Trail History](#)

**Date of Visit**

1.	Date of Visit	Jan/12/2021
2.	Erroneous Visit	

**COVID-19 Illness Visit**

3.	COVID-19 Illness Visit:	COVID_A
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090177e196ae2ee6\Final\Final On: 01-Apr-2021 03:26 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Jan/12/2021

**Form Version:** 14-Jan-2021 02:23

**Site No:** 4444

**Subject No:** 44441550

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

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

**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

[eCRF Audit Trail History](#)

**Signs and Symptoms**

1.	Date of Assessment:	Jan/12/2021
2.	Date of First Symptom Started:	Dec/30/2020
3.	Symptoms Ongoing?	NO Date of Last Symptom Resolved: Dec/31/2020

**Symptoms**

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

090177e196ae2ee6\Final\Final On: 01-Apr-2021 03:26 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Jan/12/2021

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

**Form Version:** 14-Jan-2021 02:23

**Form Status:** Data Complete

**Site No:** 4444

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

**Subject No:** 44441550

**Subject Initials:** ---

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

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

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

090177e196ae2ee6\Final\Final On: 01-Apr-2021 03:26 (GMT)

**Header Text:** c4591001

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

**Form:** MICROBIOLOGY SPECIMEN

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

**Site No:** 4444

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

**Subject No:** 44441550

**Subject Initials:** ---

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

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

#	Date of Collection	Specimen Type	Specimen Collection Location	Assay Code and Description	Device Type	Form Instance
1.	Dec/25/2020	SWABBED MATERIAL	NASOPHARYNX	SEVERE ACUTE RESPIRATORY SYNDROME CORONAVIRUS 2	SARS-COV-2 DIAGNOSTIC TEST	<a href="#">Repeating Pages</a>
2.	Dec/30/2020	SWABBED MATERIAL	NASOPHARYNX	SEVERE ACUTE RESPIRATORY SYNDROME CORONAVIRUS 2	SARS-COV-2 DIAGNOSTIC TEST	<a href="#">Repeating Pages</a>

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**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Jan/12/2021

**Form:** MICROBIOLOGY SPECIMEN

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

**Form Status:** Data Complete

**Site No:** 4444

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

**Subject No:** 44441550

**Subject Initials:** ---

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

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

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**Microbiology Specimen**

1.	Actual Date of Collection:	Dec/25/2020
2.	Specimen Type:	SWABBED MATERIAL
3.	Specimen Collection Location:	NASOPHARYNX
4.	Assay Code and Description:	SEVERE ACUTE RESP SYNDROME CORONAVIRUS 2
5.	Device Type:	SARS-COV-2 DIAGNOSTIC TEST
6.	Trade Name:	OTHER
7.	Test Result:	NEGATIVE
8.	Comments/Findings /Details:	[ ]
9.	Trade Name Other, Specify:	[NALT Unknown]

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**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Jan/12/2021

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

**Site No:** 4444

**Subject No:** 44441550

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

**Form:** MICROBIOLOGY SPECIMEN

**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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**Microbiology Specimen**

1.	Actual Date of Collection:	Dec/30/2020
2.	Specimen Type:	SWABBED MATERIAL
3.	Specimen Collection Location:	NASOPHARYNX
4.	Assay Code and Description:	SEVERE ACUTE RESP SYNDROME CORONAVIRUS 2
5.	Device Type:	SARS-COV-2 DIAGNOSTIC TEST
6.	Trade Name:	OTHER
7.	Test Result:	NEGATIVE
8.	Comments/Findings /Details:	[ ]
9.	Trade Name Other, Specify:	[NALT Unknown]

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**Header Text:** c4591001**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Jan/12/2021**Form Version:** 22-Apr-2020 21:03**Site No:** 4444**Subject No:** 44441550**Generated By:** (b) (4)**Form:** ELECTRONIC SAMPLE TRACKING - NASAL  
SWAB SELF**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](#)**Electronic Sample Tracking**

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB_SELF
3.	Sample Collected?	NO
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[Subject refused home visit and swab due to having 2 swabs done on DEC 25 and DEC 30]

**Aliquot**

Please enter barcode for each aliquot.

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

**Header Text:** c4591001**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Jan/12/2021**Form Version:** 22-Apr-2020 21:03**Site No:** 4444**Subject No:** 44441550**Generated By:** (b) (4)**Form:** ELECTRONIC SAMPLE TRACKING - NASAL  
SWAB**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](#)**Electronic Sample Tracking**

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB
3.	Sample Collected?	NO
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[Subject refused home visit and swab due to having 2 swabs done on DEC 25 and DEC 30]

**Aliquot**

Please enter barcode for each aliquot.

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

**Header Text:** c4591001**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Jan/12/2021**Form:** HEALTH CARE UTILIZATION**Form Version:** 14-Jan-2021 02:24**Form Status:** Data Complete**Site No:** 4444**Site Name:** (4444) Hospital Militar Central Cirujano  
Mayor Dr Cosme Argerich**Subject No:** 44441550**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 17:38[eCRF Audit Trail History](#)**Health Care Utilization**

1.a	Physician or Healthcare Professional:	SPECIALIST
	Occurrence of Visits or Contacts:	NO
1.b	Physician or Healthcare Professional:	EMERGENCY ROOM
	Occurrence of Visits or Contacts:	YES Number of Visits or Contacts: [4]
1.c	Physician or Healthcare Professional:	PRIMARY CARE PHYSICIAN
	Occurrence of Visits or Contacts:	NO
1.d	Physician or Healthcare Professional:	URGENT CARE
	Occurrence of Visits or Contacts:	NO
1.e	Physician or Healthcare Professional:	TELEPHONE CONSULTATION
	Occurrence of Visits or Contacts:	NO

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Jan/12/2021

**Form:** HEALTH CARE UTILIZATION

**Form Version:** 14-Jan-2021 02:24

**Form Status:** Data Complete

**Site No:** 4444

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

**Subject No:** 44441550

**Subject Initials:** ---

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

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

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

**Health Care Utilization Other**

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

**Health Care Utilization**

3.	Has the subject been hospitalized due to potential COVID-19 illness?	YES Has the subject been in intensive care due to potential COVID-19 illness? NO
----	--	--

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**Header Text:** c4591001

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

**Form:** HOSPITALIZATION DETAILS

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

**Site No:** 4444

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

**Subject No:** 44441550

**Subject Initials:** ---

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

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

#	Hospitalization Category	Hospitalization Term	Admission Date	Ongoing	Form Instance
1.	HOSPITALIZATION STATUS	HOSPITAL	Dec/23/2020	NO Discharge Date:  Dec/31/2020	<a href="#">Repeating Pages</a>

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**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Jan/12/2021

**Form:** HOSPITALIZATION DETAILS

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

**Form Status:** Data Complete

**Site No:** 4444

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

**Subject No:** 44441550

**Subject Initials:** ---

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

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

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**Hospitalization Details**

1.	Hospitalization Category:	HOSPITALIZATION STATUS
2.	Hospitalization Term:	HOSPITAL
3.	Admission Date:	Dec/23/2020
4.	Ongoing?	NO Discharge Date: Dec/31/2020

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**Header Text:** c4591001

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

**Form:** RESPIRATORY TREATMENT

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

**Site No:** 4444

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

**Subject No:** 44441550

**Subject Initials:** ---

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

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

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

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Jan/12/2021

**Form:** RESPIRATORY TREATMENT

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

**Form Status:** Not Started

**Site No:** 4444

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

**Subject No:** 44441550

**Subject Initials:** ---

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

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

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**Respiratory Treatment**

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

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**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Jan/12/2021

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

**Site No:** 4444

**Subject No:** 44441550

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

**Form:** ILLNESS DETAILS

**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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**Illness Details**

1.	Category of Clinical Event:	POTENTIAL COVID-19 ILLNESS
2.	Was a diagnosis obtained for Potential COVID-19 Illness?	YES Respiratory Illness Diagnosis: [Hospital-acquired pneumonia]  Date of Diagnosis: Dec/30/2020
3.	Toxicity Grade:	3

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**Header Text:** c4591001

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

**Form:** ILLNESS DETAILS - SEVERE

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

**Site No:** 4444

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

**Subject No:** 44441550

**Subject Initials:** ---

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

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

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Jan/12/2021

**Form:** ILLNESS DETAILS - SEVERE

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

**Form Status:** Not Started

**Site No:** 4444

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

**Subject No:** 44441550

**Subject Initials:** ---

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

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

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**Illness Details**

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

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**Header Text:** c4591001

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

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

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

**Site No:** 4444

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

**Subject No:** 44441550

**Subject Initials:** ---

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

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

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

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Jan/12/2021

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

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

**Form Status:** Not Started

**Site No:** 4444

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

**Subject No:** 44441550

**Subject Initials:** ---

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

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

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**Lab Chemistry Details**

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

**Lab Result**

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

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**Header Text:** c4591001

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

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

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

**Site No:** 4444

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

**Subject No:** 44441550

**Subject Initials:** ---

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

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

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



**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Jan/12/2021

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

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

**Form Status:** Not Started

**Site No:** 4444

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

**Subject No:** 44441550

**Subject Initials:** ---

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

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

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**Laboratory Data Hematology**

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

**Lab Result**

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

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**Header Text:** c4591001

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

**Form:** VITAL SIGNS - COVID

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

**Site No:** 4444

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

**Subject No:** 44441550

**Subject Initials:** ---

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

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

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

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Jan/12/2021

**Form:** VITAL SIGNS - COVID

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

**Form Status:** Not Started

**Site No:** 4444

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

**Subject No:** 44441550

**Subject Initials:** ---

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

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

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**Vital Signs**

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

**Vital Signs Details**

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

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**Header Text:** c4591001

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

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

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

**Site No:** 4444

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

**Subject No:** 44441550

**Subject Initials:** ---

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

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

#	Date:	Vital Signs Details		Form Instance
1.	Dec/30/2020	<b>Record Identifier:</b>	<b>Oxygen Saturation</b>	<a href="#">Repeating Pages</a>
		1	93.0	

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Jan/12/2021

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

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

**Form Status:** Data Complete

**Site No:** 4444

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

**Subject No:** 44441550

**Subject Initials:** ---

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

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

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**Vital Signs**

1.	Date:	Dec/30/2020
----	-------	-------------

**Vital Signs Details**

2.a	Record Identifier:	1
	SPO2 Pulse Oximetry %	[93.0]

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**Header Text:** c4591001

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

**Form:** OXYGENATION PARAMETERS

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

**Site No:** 4444

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

**Subject No:** 44441550

**Subject Initials:** ---

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

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

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

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**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Jan/12/2021

**Form:** OXYGENATION PARAMETERS

**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:** 44441550

**Subject Initials:** ---

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

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

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**Oxygenation Parameters**

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

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**Header Text:** c4591001

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

**Form:** CONCOMITANT MEDICATIONS -  
VASOPRESSORS

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

**Site No:** 4444

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

**Subject No:** 44441550

**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:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Jan/12/2021

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

**Site No:** 4444

**Subject No:** 44441550

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

**Form:** CONCOMITANT MEDICATIONS -  
VASOPRESSORS

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

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**Header Text:** c4591001

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

**Form:** IMAGING

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

**Site No:** 4444

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

**Subject No:** 44441550

**Subject Initials:** ---

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

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

#	Date of Assessment	Location of Assessment	Imaging Method	Overall Assessment	Form Instance
1.	Dec/30/2020	CHEST	CT SCAN	ABNORMAL <i>If abnormal, specify findings:</i>  Bilateral pleural effusion, predominantly right. Consolidative opacity is observed in both lung bases with the presence of an air bronchogram in its interior, predominantly on the left	<a href="#">Repeating Pages</a>

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**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Jan/12/2021

**Form:** IMAGING

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

**Form Status:** Data Complete

**Site No:** 4444

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

**Subject No:** 44441550

**Subject Initials:** ---

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

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

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**Imaging**

1.	Date of Assessment:	Dec/30/2020
2.	Location of Assessment:	CHEST
3.	Type of Imaging Exam:	CT SCAN
4.	Assessment:	<p>ABNORMAL</p> <p>If abnormal, specify findings: [Bilateral pleural effusion, predominantly right. Consolidative opacity is observed in both lung bases with the presence of an air bronchogram in its interior, predominantly on the left]</p>

090177e196ae2ee6\Final\Final On: 01-Apr-2021 03:26 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_CONVA 1 -  
Unscheduled Visit on Feb/18/2021

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

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

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

**Site No:** 4444

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

**Subject No:** 44441550

**Subject Initials:** ---

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

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

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**Date of Visit**

1.	Date of Visit	Feb/18/2021
2.	Erroneous Visit	

**COVID-19 Illness Visit**

3.	COVID-19 Illness Visit:	COVID_A1
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**Header Text:** c4591001

**Visit:** POT\_COVID\_CONVA 1 -  
Unscheduled Visit on Feb/18/2021

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

**Site No:** 4444

**Subject No:** 44441550

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

**Form:** ELECTRONIC SAMPLE TRACKING -  
IMMUNOGENICITY

**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](#)

**Electronic Sample Tracking**

1.	Data Origin	SITE
2.	Sample Type	SERUM
3.	Sample Collected?	YES Date of Collection: Feb/18/2021
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[ ]

**Aliquot**

Please enter barcode for each aliquot.

5.a	Sample ID	[BS1RVT]
5.b	Sample ID	[BS1RW5]
5.c	Sample ID	[BRM90C]

090177e196ae2ee6\Final\Final On: 01-Apr-2021 03:26 (GMT)

**Header Text:** c4591001

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

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

**Site No:** 4444

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

**Subject No:** 44441550

**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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**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:** 44441550**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:** Unplanned - New Unscheduled **Form:** DATE OF VISIT  
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:** 44441550

**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:** 44441550    **Subject Initials:** ---

**Generated By:** (b) (4)    **Generated Time (GMT):** 29-Mar-2021 17:38

**Unplanned Assessments**

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

090177e196ae2ee6\Final\Final On: 01-Apr-2021 03:26 (GMT)

**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:** 44441550

**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	Intestinal perforation	Dec/23/2020 09:00	NO End Date Time:  Jan/13/2021 15:00	<a href="#">Repeating Pages</a>
2.	ADVERSE EVENT	2	Hospital-acquired pneumonia	Dec/30/2020 09:00	NO End Date Time:  Jan/13/2021 15:00	<a href="#">Repeating Pages</a>

090177e196ae2ee6\Final\Final On: 01-Apr-2021 03:26 (GMT)

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

**Form:** ADVERSE EVENT REPORT

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

**Form Status:** Data Complete, Frozen

**Site No:** 4444

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

**Subject No:** 44441550

**Subject Initials:** ---

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

**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)	[Intestinal perforation]
4.	Start Date Time:	Dec/23/2020 09:00
5.	Is the adverse event still ongoing?	NO End Date Time: Jan/13/2021 15:00
6.	Toxicity Grade:	3

090177e196ae2ee6\Final\Final On: 01-Apr-2021 03:26 (GMT)

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 4444

**Subject No:** 44441550

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

**Form:** ADVERSE EVENT REPORT

**Form Status:** Data Complete, Frozen

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

**Subject Initials:** ---

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

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

090177e196ae2ee6\Final\Final On: 01-Apr-2021 03:26 (GMT)

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

**Form:** ADVERSE EVENT REPORT

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

**Form Status:** Data Complete, Frozen

**Site No:** 4444

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

**Subject No:** 44441550

**Subject Initials:** ---

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

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

10.	Latest Action Taken with Study Treatment:	NOT APPLICABLE
11.	Was a Concomitant Medication given?	YES
12.	Was a Non-Drug Treatment given?	YES
13.	What was the outcome of this adverse event?:	RECOVERED/RESOLVED
14.	Did the adverse event cause the subject to be discontinued from the study?	NO
15.	Serious Adverse Event Number: For Pfizer Use Only	[2021012994]

090177e196ae2ee6\Final\Final On: 01-Apr-2021 03:26 (GMT)

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 4444

**Subject No:** 44441550

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

**Form:** ADVERSE EVENT REPORT

**Form Status:** Data Complete, Frozen

**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:	[2]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[Hospital-acquired pneumonia]
4.	Start Date Time:	Dec/30/2020 09:00
5.	Is the adverse event still ongoing?	NO End Date Time: Jan/13/2021 15:00
6.	Toxicity Grade:	3

090177e196ae2ee6\Final\Final On: 01-Apr-2021 03:26 (GMT)

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 4444

**Subject No:** 44441550

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

**Form:** ADVERSE EVENT REPORT

**Form Status:** Data Complete, Frozen

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

**Subject Initials:** ---

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

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

090177e196ae2ee6\Final\Final On: 01-Apr-2021 03:26 (GMT)

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

**Form:** ADVERSE EVENT REPORT

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

**Form Status:** Data Complete, Frozen

**Site No:** 4444

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

**Subject No:** 44441550

**Subject Initials:** ---

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

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

10.	Latest Action Taken with Study Treatment:	NOT APPLICABLE
11.	Was a Concomitant Medication given?	YES
12.	Was a Non-Drug Treatment given?	NO
13.	What was the outcome of this adverse event?:	RECOVERED/RESOLVED
14.	Did the adverse event cause the subject to be discontinued from the study?	NO
15.	Serious Adverse Event Number: For Pfizer Use Only	[2021012994]

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**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:** 44441550

**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:** 44441550

**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	[ ]

090177e196ae2ee6\Final\Final On: 01-Apr-2021 03:26 (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:** 44441550

**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:** CONCOMITANT MEDICATIONS - NON STUDY VACCINATIONS

**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:** 44441550

**Subject Initials:** ---

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

**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:	//

090177e196ae2ee6\Final\Final On: 01-Apr-2021 03:26 (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:** 44441550

**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>

090177e196ae2ee6\Final\Final On: 01-Apr-2021 03:26 (GMT)

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

**Form:** CONCOMITANT MEDICATIONS - PROHIBITED

**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:** 44441550

**Subject Initials:** ---

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

**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?	

090177e196ae2ee6\Final\Final On: 01-Apr-2021 03:26 (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:** 44441550

**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:** RADIATION TREATMENT

**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:** 44441550

**Subject Initials:** ---

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

**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?	

090177e196ae2ee6\Final\Final On: 01-Apr-2021 03:26 (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:** 44441550

**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:** TRANSFUSIONS

**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:** 44441550

**Subject Initials:** ---

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

**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:** DISPOSITION - TREATMENT

**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:** 44441550

**Subject Initials:** ---

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

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

[eCRF Audit Trail History](#)

**Disposition - Treatment**

1.	Date of Completion/Discontinuation /Death :	Nov/12/2020
2.	Phase of Disposition:	VACCINATION
3.	Status:	COMPLETED
4.	Specify Status:	[ ]

090177e196ae2ee6\Final\Final On: 01-Apr-2021 03:26 (GMT)

**Header Text:** c4591001

**Visit:** Unplanned Vaccination -  
Unscheduled

**Form:** DATE OF VISIT

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

**Form Status:** Not Started

**Site No:** 4444

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

**Subject No:** 44441550

**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:** 44441550

**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:	

090177e196ae2ee6\Final\Final On: 01-Apr-2021 03:26 (GMT)

**Header Text:** c4591001**Visit:** Unplanned Vaccination -  
Unscheduled**Form:** LAB URINALYSIS - PREGNANCY TEST**Form Version:** 20-Feb-2021 02:14**Form Status:** Not Started**Site No:** 4444**Site Name:** (4444) Hospital Militar Central Cirujano  
Mayor Dr Cosme Argerich**Subject No:** 44441550**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:	

**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:** 44441550

**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?	

090177e196ae2ee6\Final\Final On: 01-Apr-2021 03:26 (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:** 44441550

**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:** 44441550

**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 - **Form:** DATE OF VISIT  
Unscheduled

**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:** 44441550

**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:** 44441550

**Subject Initials:** ---

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

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

**Informed Consent - Asymptomatic Surveillance**

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

090177e196ae2ee6\Final\Final On: 01-Apr-2021 03:26 (GMT)

**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:** 44441550**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:** 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:** 44441550**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:** Follow-Up - Unscheduled

**Form:** DISPOSITION - FOLLOW-UP

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

**Form Status:** Not Started

**Site No:** 4444

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

**Subject No:** 44441550

**Subject Initials:** ---

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

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

**Disposition - Follow-Up**

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

**Header Text:** c4591001

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

Unscheduled

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

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

**Site No:** 4444

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

**Subject No:** 44441550

**Subject Initials:** ---

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

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

[eCRF Audit Trail History](#)

**Date of Visit**

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

090177e196ae2ee6\Final\Final On: 01-Apr-2021 03:26 (GMT)

**Header Text:** c4591001

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

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

**Site No:** 4444

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

**Subject No:** 44441550

**Subject Initials:** ---

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

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

[eCRF Audit Trail History](#)

**Further Vaccination Confirmation**

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



**Header Text:** c4591001

**Visit:** Disposition - Unscheduled

**Form:** TREATMENT UNBLINDED

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

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

**Site No:** 4444

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

**Subject No:** 44441550

**Subject Initials:** ---

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

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

[eCRF Audit Trail History](#)

**Treatment Unblinded**

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

**Header Text:** c4591001

**Visit:** Disposition - Unscheduled

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

**Site No:** 4444

**Subject No:** 44441550

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

**Form:** WITHDRAWAL OF CONSENT

**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

**Withdrawal Of Consent**

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

**Header Text:** c4591001

**Visit:** Disposition - Unscheduled

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

**Site No:** 4444

**Subject No:** 44441550

**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:	//
----	--	----

**Cause of Death**

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

090177e196ae2ee6\Final\Final On: 01-Apr-2021 03:26 (GMT)

**Header Text:** c4591001

**Visit:** Subject Status - Unscheduled

**Form:** SUBJECT STATUS

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

**Form Status:** Data Complete, Verified

**Site No:** 4444

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

**Subject No:** 44441550

**Subject Initials:** ---

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

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

[eCRF Audit Trail History](#)

**Subject Status**

1.	Subject Status	FOLLOW-UP
2.	Subject Status Date	Nov/12/2020

**Header Text:** c4591001

**Visit:** Investigator Signature -  
Unscheduled

**Form:** CASEBOOK SIGNATURE FORM

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

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

**Site No:** 4444

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

**Subject No:** 44441550

**Subject Initials:** ---

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

**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:** 44441550

**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
(b) (6)	Approved	Mar-11-2021 07:44:49 (UTC-03:00) City of Buenos Aires	BOOK	Signed

**Affidavit:**

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

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

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

**Header Text:** c4591001

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

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

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

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

**Site No:** 4444

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

**Subject No:** 44441550

**Subject Initials:** ---

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

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

[Back to Form](#)

Item	Date	User	Comment
Form	Sep-23-2020 14:26:34 (UTC-03:00) City of Buenos Aires	(b) (4), (b) (6)	Not Applicable

090177e196ae2ee6\Final\Final On: 01-Apr-2021 03:26 (GMT)

**Header Text:** c4591001

**Visit:** Investigator Signature -  
Unscheduled

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

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

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

**Site No:** 4444

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

**Subject No:** 44441550

**Subject Initials:** ---

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

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

[Back to Form](#)

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

- CRF\_Sign

Name	Signature Meaning	Date	Type	Action
(b) (6)	Approved	Mar-11-2021 07:44:49 (UTC-03:00) City of Buenos Aires	BOOK	Signed

**Affidavit:**

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

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

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

(b) (6)	N/A	Feb-19-2021 10:15:36 (UTC-03:00) City of Buenos Aires		Edit - All signatures invalidated
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**Affidavit:**

N/A

(b) (6)	Approved	Feb-08-2021 19:49:37 (UTC-03:00) City of Buenos Aires	BOOK	Signed
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090177e196ae2ee6\Final\Final On: 01-Apr-2021 03:26 (GMT)



**Header Text:** c4591001

**Visit:** Investigator Signature -  
Unscheduled

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

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

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

**Site No:** 4444

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

**Subject No:** 44441550

**Subject Initials:** ---

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

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

**Affidavit:**

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

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

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

(b) (6)	N/A	Feb-05-2021 13:44:31 (UTC-03:00) City of Buenos Aires		Edit - All signatures invalidated
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**Affidavit:**

N/A

Gonzalo Perez Marc	Approved	Jan-22-2021 15:57:22 (UTC-03:00) City of Buenos Aires	BOOK	Signed
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090177e196ae2ee6\Final\Final On: 01-Apr-2021 03:26 (GMT)

**Header Text:** c4591001

**Visit:** Investigator Signature -  
Unscheduled

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

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

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

**Site No:** 4444

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

**Subject No:** 44441550

**Subject Initials:** ---

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

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

**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	Jan-08-2021 10:56:54 (UTC-03:00) City of Buenos Aires		Edit - All signatures invalidated
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**Affidavit:**

N/A

Vanesa Fainboim	Approved	Nov-14-2020 12:22:18 (UTC-03:00) City of Buenos Aires	BOOK	Signed
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090177e196ae2ee6\Final\Final On: 01-Apr-2021 03:26 (GMT)

**Header Text:** c4591001

**Visit:** Investigator Signature -  
Unscheduled

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

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

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

**Site No:** 4444

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

**Subject No:** 44441550

**Subject Initials:** ---

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

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

**Affidavit:**

By my dated signature below, I, VanesaFainboim, 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-13-2020 17:33:24 (UTC-03:00) City of Buenos Aires		Edit - All signatures invalidated
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**Affidavit:**

N/A

(b) (6)	Approved	Nov-13-2020 09:57:22 (UTC-03:00) City of Buenos Aires	BOOK	Signed
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090177e196ae2ee6\Final\Final On: 01-Apr-2021 03:26 (GMT)

**Header Text:** c4591001

**Visit:** Investigator Signature -  
Unscheduled

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

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

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

**Site No:** 4444

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

**Subject No:** 44441550

**Subject Initials:** ---

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

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

**Affidavit:**

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

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

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

(b) (6)	N/A	Nov-12-2020 16:35:07 (UTC-03:00) City of Buenos Aires		Edit - All signatures invalidated
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**Affidavit:**

N/A

Vanesa Fainboim	Approved	Nov-10-2020 11:54:55 (UTC-03:00) City of Buenos Aires	BOOK	Signed
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090177e196ae2ee6\Final\Final On: 01-Apr-2021 03:26 (GMT)

**Header Text:** c4591001

**Visit:** Investigator Signature -  
Unscheduled

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

**Site No:** 4444

**Subject No:** 44441550

**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, VanesaFainboim, 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.

090177e196ae2ee6\Final\Final On: 01-Apr-2021 03:26 (GMT)

**Header Text:** c4591001

**Visit:** COHORT\_SELECTION

**Form:** COHORT SELECTION - 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:** 44441550

**Subject Initials:** ---

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

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

[Back to Form](#)

*1. Select appropriate response - Protocol version*

Date	Location	User	Value	Reason
Sep-23-2020 14:25:42 (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-23-2020 14:25:42 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> STAGE 3 COHORTS	Initial Entry

090177e196ae2ee6\Final\Final On: 01-Apr-2021 03:26 (GMT)

**Header Text:** c4591001

**Visit:** COHORT\_SELECTION

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

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

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

**Site No:** 4444

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

**Subject No:** 44441550

**Subject Initials:** ---

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

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

[Back to Form](#)

*1. Consent Was:*

Date	Location	User	Value	Reason
Sep-23-2020 14:25:55 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> OBTAINED Date Written Consen t Obtained  Sep/23/2020	Initial Entry

090177e196ae2ee6\Final\Final On: 01-Apr-2021 03:26 (GMT)

**Header Text:** c4591001

**Visit:** COHORT\_SELECTION

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

**Site No:** 4444

**Subject No:** 44441550

**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

[Back to Form](#)

**1. Subject ID**

Date	Location	User	Value	Reason
Sep-23-2020 09:36:19 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 44441550	Item copied from previous form

**2. Birth Date:**

Date	Location	User	Value	Reason
Sep-23-2020 09:36:15 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> (b) (6)/1971	Enrollment Entry

**3. Sex:**

Date	Location	User	Value	Reason
Sep-23-2020 14:26:08 (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-23-2020 14:26:08	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> HISPANIC OR LATI	Initial Entry

090177e196ae2ee6\Final\Final On: 01-Apr-2021 03:26 (GMT)



**Header Text:** c4591001

**Visit:** COHORT\_SELECTION

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

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

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

**Site No:** 4444

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

**Subject No:** 44441550

**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)	NO(A) OR OF SPANISH ORIGIN
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**5. Race: (Check X all that apply):**

Date	Location	User	Value	Reason
Sep-23-2020 14:26:08 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> WHITE	Initial Entry

090177e196ae2ee6\Final\Final On: 01-Apr-2021 03:26 (GMT)

**Header Text:** c4591001

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

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

**Site No:** 4444

**Subject No:** 44441550

**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

[Back to Form](#)

*1. Date of Visit*

Date	Location	User	Value	Reason
Sep-23-2020 14:26:20 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sep/23/2020	Initial Entry

**Header Text:** c4591001

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

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

**Site No:** 4444

**Subject No:** 44441550

**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

[Back to Form](#)

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

Date	Location	User	Value	Reason
Sep-23-2020 14:26:51 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sep/23/2020	Initial Entry

**2. Phase of Disposition:**

Date	Location	User	Value	Reason
Sep-23-2020 14:26:51 (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-23-2020 14:26:51 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> COMPLETED	Initial Entry

090177e196ae2ee6\Final\Final On: 01-Apr-2021 03:26 (GMT)

**Header Text:** c4591001**Visit:** V1\_DAY1\_VAX1\_L**Form:** GENERAL MEDICAL HISTORY - eCRF Audit Trail History**Form Version:** 22-Apr-2020 21:03**Form Status:** Data Complete, Frozen, Verified**Site No:** 4444**Site Name:** (4444) Hospital Militar Central Cirujano Mayor Dr Cosme Argerich**Subject No:** 44441550**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 17:38[Back to Form](#)*1.a*

Date	Location	User	Value	Reason
Sep-23-2020 14:27:33 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Line/MH</b> 1 <b>Number:</b> <b>Medical H</b> Climacter <b>istory Ter</b> ic syndro <b>m:</b> me <b>Start Date</b> Jan/1/201 <b>:</b> 2 <b>Ongoing:</b> YES	Initial Entry

*1.a Line/MH Number:*

Date	Location	User	Value	Reason
Sep-23-2020 14:27:33 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 1	Initial Entry

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

Date	Location	User	Value	Reason
Sep-23-2020 14:27:33 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Climacteric syndrome	Initial Entry

**Header Text:** c4591001

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

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

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

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

**Site No:** 4444

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

**Subject No:** 44441550

**Subject Initials:** ---

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

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

**1.a Start Date:**

Date	Location	User	Value	Reason
Sep-23-2020 14:27:33 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Jan/1/2012	Initial Entry

**1.a Ongoing:**

Date	Location	User	Value	Reason
Sep-23-2020 14:27:33 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

**1.b**

Date	Location	User	Value	Reason
Nov-13-2020 17:33:24 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Line/M</b> 2 <b>H Number:</b> <b>Medical History</b> bilateral breast implant placement <b>Term:</b> acement <b>Start Date:</b> Feb/13/2020	Initial Entry

090177e196ae2ee6\Final\Final On: 01-Apr-2021 03:26 (GMT)

**Header Text:** c4591001

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

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

**Site No:** 4444

**Subject No:** 44441550

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

**Form:** GENERAL MEDICAL HISTORY - 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

			<b>Ongoing:</b>	<b>NO</b> End Date: Feb/13/20 20	
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**Header Text:** c4591001

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

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

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

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

**Site No:** 4444

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

**Subject No:** 44441550

**Subject Initials:** ---

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

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

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

Date	Location	User	Value	Reason
Nov-13-2020 17:33:24 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 2	Initial Entry

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

Date	Location	User	Value	Reason
Nov-13-2020 17:33:24 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> bilateral breast im plant placement	Initial Entry

**1.b Start Date:**

Date	Location	User	Value	Reason
Nov-13-2020 17:33:24 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Feb/13/2020	Initial Entry

**1.b Ongoing:**

Date	Location	User	Value	Reason
Nov-13-2020 17:33:24	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

090177e196ae2ee6\Final\Final On: 01-Apr-2021 03:26 (GMT)

**Header Text:** c4591001

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

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

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

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

**Site No:** 4444

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

**Subject No:** 44441550

**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)

End Date:

Feb/13/2020

*I.c*

Date	Location	User	Value	Reason
Jan-13-2021 12:46:47 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Line/MH N 3</b> <b>umber:</b> <b>Medical Hi</b> gallstones <b>story Term:</b> <b>Start Date:</b> Feb/1/20 20 <b>Ongoing:</b> NO End Dat e: Dec/2 3/2020	Initial Entry

090177e196ae2ee6\Final\Final On: 01-Apr-2021 03:26 (GMT)



Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 4444

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

Subject No: 44441550

Subject Initials: ---

Generated By: (b) (4)

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

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

Date	Location	User	Value	Reason
Jan-13-2021 12:46:47 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 3	Initial Entry

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

Date	Location	User	Value	Reason
Jan-13-2021 12:46:47 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> gallstones	Initial Entry

**I.c Start Date:**

Date	Location	User	Value	Reason
Jan-13-2021 12:46:47 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Feb/1/2020	Initial Entry

**I.c Ongoing:**

Date	Location	User	Value	Reason
Jan-13-2021 12:46:47	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

090177e196ae2ee6\Final\Final On: 01-Apr-2021 03:26 (GMT)

**Header Text:** c4591001

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

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

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

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

**Site No:** 4444

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

**Subject No:** 44441550

**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)

End Date:

Dec/23/2020

**Header Text:** c4591001

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

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

**Site No:** 4444

**Subject No:** 44441550

**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-23-2020 14:27:43 (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

090177e196ae2ee6\Final\Final On: 01-Apr-2021 03:26 (GMT)

**Header Text:** c4591001

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

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

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

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

**Site No:** 4444

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

**Subject No:** 44441550

**Subject Initials:** ---

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

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

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**1. Date:**

Date	Location	User	Value	Reason
Sep-23-2020 14:29:26 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Sep-23-2020 14:29:26 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sep/23/2020	Transcription Error
Sep-23-2020 14:28:17 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	Vital signs Date 22/Sep/2020 is not same as Date of Visit 23/Sep/2020. Please review and update as appropriate or clarify.
Sep-23-2020 14:28:17 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sep/22/2020	Initial Entry

**2. Weight:**

Date	Location	User	Value	Reason
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090177e196ae2ee6\Final\Final On: 01-Apr-2021 03:26 (GMT)

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form: VITAL SIGNS - BASELINE - eCRF Audit Trail History

Form Version: 15-Sep-2020 21:56

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 4444

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

Subject No: 44441550

Subject Initials: ---

Generated By: (b) (4)

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

Sep-23-2020 14:28:17 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 59.0	Initial Entry
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**3. Unit:**

Date	Location	User	Value	Reason
Sep-23-2020 14:28:17 (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-23-2020 14:28:17 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 170.0	Initial Entry

**5. Unit:**

Date	Location	User	Value	Reason
Sep-23-2020 14:28:17 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> cm	Initial Entry

**6. Body Mass Index:**

090177e196ae2ee6\Final\Final On: 01-Apr-2021 03:26 (GMT)

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form: VITAL SIGNS - BASELINE - eCRF Audit Trail History

Form Version: 15-Sep-2020 21:56

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 4444

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

Subject No: 44441550

Subject Initials: ---

Generated By: (b) (4)

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

Date	Location	User	Value	Reason
Sep-23-2020 14:28:17 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 20.4	Initial Entry

7.a

Date	Location	User	Value	Reason
Sep-23-2020 14:28:17 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Record Identifier: Temperature: Temperature Unit: Temperature Location: Y	Initial Entry

7.a Record Identifier:

Date	Location	User	Value	Reason
Sep-23-2020 14:28:17 (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
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090177e196ae2ee6\Final\Final On: 01-Apr-2021 03:26 (GMT)

**Header Text:** c4591001

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

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

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

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

**Site No:** 4444

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

**Subject No:** 44441550

**Subject Initials:** ---

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

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

Sep-23-2020 14:28:17 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 36.5	Initial Entry
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**7.a Unit:**

Date	Location	User	Value	Reason
Sep-23-2020 14:28:17 (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-23-2020 14:28:17 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> ORAL CAVITY	Initial Entry

090177e196ae2ee6\Final\Final On: 01-Apr-2021 03:26 (GMT)

**Header Text:** c4591001

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

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

**Site No:** 4444

**Subject No:** 44441550

**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-23-2020 14:28:28 (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-23-2020 14:28:28 (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-23-2020 14:28:28 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sep/23/2020	Initial Entry

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

Date	Location	User	Value	Reason
Sep-23-2020	ACV0PFEINFP6000	auto calc	<b>Data Entry:</b>	Initial Entry

090177e196ae2ee6\Final\Final On: 01-Apr-2021 03:26 (GMT)



Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

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

Form Version: 15-Sep-2020 21:51

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 4444

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

Subject No: 44441550

Subject Initials: ---

Generated By: (b) (4)

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

14:28:28  
(UTC-03:00) City  
of Buenos Aires

(autocalc) STUDY SITE

5. Specimen Type:

Date	Location	User	Value	Reason
Sep-23-2020 14:28:28 (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-23-2020 14:28:28 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Sponsor-</b> 113 <b>Defined I</b> <b>dentifier:</b> <b>Test::</b> Choriogon adotropin Beta_PX11 3 <b>Result::</b> NEGATIV E <b>Not Done</b> ::	Initial Entry

6.a Sponsor ID:

Date	Location	User	Value	Reason
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090177e196ae2ee6\Final\Final On: 01-Apr-2021 03:26 (GMT)

**Header Text:** c4591001

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

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

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

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

**Site No:** 4444

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

**Subject No:** 44441550

**Subject Initials:** ---

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

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

Sep-23-2020 14:28:28 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 113	Initial Entry
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**6.a Test:**

Date	Location	User	Value	Reason
Sep-23-2020 14:28:28 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Choriogonadotropin B eta_PX113	Initial Entry

**6.a Result:**

Date	Location	User	Value	Reason
Sep-23-2020 14:28:28 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NEGATIVE	Initial Entry

090177e196ae2ee6\Final\Final On: 01-Apr-2021 03:26 (GMT)

**Header Text:** c4591001

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

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

**Site No:** 4444

**Subject No:** 44441550

**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-23-2020 14:28:58 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sep/23/2020	Initial Entry

**2. Randomization Number:**

Date	Location	User	Value	Reason
Sep-23-2020 14:28:58 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 97257	Initial Entry

090177e196ae2ee6\Final\Final On: 01-Apr-2021 03:26 (GMT)

**Header Text:** c4591001

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

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

**Site No:** 4444

**Subject No:** 44441550

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

**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - 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. Data Origin**

Date	Location	User	Value	Reason
Sep-23-2020 14:29:06 (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-23-2020 14:29:06 (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-24-2020 10:17:15 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Sep-24-2020 06:29:28 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	'Sample Collected?' is Yes, however no barcodes are entered.

090177e196ae2ee6\Final\Final On: 01-Apr-2021 03:26 (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:** 44441550**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 17:38

				Please review and correct as appropriate.
Sep-23-2020 14:29:06 (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-23-2020 14:29:06 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES Date of Collection: Sep/23/2020	Initial Entry

**5.a**

Date	Location	User	Value	Reason
Sep-24-2020 10:17:15 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sample I BRVLG D: S	Initial Entry

**5.a Sample ID**

Date	Location	User	Value	Reason
Sep-24-2020 10:17:15 (UTC-03:00) City	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BRVLGS	Initial Entry

**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:** 44441550

**Subject Initials:** ---

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

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

of Buenos Aires				
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**5.b**

Date	Location	User	Value	Reason
Sep-24-2020 10:18:12 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sample I BRVLG D: T	Initial Entry

**5.b Sample ID**

Date	Location	User	Value	Reason
Sep-24-2020 10:18:12 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BRVLGT	Initial Entry

**5.c**

Date	Location	User	Value	Reason
Sep-24-2020 12:45:06 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sample I BHXG7 D: V	Initial Entry

090177e196ae2ee6\Final\Final On: 01-Apr-2021 03:26 (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:** 44441550

**Subject Initials:** ---

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

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

**5.c Sample ID**

Date	Location	User	Value	Reason
Sep-24-2020 12:45:06 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BHXG7V	Initial Entry

**5.d**

Date	Location	User	Value	Reason
Sep-24-2020 13:15:29 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sample I BRVLH D: G	Initial Entry

**5.d Sample ID**

Date	Location	User	Value	Reason
Sep-24-2020 13:15:29 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BRVLHG	Initial Entry

090177e196ae2ee6\Final\Final On: 01-Apr-2021 03:26 (GMT)

**Header Text:** c4591001

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

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

**Site No:** 4444

**Subject No:** 44441550

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

**Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB - 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. Data Origin**

Date	Location	User	Value	Reason
Sep-23-2020 14:29:37 (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-23-2020 14:29:37 (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-23-2020 15:05:13 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Sep-23-2020 14:29:37 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered.

090177e196ae2ee6\Final\Final On: 01-Apr-2021 03:26 (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:** 44441550

**Subject Initials:** ---

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

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

				Please review and correct as appropriate.
Sep-23-2020 14:29:37 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES Date of Collection:  Sep/23/2020	Initial Entry

**5.a**

Date	Location	User	Value	Reason
Sep-23-2020 15:05:13 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample I</b> BPWBV <b>D:</b> 2	Initial Entry

**5.a Sample ID**

Date	Location	User	Value	Reason
Sep-23-2020 15:05:13 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BPWBV2	Initial Entry

090177e196ae2ee6\Final\Final On: 01-Apr-2021 03:26 (GMT)

**Header Text:** c4591001

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

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

**Site No:** 4444

**Subject No:** 44441550

**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-23-2020 14:29:59 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**2. Treatment Name**

Date	Location	User	Value	Reason
Sep-23-2020 14:29:59 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> BLINDED THERAPY	Initial Entry

**3. Formulation:**

Date	Location	User	Value	Reason
Sep-23-2020 14:29:59 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> INJECTION	Initial Entry

**4. Dose Date Time:**

Date	Location	User	Value	Reason
Sep-23-2020 14:29:59	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sep/23/2020 10:00	Initial Entry

090177e196ae2ee6\Final\Final On: 01-Apr-2021 03:26 (GMT)

**Header Text:** c4591001

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

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

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

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

**Site No:** 4444

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

**Subject No:** 44441550

**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)
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**5. Anatomical Location:**

Date	Location	User	Value	Reason
Sep-23-2020 14:29:59 (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-23-2020 14:29:59 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> LEFT	Initial Entry

**7. Route:**

Date	Location	User	Value	Reason
Sep-23-2020 14:29:59 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> INTRAMUSCULAR	Initial Entry

**10. Timeframe Subject Was Observed**

Date	Location	User	Value	Reason
Sep-23-2020 14:29:59	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> THE PROTOCOL SPE	Initial Entry

090177e196ae2ee6\Final\Final On: 01-Apr-2021 03:26 (GMT)

**Header Text:** c4591001

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

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

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

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

**Site No:** 4444

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

**Subject No:** 44441550

**Subject Initials:** ---

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

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

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

Date	Location	User	Value	Reason
Sep-23-2020 14:29:59 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

090177e196ae2ee6\Final\Final On: 01-Apr-2021 03:26 (GMT)

**Header Text:** c4591001

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

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

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

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

**Site No:** 4444

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

**Subject No:** 44441550

**Subject Initials:** ---

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

**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-23-2020 14:30:08 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO - REACTOGENI CITY E-DIARY NOT COLLECTED FOR T HIS SUBJECT	Initial Entry

090177e196ae2ee6\Final\Final On: 01-Apr-2021 03:26 (GMT)

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

**Site No:** 4444

**Subject No:** 44441550

**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
Oct-15-2020 13:26:25 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Oct/15/2020	Initial Entry

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

**Site No:** 4444

**Subject No:** 44441550

**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
Oct-15-2020 13:26:38 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Oct/15/2020	Initial Entry

**2.a**

Date	Location	User	Value	Reason
Oct-15-2020 13:26:38 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Record Id 1</b> <b>entifier::</b> <b>Temperat 36.2</b> <b>ure:</b> <b>Temperat C</b> <b>ure Unit:</b> <b>Temperat ORAL</b> <b>ure Locat CAVIT</b> <b>ion:: Y</b>	Initial Entry

**2.a Record Identifier:**

Date	Location	User	Value	Reason
Oct-15-2020 13:26:38 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 1	Initial Entry

090177e196ae2ee6\Final\Final On: 01-Apr-2021 03:26 (GMT)

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

**Site No:** 4444

**Subject No:** 44441550

**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

**2.a Temperature:**

Date	Location	User	Value	Reason
Oct-15-2020 13:26:38 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 36.2	Initial Entry

**2.a Unit:**

Date	Location	User	Value	Reason
Oct-15-2020 13:26:38 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> C	Initial Entry

**2.a Temperature Location:**

Date	Location	User	Value	Reason
Oct-15-2020 13:26:38 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> ORAL CAVITY	Initial Entry

090177e196ae2ee6\Final\Final On: 01-Apr-2021 03:26 (GMT)



**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

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

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

**Site No:** 4444

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

**Subject No:** 44441550

**Subject Initials:** ---

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

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

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**1. Lab Panel:**

Date	Location	User	Value	Reason
Oct-15-2020 13:26:47 (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
Oct-15-2020 13:26:47 (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
Oct-15-2020 13:26:47 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Oct/15/2020	Initial Entry

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

Date	Location	User	Value	Reason
Oct-15-2020	ACV0PFEINFP6000	auto calc	<b>Data Entry:</b>	Initial Entry

090177e196ae2ee6\Final\Final On: 01-Apr-2021 03:26 (GMT)

Header Text: c4591001

Visit: V2\_VAX2\_L

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

Form Version: 15-Sep-2020 21:51

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 4444

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

Subject No: 44441550

Subject Initials: ---

Generated By: (b) (4)

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

13:26:47 (UTC-03:00) City of Buenos Aires		(autocalc)	STUDY SITE	
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5. Specimen Type:

Date	Location	User	Value	Reason
Oct-15-2020 13:26:47 (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
Oct-15-2020 13:26:47 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> Sponsor- 113 Defined Identifier: Test:: Choriogon adotropin Beta_PX113 Result:: NEGATIVE Not Done ::	Initial Entry

6.a Sponsor ID:

Date	Location	User	Value	Reason
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090177e196ae2ee6\Final\Final On: 01-Apr-2021 03:26 (GMT)

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

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

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

**Site No:** 4444

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

**Subject No:** 44441550

**Subject Initials:** ---

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

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

Oct-15-2020 13:26:47 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 113	Initial Entry
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**6.a Test:**

Date	Location	User	Value	Reason
Oct-15-2020 13:26:47 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Choriogonadotropin Beta_PX113	Initial Entry

**6.a Result:**

Date	Location	User	Value	Reason
Oct-15-2020 13:26:47 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NEGATIVE	Initial Entry

090177e196ae2ee6\Final\Final On: 01-Apr-2021 03:26 (GMT)

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

**Site No:** 4444

**Subject No:** 44441550

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

**Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB - 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. Data Origin**

Date	Location	User	Value	Reason
Oct-15-2020 13:02:12 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SITE	Initial Entry

**2. Sample Type**

Date	Location	User	Value	Reason
Oct-15-2020 13:02:12 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> NASAL_SWAB	Initial Entry

**3. Sample Collected?**

Date	Location	User	Value	Reason
Oct-15-2020 13:02:31 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Oct-15-2020 13:02:12 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered.

090177e196ae2ee6\Final\Final On: 01-Apr-2021 03:26 (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:** 44441550

**Subject Initials:** ---

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

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

				Please review and correct as appropriate.
Oct-15-2020 13:02:12 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES Date of Collection:  Oct/15/2020	Initial Entry

**5.a**

Date	Location	User	Value	Reason
Oct-15-2020 13:02:31 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sample I BKNZD D: P	Initial Entry

**5.a Sample ID**

Date	Location	User	Value	Reason
Oct-15-2020 13:02:31 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BKNZDP	Initial Entry

090177e196ae2ee6\Final\Final On: 01-Apr-2021 03:26 (GMT)

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

**Site No:** 4444

**Subject No:** 44441550

**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
Oct-15-2020 13:27:04 (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
Oct-15-2020 13:27:04 (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
Oct-15-2020 13:27:04 (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
Oct-15-2020 13:27:04	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Oct/15/2020 10:56	Initial Entry

090177e196ae2ee6\Final\Final On: 01-Apr-2021 03:26 (GMT)

Header Text: c4591001

Visit: V2\_VAX2\_L

Form Version: 22-Apr-2020 21:04

Site No: 4444

Subject No: 44441550

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)		
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5. Anatomical Location:

Date	Location	User	Value	Reason
Oct-15-2020 13:27:04 (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
Oct-15-2020 13:27:04 (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
Oct-15-2020 13:27:04 (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
Oct-15-2020 13:27:04	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> THE PROTOCOL SPE	Initial Entry

090177e196ae2ee6\Final\Final On: 01-Apr-2021 03:26 (GMT)

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

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

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

**Site No:** 4444

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

**Subject No:** 44441550

**Subject Initials:** ---

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

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

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

Date	Location	User	Value	Reason
Oct-15-2020 13:27:04 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

090177e196ae2ee6\Final\Final On: 01-Apr-2021 03:26 (GMT)



**Header Text:** c4591001

**Visit:** V3\_MONTH1\_POSTVAX2\_L **Form:** DATE OF VISIT - eCRF Audit Trail History

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

**Site No:** 4444 **Site Name:** (4444) Hospital Militar Central Cirujano  
Mayor Dr Cosme Argerich

**Subject No:** 44441550 **Subject Initials:** ---

**Generated By:** (b) (4) **Generated Time (GMT):** 29-Mar-2021 17:38

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*1. Date of Visit*

Date	Location	User	Value	Reason
Nov-12-2020 16:35:07 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Nov/12/2020	Initial Entry

090177e196ae2ee6\Final\Final On: 01-Apr-2021 03:26 (GMT)

**Header Text:** c4591001

**Visit:** V3\_MONTH1\_POSTVAX2\_L **Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - eCRF Audit Trail History

**Form Version:** 22-Apr-2020 21:03 **Form Status:** Data Complete, Locked, Frozen, Verified

**Site No:** 4444 **Site Name:** (4444) Hospital Militar Central Cirujano Mayor Dr Cosme Argerich

**Subject No:** 44441550 **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-12-2020 16:35:31 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SITE	Initial Entry

**2. Sample Type**

Date	Location	User	Value	Reason
Nov-12-2020 16:35:31 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SERUM	Initial Entry

**3. Sample Collected?**

Date	Location	User	Value	Reason
Nov-12-2020 19:43:35 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Nov-12-2020 16:35:31 (UTC-03:00) City of Buenos	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candida te	'Sample Collected?' is Yes, however no barcodes

090177e196ae2ee6\Final\Final On: 01-Apr-2021 03:26 (GMT)

Header Text: c4591001

Visit: V3\_MONTH1\_POSTVAX2\_L Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03 Form Status: Data Complete, Locked, Frozen, Verified

Site No: 4444 Site Name: (4444) Hospital Militar Central Cirujano Mayor Dr Cosme Argerich

Subject No: 44441550 Subject Initials: ---

Generated By: (b) (4) Generated Time (GMT): 29-Mar-2021 17:38

Aires				are entered. Please review and correct as appropriate.
Nov-12-2020 16:35:31 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES Date of Collection:  Nov/12/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Nov-12-2020 19:43:35 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	Alan Colombo (b) (4)	<b>Data Entry:</b> <b>Sample I</b> BNV0 <b>D:</b> WS	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Nov-12-2020 19:43:35 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	Alan Colombo (b) (4)	<b>Data Entry:</b> BNV0WS	Initial Entry

5.b

Date	Location	User	Value	Reason
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090177e196ae2ee6\Final\Final On: 01-Apr-2021 03:26 (GMT)

Header Text: c4591001

Visit: V3\_MONTH1\_POSTVAX2\_L Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03 Form Status: Data Complete, Locked, Frozen, Verified

Site No: 4444 Site Name: (4444) Hospital Militar Central Cirujano Mayor Dr Cosme Argerich

Subject No: 44441550 Subject Initials: ---

Generated By: (b) (4) Generated Time (GMT): 29-Mar-2021 17:38

Nov-13-2020 09:08:06 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample ID</b> BP1R1 : H	Initial Entry
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**5.b Sample ID**

Date	Location	User	Value	Reason
Nov-13-2020 09:08:06 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BP1R1H	Initial Entry

**5.c**

Date	Location	User	Value	Reason
Nov-13-2020 09:35:24 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample I</b> BNV0T <b>D:</b> W	Initial Entry

**5.c Sample ID**

Date	Location	User	Value	Reason
Nov-13-2020 09:35:24 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BNV0TW	Initial Entry

090177e196ae2ee6\Final\Final On: 01-Apr-2021 03:26 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Jan/12/2021

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

**Site No:** 4444

**Subject No:** 44441550

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

**Form:** DATE OF VISIT - ILLNESS ONSET - 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. Date of Visit*

Date	Location	User	Value	Reason
Feb-23-2021 07:00:51 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Closed	Closed as Convalescent Visit completed.
Feb-23-2021 06:58:17 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Reissue d:Opened	PDQ: RQ1: Thank you for response; Please respond to query once data available. Else clarify.
Feb-18-2021 05:34:49 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Reissue d:Candidate	PDQ:RQ1: Please review corresponding CONVA once entered per site response. Thank you.
Feb-17-2021 11:59:29 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Answered	The visit will take place on 18 Feb 2021, outside the window, since the participant

090177e196ae2ee6\Final\Final On: 01-Apr-2021 03:26 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Jan/12/2021

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

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

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

**Site No:** 4444

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

**Subject No:** 44441550

**Subject Initials:** ---

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

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

				could not attend for personal reasons. The information will be updated as soon as possible.
Feb-17-2021 06:26:48 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Opened	PDQ: Convalescent visit is missing and 35 days (36) have passed since COVID Illness Visit. If visit occurred record data as a matching CONVA visit; if visit did not occur attempt to schedule visit even if OOW and obtain the CONVA sample else clarify.
Jan-18-2021 04:38:29 (UTC-03:00)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query

090177e196ae2ee6\Final\Final On: 01-Apr-2021 03:26 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Jan/12/2021

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

**Site No:** 4444

**Subject No:** 44441550

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

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

City of Buenos Aires				
Jan-15-2021 14:29:15 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	Santiago Corradetti (b) (4)	Query 1: Answered	The reason why home visit and the sample collection was not done is explained clearly in the corresponding form. Thank you.
Jan-15-2021 09:48:51 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	PDQ : Details of Sample ID (barcode) and collection date for either Nasal Swab Self or Nasal Swab expected to be completed. Please check and update else clarify.
Jan-14-2021 13:58:20 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Deleted	Close Auto Query
Jan-14-2021	ACV0PFEINFP6000	auto query	Query 2: Candida	Date of Visit is

090177e196ae2ee6\Final\Final On: 01-Apr-2021 03:26 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Jan/12/2021

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

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

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

**Site No:** 4444

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

**Subject No:** 44441550

**Subject Initials:** ---

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

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

13:56:51 (UTC-03:00) City of Buenos Aires		(autoquery)	te	completed but Date of Assessment in the Signs and Symptoms form is missing. Please review and update as appropriate.
Jan-14-2021 13:56:51 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candida te	Date of Visit is completed but Date of Collection in both Nasal Swab Self and Nasal Swab are missing. Please review and update as appropriate.
Jan-14-2021 13:56:51 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Jan/12/2021	Initial Entry

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

Date	Location	User	Value	Reason
Jan-14-2021	ACV0PFEINFP6000	auto calc	<b>Data Entry:</b>	Initial Entry

090177e196ae2ee6\Final\Final On: 01-Apr-2021 03:26 (GMT)



**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Jan/12/2021

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

**Site No:** 4444

**Subject No:** 44441550

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

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

13:56:51 (UTC-03:00) City of Buenos Aires		(autocalc)	COVID_A	
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**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Jan/12/2021

**Form:** SIGNS AND SYMPTOMS OF POTENTIAL  
COVID-19 - eCRF Audit Trail History

**Form Version:** 14-Jan-2021 02:23

**Form Status:** Data Complete

**Site No:** 4444

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

**Subject No:** 44441550

**Subject Initials:** ---

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

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

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**1. Date of Assessment:**

Date	Location	User	Value	Reason
Jan-14-2021 13:58:20 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Jan/12/2021	Initial Entry

**2. Date of First Symptom Started:**

Date	Location	User	Value	Reason
Jan-14-2021 13:58:20 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Dec/30/2020	Initial Entry

**3. Symptoms Ongoing?**

Date	Location	User	Value	Reason
Jan-14-2021 13:58:20 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO Date of Last Sympto m Resolved:  Dec/31/2020	Initial Entry

**4.a**

Date	Location	User	Value	Reason
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090177e196ae2ee6\Final\Final On: 01-Apr-2021 03:26 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Jan/12/2021

**Form:** SIGNS AND SYMPTOMS OF POTENTIAL  
COVID-19 - eCRF Audit Trail History

**Form Version:** 14-Jan-2021 02:23

**Form Status:** Data Complete

**Site No:** 4444

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

**Subject No:** 44441550

**Subject Initials:** ---

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

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

Jan-14-2021 13:58:20 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptoms:</b> FEV ER <b>Symptom Pre</b> YES <b>sent:</b>	Initial Entry
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**4.a Symptoms:**

Date	Location	User	Value	Reason
Jan-14-2021 13:58:20 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> FEVER	Initial Entry

**4.a Was symptom present?**

Date	Location	User	Value	Reason
Jan-14-2021 13:58:20 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

**4.b**

Date	Location	User	Value	Reason
Jan-14-2021 13:58:20 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sympt</b> NEW OR I <b>oms:</b> NCREASE D COUGH	Initial Entry

090177e196ae2ee6\Final\Final On: 01-Apr-2021 03:26 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Jan/12/2021

**Form Version:** 14-Jan-2021 02:23

**Site No:** 4444

**Subject No:** 44441550

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

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

			<b>Symptom Present:</b>	
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**4.b Symptoms:**

Date	Location	User	Value	Reason
Jan-14-2021 13:58:20 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NEW OR INCREASED COUGH	Initial Entry

**4.b Was symptom present?**

Date	Location	User	Value	Reason
Jan-14-2021 13:58:20 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**4.c**

Date	Location	User	Value	Reason
Jan-14-2021 13:58:20 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptoms:</b> NEW OR INCREASED SHORTNESS OF BREATH	Initial Entry

090177e196ae2ee6\Final\Final On: 01-Apr-2021 03:26 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Jan/12/2021

**Form:** SIGNS AND SYMPTOMS OF POTENTIAL  
COVID-19 - eCRF Audit Trail History

**Form Version:** 14-Jan-2021 02:23

**Form Status:** Data Complete

**Site No:** 4444

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

**Subject No:** 44441550

**Subject Initials:** ---

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

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

			<b>Symp YES tom P resen t:</b>	
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**4.c Symptoms:**

Date	Location	User	Value	Reason
Jan-14-2021 13:58:20 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NEW OR INCREAS ED SHORTNESS OF BREATH	Initial Entry

**4.c Was symptom present?**

Date	Location	User	Value	Reason
Jan-14-2021 13:58:20 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

**4.d**

Date	Location	User	Value	Reason
Jan-14-2021 13:58:20 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptoms:</b> CHIL LS <b>Symptom Pr</b> NO <b>esent:</b>	Initial Entry

090177e196ae2ee6\Final\Final On: 01-Apr-2021 03:26 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Jan/12/2021

**Form Version:** 14-Jan-2021 02:23

**Site No:** 4444

**Subject No:** 44441550

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

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

**4.d Symptoms:**

Date	Location	User	Value	Reason
Jan-14-2021 13:58:20 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> CHILLS	Initial Entry

**4.d Was symptom present?**

Date	Location	User	Value	Reason
Jan-14-2021 13:58:20 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**4.e**

Date	Location	User	Value	Reason
Jan-14-2021 13:58:20 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sympt</b> NEW OR IN <b>oms:</b> CREASED MUSCLE PA IN <b>Sympt</b> NO <b>om Pr</b> <b>esent:</b>	Initial Entry

090177e196ae2ee6\Final\Final On: 01-Apr-2021 03:26 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Jan/12/2021

**Form Version:** 14-Jan-2021 02:23

**Site No:** 4444

**Subject No:** 44441550

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

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

**4.e Symptoms:**

Date	Location	User	Value	Reason
Jan-14-2021 13:58:20 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NEW OR INCREASED MUSCLE PAIN	Initial Entry

**4.e Was symptom present?**

Date	Location	User	Value	Reason
Jan-14-2021 13:58:20 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**4.f**

Date	Location	User	Value	Reason
Jan-14-2021 13:58:20 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptoms:</b> NEW LOSS OF TASTE OR SMELL <b>Symptom Present:</b> NO	Initial Entry

090177e196ae2ee6\Final\Final On: 01-Apr-2021 03:26 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Jan/12/2021

**Form Version:** 14-Jan-2021 02:23

**Site No:** 4444

**Subject No:** 44441550

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

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

**4.f Symptoms:**

Date	Location	User	Value	Reason
Jan-14-2021 13:58:20 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NEW LOSS OF TASTE OR SMELL	Initial Entry

**4.f Was symptom present?**

Date	Location	User	Value	Reason
Jan-14-2021 13:58:20 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**4.g**

Date	Location	User	Value	Reason
Jan-14-2021 13:58:20 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Symptom: NEW OR INCREASED SORE THROAT Symptom Present: NO	Initial Entry

090177e196ae2ee6\Final\Final On: 01-Apr-2021 03:26 (GMT)



**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Jan/12/2021

**Form Version:** 14-Jan-2021 02:23

**Site No:** 4444

**Subject No:** 44441550

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

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

**4.g Symptoms:**

Date	Location	User	Value	Reason
Jan-14-2021 13:58:20 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NEW OR INCREAS ED SORE THROAT	Initial Entry

**4.g Was symptom present?**

Date	Location	User	Value	Reason
Jan-14-2021 13:58:20 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**4.h**

Date	Location	User	Value	Reason
Jan-14-2021 13:58:20 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptoms:</b> DIARR HEA <b>Symptom P NO</b> <b>resent:</b>	Initial Entry

090177e196ae2ee6\Final\Final On: 01-Apr-2021 03:26 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Jan/12/2021

**Form Version:** 14-Jan-2021 02:23

**Site No:** 4444

**Subject No:** 44441550

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

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

**4.h Symptoms:**

Date	Location	User	Value	Reason
Jan-14-2021 13:58:20 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> DIARRHEA	Initial Entry

**4.h Was symptom present?**

Date	Location	User	Value	Reason
Jan-14-2021 13:58:20 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**4.i**

Date	Location	User	Value	Reason
Jan-14-2021 13:58:20 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptoms:</b> VOMIT ING <b>Symptom P NO</b> <b>resent:</b>	Initial Entry

090177e196ae2ee6\Final\Final On: 01-Apr-2021 03:26 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Jan/12/2021

**Form Version:** 14-Jan-2021 02:23

**Site No:** 4444

**Subject No:** 44441550

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

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

**4.i Symptoms:**

Date	Location	User	Value	Reason
Jan-14-2021 13:58:20 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> VOMITING	Initial Entry

**4.i Was symptom present?**

Date	Location	User	Value	Reason
Jan-14-2021 13:58:20 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

090177e196ae2ee6\Final\Final On: 01-Apr-2021 03:26 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Jan/12/2021

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

**Site No:** 4444

**Subject No:** 44441550

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

**Form:** MICROBIOLOGY SPECIMEN - 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
Jan-14-2021 14:00:43 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Created	

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Jan/12/2021

**Form:** MICROBIOLOGY SPECIMEN - Audit Trail

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

**Form Status:**

**Site No:** 4444

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

**Subject No:** 44441550

**Subject Initials:** ---

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

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

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Date	Location	User	Value	Reason
Jan-14-2021 14:01:08 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Created	

090177e196ae2ee6\Final\Final On: 01-Apr-2021 03:26 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Jan/12/2021

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

**Site No:** 4444

**Subject No:** 44441550

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

**Form:** MICROBIOLOGY SPECIMEN - 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. Actual Date of Collection:**

Date	Location	User	Value	Reason
Jan-14-2021 14:00:43 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Dec/25/2020	Initial Entry

**2. Specimen Type:**

Date	Location	User	Value	Reason
Jan-14-2021 14:00:43 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> SWABBED MATERI AL	Initial Entry

**3. Specimen Collection Location:**

Date	Location	User	Value	Reason
Jan-14-2021 14:00:43 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NASOPHARYNX	Initial Entry

**4. Assay Code and Description:**

Date	Location	User	Value	Reason
Jan-14-2021 14:00:43	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SEVERE ACUTE RES	Initial Entry

090177e196ae2ee6\Final\Final On: 01-Apr-2021 03:26 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Jan/12/2021

**Form:** MICROBIOLOGY SPECIMEN - eCRF Audit  
Trail History

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

**Form Status:** Data Complete

**Site No:** 4444

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

**Subject No:** 44441550

**Subject Initials:** ---

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

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

(UTC-03:00) City  
of Buenos Aires

P SYNDROME CORO  
NAVIRUS 2

**5. Device Type:**

Date	Location	User	Value	Reason
Jan-14-2021 14:00:43 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SARS-COV-2 DIAGN OSTIC TEST	Initial Entry

**6. Trade Name:**

Date	Location	User	Value	Reason
Jan-14-2021 14:00:43 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> OTHER	Initial Entry

**7. Test Result:**

Date	Location	User	Value	Reason
Jan-14-2021 14:00:43 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NEGATIVE	Initial Entry

**9. Trade Name Other, Specify:**

Date	Location	User	Value	Reason
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090177e196ae2ee6\Final\Final On: 01-Apr-2021 03:26 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Jan/12/2021

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

**Site No:** 4444

**Subject No:** 44441550

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

**Form:** MICROBIOLOGY SPECIMEN - 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

Jan-14-2021 14:00:43 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NALT Unknown	Initial Entry
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**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Jan/12/2021

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

**Site No:** 4444

**Subject No:** 44441550

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

**Form:** MICROBIOLOGY SPECIMEN - 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. Actual Date of Collection:**

Date	Location	User	Value	Reason
Jan-14-2021 14:01:08 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Dec/30/2020	Initial Entry

**2. Specimen Type:**

Date	Location	User	Value	Reason
Jan-14-2021 14:01:08 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> SWABBED MATERI AL	Initial Entry

**3. Specimen Collection Location:**

Date	Location	User	Value	Reason
Jan-14-2021 14:01:08 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NASOPHARYNX	Initial Entry

**4. Assay Code and Description:**

Date	Location	User	Value	Reason
Jan-14-2021	ACV0PFEINFP6000	auto calc	<b>Data Entry:</b>	Initial Entry

090177e196ae2ee6\Final\Final On: 01-Apr-2021 03:26 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Jan/12/2021

**Form:** MICROBIOLOGY SPECIMEN - eCRF Audit  
Trail History

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

**Form Status:** Data Complete

**Site No:** 4444

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

**Subject No:** 44441550

**Subject Initials:** ---

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

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

14:01:08 (UTC-03:00) City of Buenos Aires		(autocalc)	SEVERE ACUTE RES P SYNDROME CORO NAVIRUS 2	
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**5. Device Type:**

Date	Location	User	Value	Reason
Jan-14-2021 14:01:08 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SARS-COV-2 DIAGN OSTIC TEST	Initial Entry

**6. Trade Name:**

Date	Location	User	Value	Reason
Jan-14-2021 14:01:08 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> OTHER	Initial Entry

**7. Test Result:**

Date	Location	User	Value	Reason
Jan-14-2021 14:01:08 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NEGATIVE	Initial Entry

**9. Trade Name Other, Specify:**

Date	Location	User	Value	Reason
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090177e196ae2ee6\Final\Final On: 01-Apr-2021 03:26 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Jan/12/2021

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

**Site No:** 4444

**Subject No:** 44441550

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

**Form:** MICROBIOLOGY SPECIMEN - 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

Jan-14-2021 14:01:08 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NALT Unknown	Initial Entry
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**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Jan/12/2021

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

**Site No:** 4444

**Subject No:** 44441550

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

**Form:** ELECTRONIC SAMPLE TRACKING - NASAL  
SWAB SELF - 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. Data Origin**

Date	Location	User	Value	Reason
Jan-14-2021 14:03:43 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SITE	Initial Entry

**2. Sample Type**

Date	Location	User	Value	Reason
Jan-14-2021 14:03:43 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> NASAL_SWAB_SELF	Initial Entry

**3. Sample Collected?**

Date	Location	User	Value	Reason
Jan-14-2021 14:03:43 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**4. If no sample was collected or sample was not collected according to protocol, please provide reason:**

Date	Location	User	Value	Reason
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090177e196ae2ee6\Final\Final On: 01-Apr-2021 03:26 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Jan/12/2021

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

**Site No:** 4444

**Subject No:** 44441550

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

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

Jan-14-2021 14:03:43 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Subject refused home visit and swab due to having 2 swabs done on DEC 25 and DEC 30	Initial Entry
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**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Jan/12/2021

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

**Site No:** 4444

**Subject No:** 44441550

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

**Form:** ELECTRONIC SAMPLE TRACKING - NASAL  
SWAB - 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. Data Origin**

Date	Location	User	Value	Reason
Jan-14-2021 14:03:55 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SITE	Initial Entry

**2. Sample Type**

Date	Location	User	Value	Reason
Jan-14-2021 14:03:55 (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
Jan-14-2021 14:03:55 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**4. If no sample was collected or sample was not collected according to protocol, please provide reason:**

Date	Location	User	Value	Reason
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090177e196ae2ee6\Final\Final On: 01-Apr-2021 03:26 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Jan/12/2021

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

**Site No:** 4444

**Subject No:** 44441550

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

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

Jan-14-2021 14:03:55 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Subject refused home visit and swab due to having 2 swabs done on DEC 25 and DEC 30	Initial Entry
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**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Jan/12/2021

**Form:** HEALTH CARE UTILIZATION - eCRF Audit  
Trail History

**Form Version:** 14-Jan-2021 02:24

**Form Status:** Data Complete

**Site No:** 4444

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

**Subject No:** 44441550

**Subject Initials:** ---

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

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

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*1.a*

Date	Location	User	Value	Reason
Jan-14-2021 14:05:03 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Type of Practitioner:</b> IALIST <b>Occurrence of Visits or Contacts:</b> NO	Initial Entry

*1.a Physician or Healthcare Professional:*

Date	Location	User	Value	Reason
Jan-14-2021 14:05:03 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> SPECIALIST	Initial Entry

*1.a Occurrence of Visits or Contacts:*

Date	Location	User	Value	Reason
Jan-14-2021 14:05:03 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

*1.b*

090177e196ae2ee6\Final\Final On: 01-Apr-2021 03:26 (GMT)



**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Jan/12/2021

**Form:** HEALTH CARE UTILIZATION - eCRF Audit  
Trail History

**Form Version:** 14-Jan-2021 02:24

**Form Status:** Data Complete

**Site No:** 4444

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

**Subject No:** 44441550

**Subject Initials:** ---

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

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

Date	Location	User	Value	Reason
Jan-14-2021 14:05:03 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Type of P EMERGE ractition NCY RO er: OM <b>Occurren YES</b> <b>ce of Visi Number</b> <b>ts or Con of Visits</b> <b>tacts: or Conta</b>  4	Initial Entry

***1.b Physician or Healthcare Professional:***

Date	Location	User	Value	Reason
Jan-14-2021 14:05:03 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> EMERGENCY ROO M	Initial Entry

***1.b Occurrence of Visits or Contacts:***

Date	Location	User	Value	Reason
Jan-14-2021 14:05:03 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES Number of Visits or Contacts:  4	Initial Entry

090177e196ae2ee6\Final\Final On: 01-Apr-2021 03:26 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Jan/12/2021

**Form:** HEALTH CARE UTILIZATION - eCRF Audit  
Trail History

**Form Version:** 14-Jan-2021 02:24

**Form Status:** Data Complete

**Site No:** 4444

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

**Subject No:** 44441550

**Subject Initials:** ---

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

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

***I.c***

Date	Location	User	Value	Reason
Jan-14-2021 14:05:03 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Type of P</b> PRIMAR <b>ractitione</b> Y CARE <b>r:</b> PHYSICI AN <b>Occurren</b> NO <b>ce of Visit</b> <b>s or Cont</b> <b>acts:</b>	Initial Entry

***I.c Physician or Healthcare Professional:***

Date	Location	User	Value	Reason
Jan-14-2021 14:05:03 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> PRIMARY CARE PH YSICIAN	Initial Entry

***I.c Occurrence of Visits or Contacts:***

Date	Location	User	Value	Reason
Jan-14-2021 14:05:03 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

***I.d***

090177e196ae2ee6\Final\Final On: 01-Apr-2021 03:26 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Jan/12/2021

**Form:** HEALTH CARE UTILIZATION - eCRF Audit  
Trail History

**Form Version:** 14-Jan-2021 02:24

**Form Status:** Data Complete

**Site No:** 4444

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

**Subject No:** 44441550

**Subject Initials:** ---

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

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

Date	Location	User	Value	Reason
Jan-14-2021 14:05:03 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Type of Prac</b> URGE <b>itioner:</b> NT C ARE <b>Occurrence</b> NO <b>of Visits or</b> <b>Contacts:</b>	Initial Entry

***1.d Physician or Healthcare Professional:***

Date	Location	User	Value	Reason
Jan-14-2021 14:05:03 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> URGENT CARE	Initial Entry

***1.d Occurrence of Visits or Contacts:***

Date	Location	User	Value	Reason
Jan-14-2021 14:05:03 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

***1.e***

Date	Location	User	Value	Reason
Jan-14-2021 14:05:03	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Type of P</b> TELEPH	Initial Entry

090177e196ae2ee6\Final\Final On: 01-Apr-2021 03:26 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Jan/12/2021

**Form:** HEALTH CARE UTILIZATION - eCRF Audit  
Trail History

**Form Version:** 14-Jan-2021 02:24

**Form Status:** Data Complete

**Site No:** 4444

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

**Subject No:** 44441550

**Subject Initials:** ---

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

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

(UTC-03:00) City of Buenos Aires			<b>Practitioner:</b> ONE CONSULTATION	
			<b>Occurrence of Visits or Contacts:</b> NO	

***1.e Physician or Healthcare Professional:***

Date	Location	User	Value	Reason
Jan-14-2021 14:05:03 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> TELEPHONE CONSULTATION	Initial Entry

***1.e Occurrence of Visits or Contacts:***

Date	Location	User	Value	Reason
Jan-14-2021 14:05:03 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

***1.f***

Date	Location	User	Value	Reason
Jan-14-2021 14:05:03 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Type of Practitioner: OTHER	Initial Entry

090177e196ae2ee6\Final\Final On: 01-Apr-2021 03:26 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Jan/12/2021

**Form Version:** 14-Jan-2021 02:24

**Site No:** 4444

**Subject No:** 44441550

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

**Form:** HEALTH CARE UTILIZATION - 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

			<b>Occurrence of NO Visits or Conta cts:</b>	
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***1.f Physician or Healthcare Professional:***

Date	Location	User	Value	Reason
Jan-14-2021 14:05:03 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> OTHER	Initial Entry

***1.f Occurrence of Visits or Contacts:***

Date	Location	User	Value	Reason
Jan-14-2021 14:05:03 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

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

Date	Location	User	Value	Reason
Jan-14-2021 14:05:03 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES Has the subject been in intensive care due to potential COVID- 19 illness?  NO	Initial Entry

090177e196ae2ee6\Final\Final On: 01-Apr-2021 03:26 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Jan/12/2021

**Form:** HOSPITALIZATION DETAILS - Audit Trail

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

**Form Status:**

**Site No:** 4444

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

**Subject No:** 44441550

**Subject Initials:** ---

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

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

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Date	Location	User	Value	Reason
Jan-14-2021 14:05:45 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Created	

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Jan/12/2021

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

**Site No:** 4444

**Subject No:** 44441550

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

**Form:** HOSPITALIZATION DETAILS - 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. Hospitalization Category:**

Date	Location	User	Value	Reason
Jan-14-2021 14:05:45 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> HOSPITALIZATION S TATUS	Initial Entry

**2. Hospitalization Term:**

Date	Location	User	Value	Reason
Jan-14-2021 14:05:45 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> HOSPITAL	Initial Entry

**3. Admission Date:**

Date	Location	User	Value	Reason
Feb-22-2021 17:48:22 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Feb-22-2021 15:12:38 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	The available information has already been uploaded. The forms that were

090177e196ae2ee6\Final\Final On: 01-Apr-2021 03:26 (GMT)

**Header Text:** c4591001  
**Visit:** POT\_COVID\_ILL 1 -  
 Unscheduled Visit on Jan/12/2021  
**Form Version:** 22-Apr-2020 21:02  
**Site No:** 4444  
**Subject No:** 44441550  
**Generated By:** (b) (4)  
**Form:** HOSPITALIZATION DETAILS - 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

				not completed, it was because they were not done.
Feb-22-2021 12:22:44 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	CLIQUEY: Hospitalization: This subject had COVID-19 Illness and was hospitalized. Please enter any available information (vital signs, pulse oxymet, respiratory treatment, lab results, imaging...). Please make every effort to obtain these information.
Jan-14-2021 14:05:45 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Dec/23/2020	Initial Entry

**4. Ongoing?**

Date	Location	User	Value	Reason
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**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Jan/12/2021

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

**Site No:** 4444

**Subject No:** 44441550

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

**Form:** HOSPITALIZATION DETAILS - 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

Jan-14-2021 14:05:45 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO Discharge Date:  Dec/31/2020	Initial Entry
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090177e196ae2ee6\Final\Final On: 01-Apr-2021 03:26 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Jan/12/2021

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

**Site No:** 4444

**Subject No:** 44441550

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

**Form:** ILLNESS DETAILS - 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 of Clinical Event:**

Date	Location	User	Value	Reason
Jan-14-2021 14:08:15 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> POTENTIAL COVID- 19 ILLNESS	Initial Entry

**2. Was a diagnosis obtained for Potential COVID-19 Illness?**

Date	Location	User	Value	Reason
Jan-14-2021 14:08:15 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES <i>Respiratory Illness Diagnosis:</i>  Hospital-acquired pneumonia  Date of Diagnosis:  Dec/30/2020	Initial Entry

**3. Toxicity Grade:**

Date	Location	User	Value	Reason
Jan-14-2021 14:08:15 (UTC-03:00) City	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 3	Initial Entry

090177e196ae2ee6\Final\Final On: 01-Apr-2021 03:26 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Jan/12/2021

**Form:** ILLNESS DETAILS - eCRF Audit Trail History

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

**Form Status:** Data Complete

**Site No:** 4444

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

**Subject No:** 44441550

**Subject Initials:** ---

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

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

of Buenos Aires				
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090177e196ae2ee6\Final\Final On: 01-Apr-2021 03:26 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Jan/12/2021

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

**Site No:** 4444

**Subject No:** 44441550

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

**Form:** VITAL SIGNS - PULSE OX ROOM AIR - 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
Feb-22-2021 15:03:18 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Created	

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Jan/12/2021

**Form:** VITAL SIGNS - PULSE OX ROOM AIR - eCRF  
Audit Trail History

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

**Form Status:** Data Complete

**Site No:** 4444

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

**Subject No:** 44441550

**Subject Initials:** ---

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

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

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**1. Date:**

Date	Location	User	Value	Reason
Feb-22-2021 15:03:18 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Dec/30/2020	Initial Entry

**2.a**

Date	Location	User	Value	Reason
Feb-22-2021 15:03:18 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Record Identifie</b> 1 <b>r::</b> <b>Oxygen Saturati</b> 93. <b>on:</b> 0	Initial Entry

**2.a Record Identifier:**

Date	Location	User	Value	Reason
Feb-22-2021 15:03:18 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 1	Initial Entry

**2.a SPO2 Pulse Oximetry %**

Date	Location	User	Value	Reason
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090177e196ae2ee6\Final\Final On: 01-Apr-2021 03:26 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Jan/12/2021

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

**Site No:** 4444

**Subject No:** 44441550

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

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

Feb-22-2021 15:03:18 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 93.0	Initial Entry
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**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Jan/12/2021

**Form:** IMAGING - Audit Trail

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

**Form Status:**

**Site No:** 4444

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

**Subject No:** 44441550

**Subject Initials:** ---

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

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

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Date	Location	User	Value	Reason
Jan-14-2021 14:19:47 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Created	

090177e196ae2ee6\Final\Final On: 01-Apr-2021 03:26 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Jan/12/2021

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

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

**Form Status:** Data Complete

**Site No:** 4444

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

**Subject No:** 44441550

**Subject Initials:** ---

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

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

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**1. Date of Assessment:**

Date	Location	User	Value	Reason
Jan-14-2021 14:19:47 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Dec/30/2020	Initial Entry

**2. Location of Assessment:**

Date	Location	User	Value	Reason
Jan-14-2021 14:19:47 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> CHEST	Initial Entry

**3. Type of Imaging Exam:**

Date	Location	User	Value	Reason
Jan-14-2021 14:19:47 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> CT SCAN	Initial Entry

**4. Assessment:**

Date	Location	User	Value	Reason
Jan-14-2021 14:19:47	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> ABNORMAL	Initial Entry

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**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Jan/12/2021

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

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

**Form Status:** Data Complete

**Site No:** 4444

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

**Subject No:** 44441550

**Subject Initials:** ---

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

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

(UTC-03:00) City  
of Buenos Aires

*If abnormal, specify  
findings:*

Bilateral pleural ef  
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ntly right. Consoli  
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terior, predominant  
ly on the left

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**Header Text:** c4591001

**Visit:** POT\_COVID\_CONVA 1 -  
Unscheduled Visit on Feb/18/2021

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

**Site No:** 4444

**Subject No:** 44441550

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

**Form:** DATE OF VISIT - ILLNESS CONVALESCENT -  
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. Date of Visit**

Date	Location	User	Value	Reason
Feb-19-2021 10:15:35 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Feb/18/2021	Initial Entry

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

Date	Location	User	Value	Reason
Feb-19-2021 10:15:35 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> COVID_A1	Initial Entry

090177e196ae2ee6\Final\Final On: 01-Apr-2021 03:26 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_CONVA 1 -  
Unscheduled Visit on Feb/18/2021

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

**Site No:** 4444

**Subject No:** 44441550

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

**Form:** ELECTRONIC SAMPLE TRACKING -  
IMMUNOGENICITY - 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. Data Origin**

Date	Location	User	Value	Reason
Feb-19-2021 10:15:51 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SITE	Initial Entry

**2. Sample Type**

Date	Location	User	Value	Reason
Feb-19-2021 10:15:51 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SERUM	Initial Entry

**3. Sample Collected?**

Date	Location	User	Value	Reason
Feb-19-2021 12:08:20 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Feb-19-2021 10:15:51 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered.

090177e196ae2ee6\Final\Final On: 01-Apr-2021 03:26 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_CONVA 1 -  
Unscheduled Visit on Feb/18/2021

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

**Site No:** 4444

**Subject No:** 44441550

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

**Form:** ELECTRONIC SAMPLE TRACKING -  
IMMUNOGENICITY - 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

				Please review and correct as appropriate.
Feb-19-2021 10:15:51 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES Date of Collection:  Feb/18/2021	Initial Entry

**5.a**

Date	Location	User	Value	Reason
Feb-19-2021 12:08:20 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	Alan Colombo (b) (4)	<b>Data Entry:</b> Sample I BS1RV D: T	Initial Entry

**5.a Sample ID**

Date	Location	User	Value	Reason
Feb-19-2021 12:08:20 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	Alan Colombo (b) (4)	<b>Data Entry:</b> BS1RVT	Initial Entry

**5.b**

Date	Location	User	Value	Reason
Feb-19-2021 13:31:06 (UTC-03:00) City	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sample I BS1RW	Initial Entry

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**Header Text:** c4591001

**Visit:** POT\_COVID\_CONVA 1 -  
Unscheduled Visit on Feb/18/2021

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

**Site No:** 4444

**Subject No:** 44441550

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

**Form:** ELECTRONIC SAMPLE TRACKING -  
IMMUNOGENICITY - 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

of Buenos Aires

**D:** 5

**5.b Sample ID**

Date	Location	User	Value	Reason
Feb-19-2021 13:31:06 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	<b>Data Entry:</b> BS1RW5	Initial Entry

**5.c**

Date	Location	User	Value	Reason
Feb-19-2021 13:32:50 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	<b>Data Entry:</b> <b>Sample I</b> BRM90 <b>D:</b> C	Initial Entry

**5.c Sample ID**

Date	Location	User	Value	Reason
Feb-19-2021 13:32:50 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	<b>Data Entry:</b> BRM90C	Initial Entry

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**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 4444

**Subject No:** 44441550

**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
Jan-08-2021 10:56:54 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Created	

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

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

**Form Status:**

**Site No:** 4444

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

**Subject No:** 44441550

**Subject Initials:** ---

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

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

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Date	Location	User	Value	Reason
Feb-25-2021 10:38:52 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Created	

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen

Site No: 4444

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

Subject No: 44441550

Subject Initials: ---

Generated By: (b) (4)

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

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**1. Category:**

Date	Location	User	Value	Reason
Jan-08-2021 10:56:54 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> ADVERSE EVENT	Initial Entry

**2. AE ID:**

Date	Location	User	Value	Reason
Jan-08-2021 10:56:54 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 1	Initial Entry

**3. Adverse Event:**

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

Date	Location	User	Value	Reason
Feb-28-2021 22:57:33 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Feb-25-2021 10:40:03 (UTC-03:00) City of Buenos	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	SAE "hospital-acquired pneumonia" was entered.

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**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

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

**Form Status:** Data Complete, Frozen

**Site No:** 4444

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

**Subject No:** 44441550

**Subject Initials:** ---

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

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

Aires				Thank you.
Feb-24-2021 14:32:11 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reissued: Opened	Clinical Thank you. Please enter hospital-acquired pneumonia (SAE criterion HOSP) on a separate AE CRF line (remains part of the same SAE report); this event has different dates etc
Feb-19-2021 08:43:41 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	A report of SAE of hospital pneumonia was sent and it was written in the medical record. Thanks
Feb-18-2021 00:14:14 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reissued: Opened	Clinical Efficacy adjudication for COVID endpoint is complete & case did NOT

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**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

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

**Form Status:** Data Complete, Frozen

**Site No:** 4444

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

**Subject No:** 44441550

**Subject Initials:** ---

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

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

				meet efficacy criteria. Therefore, the pneumonia event is now handled per std Safety reporting. Please determine if pneumonia is a SAE (Med important, prolonged Hosp, etc)
Feb-01-2021 13:55:48 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	By Icon's response continues as covid disease, it is not considered SAE. The patient rejected pfizer swab
Jan-20-2021 11:29:43 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reissued: Opened	Clinical - The subject's local COVID test was negative and no swab for Pfizer has been obtained. Unless subject

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**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

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

**Form Status:** Data Complete, Frozen

**Site No:** 4444

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

**Subject No:** 44441550

**Subject Initials:** ---

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

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

				performs a swab, there is no chance this will be a COVID case, and pneumonia is reported to SAE report. Please report if no swab is coming.
Jan-15-2021 11:03:40 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Please clarify, we were requested by safety to record the pneumonia as potential covid illness on 11Jan2021.
Jan-13-2021 19:27:41 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reissued: Opened	Clinical Thank you. If COVID negative, please report through standard AE reporting / safety reporting if a SAE.
Jan-13-2021	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	As a safety

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**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

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

**Form Status:** Data Complete, Frozen

**Site No:** 4444

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

**Subject No:** 44441550

**Subject Initials:** ---

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

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

10:15:16 (UTC-03:00) City of Buenos Aires		(b) (4), (b) (6)	d	request, hospital acquired pneumonia will be reported as a possible Covid disease.
Jan-12-2021 13:06:25 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	CLINICAL On review of SAE report for Intestinal Perf, an event of bibasilar pneumonia was mentioned. Per protocol Sect 10.3.2, a complication that prolongs hospital stay would be a SAE. Please review for SAE reportability, & update as appropriate
Jan-08-2021 10:56:54 (UTC-03:00)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Intestinal perforation	Initial Entry

090177e196ae2ee6\Final\Final On: 01-Apr-2021 03:26 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen

Site No: 4444

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

Subject No: 44441550

Subject Initials: ---

Generated By: (b) (4)

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

City of Buenos Aires

4. Start Date Time:

Date	Location	User	Value	Reason
Jan-08-2021 10:56:54 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Dec/23/2020 09:00	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Jan-15-2021 11:05:02 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO End Date Time: Jan/13/2021 15:00	New Information
Jan-08-2021 10:56:54 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

6. Toxicity Grade:

Date	Location	User	Value	Reason
Jan-08-2021 10:56:54 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 3	Initial Entry

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**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

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

**Form Status:** Data Complete, Frozen

**Site No:** 4444

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

**Subject No:** 44441550

**Subject Initials:** ---

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

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

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

**If Yes, NOTIFY PFIZER IMMEDIATELY.**

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

Date	Location	User	Value	Reason
Jan-11-2021 04:25:30 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Jan-08-2021 12:37:28 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Closed	Close Auto Query
Jan-08-2021 12:37:28 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES Is this serious event associated with congenital anomaly or birth defect?  NO  Did this serious event result in death?  NO	New Information

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**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

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

**Form Status:** Data Complete, Frozen

**Site No:** 4444

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

**Subject No:** 44441550

**Subject Initials:** ---

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

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

			<p>Did this serious event require or prolong hospitalization?</p> <p>YES</p> <p>Did this serious event result in persistent or significant disability/incapacity?</p> <p>NO</p> <p>Is this serious event life threatening?</p> <p>NO</p> <p>Other medically important serious event</p> <p>NO</p>	
Jan-08-2021 10:56:54 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Opened	Is this adverse event serious?' is reported 'Yes', but at least one seriousness criteria is missing. Please review and

090177e196ae2ee6\Final\Final On: 01-Apr-2021 03:26 (GMT)

**Header Text:** c4591001**Visit:** Logs - Unscheduled**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History**Form Version:** 22-Apr-2020 21:02**Form Status:** Data Complete, Frozen**Site No:** 4444**Site Name:** (4444) Hospital Militar Central Cirujano Mayor Dr Cosme Argerich**Subject No:** 44441550**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 17:38

				update as appropriate.
Jan-08-2021 10:56:54 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	For AE Intestinal perforation: Response to "Is the adverse event serious?" is 'Yes' but "Serious Adverse Event Number" is blank.
Jan-08-2021 10:56:54 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

**8. Is this adverse event the result of a study Medication Error?***If Yes, record the type of medication error on the Medication Error Log.*

Date	Location	User	Value	Reason
Jan-08-2021 10:56:54 (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
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**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

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

**Form Status:** Data Complete, Frozen

**Site No:** 4444

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

**Subject No:** 44441550

**Subject Initials:** ---

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

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

Jan-15-2021 09:30:16 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Jan-13-2021 18:41:03 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	Santiago Corradetti (b) (4)	Query 1: Answered	Changed data per query
Jan-13-2021 16:49:10 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reissued:Opened	MEDHX is unblocked so please add medical record of gallstone. Thank you.
Jan-12-2021 13:15:42 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	preplanned surgery. subject with medical record of gallstone. please unblock MEDHX in order to update it. thank you
Jan-11-2021 09:40:08 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	Clinquery: I see AE down as related to 'surgical

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**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

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

**Form Status:** Data Complete, Frozen

**Site No:** 4444

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

**Subject No:** 44441550

**Subject Initials:** ---

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

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

Aires				intervention'. I assume that the perforation was caused by surgery. I see this only 1 AE, so why was the surgery being done? For another AE, or planned surgery? If the former, (S)AE needs to be added. Thank
Jan-08-2021 12:38:30 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NOT RELATED If Not Related to study treatment(s), this event is due to:  OTHER  <i>If Other, specify:</i>  surgical intervention	New Information
Jan-08-2021 10:56:54	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NOT RELATED	Initial Entry

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Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen

Site No: 4444

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

Subject No: 44441550

Subject Initials: ---

Generated By: (b) (4)

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

(UTC-03:00)  
City of Buenos  
Aires

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Jan-08-2021 10:56:54 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NOT APPLICABLE	Initial Entry

11. Was a Concomitant Medication given?

Date	Location	User	Value	Reason
Jan-08-2021 10:56:54 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Jan-08-2021 10:56:54 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

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

Date	Location	User	Value	Reason
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**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

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**Form Status:** Data Complete, Frozen

**Site No:** 4444

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

**Subject No:** 44441550

**Subject Initials:** ---

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

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

Jan-15-2021 11:05:20 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Jan-15-2021 11:05:20 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> RECOVERED/ RESOLVED	New Information
Jan-15-2021 11:05:02 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	For AE Intestinal perforation: Response to "What was the outcome of this adverse event?" is 'Recovering/Resolving' but AE End Date/Time is present.
Jan-08-2021 10:56:54 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> RECOVERING /RESOLVING	Initial Entry

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

Date	Location	User	Value	Reason
Jan-08-2021 10:56:54 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

090177e196ae2ee6\Final\Final On: 01-Apr-2021 03:26 (GMT)

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

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

**Form Status:** Data Complete, Frozen

**Site No:** 4444

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

**Subject No:** 44441550

**Subject Initials:** ---

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

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

**15. Serious Adverse Event Number: For Pfizer Use Only**

Date	Location	User	Value	Reason
Jan-11-2021 04:25:30 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 2021012994	Initial Entry

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**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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**Form Status:** Data Complete, Frozen

**Site No:** 4444

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

**Subject No:** 44441550

**Subject Initials:** ---

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

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

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**1. Category:**

Date	Location	User	Value	Reason
Feb-25-2021 10:38:52 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> ADVERSE EVENT	Initial Entry

**2. AE ID:**

Date	Location	User	Value	Reason
Feb-25-2021 10:38:52 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 2	Initial Entry

**3. Adverse Event:**

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

Date	Location	User	Value	Reason
Feb-25-2021 10:38:52 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Hospital-acquired pneumonia	Initial Entry

**4. Start Date Time:**

Date	Location	User	Value	Reason
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Site No: 4444

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

Subject No: 44441550

Subject Initials: ---

Generated By: (b) (4)

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

Feb-25-2021 10:38:52 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Dec/30/2020 09:00	Initial Entry
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**5. Is the adverse event still ongoing?**

Date	Location	User	Value	Reason
Feb-25-2021 10:38:52 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO End Date Time: Jan/13/2021 15:00	Initial Entry

**6. Toxicity Grade:**

Date	Location	User	Value	Reason
Feb-25-2021 10:38:52 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 3	Initial Entry

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

**If Yes, NOTIFY PFIZER IMMEDIATELY.**

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

Date	Location	User	Value	Reason
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**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

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**Form Status:** Data Complete, Frozen

**Site No:** 4444

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

**Subject No:** 44441550

**Subject Initials:** ---

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

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

<p>Mar-05-2021 14:00:19 (UTC-03:00) City of Buenos Aires</p>	<p>ACV0PFEINFP6000</p>	<p>(b) (4), (b) (6)</p>	<p><b>Data Entry:</b> YES Is this serious event associated with congenital anomaly or birth defect?  NO Did this serious event result in death?  NO 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 im</p>	<p>New Information</p>
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**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

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**Form Status:** Data Complete, Frozen

**Site No:** 4444

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

**Subject No:** 44441550

**Subject Initials:** ---

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

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

			portant serious event YES	
Feb-26-2021 03:05:36 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Feb-25-2021 10:38:52 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	For AE Hospital-acquired pneumonia: Response to "Is the adverse event serious?" is 'Yes' but "Serious Adverse Event Number" is blank.
Feb-25-2021 10:38:52 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES Is this serious event associated with congenital anomaly or birth defect?  NO  Did this serious event result in death?	Initial Entry

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**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

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**Form Status:** Data Complete, Frozen

**Site No:** 4444

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

**Subject No:** 44441550

**Subject Initials:** ---

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

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

			<p>NO</p> <p>Did this serious event require or prolong hospitalization?</p> <p>YES</p> <p>Did this serious event result in persistent or significant disability/incapacity?</p> <p>NO</p> <p>Is this serious event life threatening?</p> <p>NO</p> <p>Other medically important serious event</p> <p>YES</p>
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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
Feb-25-2021 10:38:52	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

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Form Status: Data Complete, Frozen

Site No: 4444

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

Subject No: 44441550

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)	
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9. Is this event related to study treatment:

Date	Location	User	Value	Reason
Feb-25-2021 10:38:52 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NOT RELATED If Not Related to study treatment(s), this event is due to:  OTHER  <i>If Other, specify:</i>  Intestinal perforation	Initial Entry

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Feb-25-2021 10:38:52 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NOT APPLICABLE	Initial Entry

11. Was a Concomitant Medication given?

Date	Location	User	Value	Reason
Feb-25-2021	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>	Initial Entry

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**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

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**Form Status:** Data Complete, Frozen

**Site No:** 4444

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

**Subject No:** 44441550

**Subject Initials:** ---

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

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

10:38:52 (UTC-03:00) City of Buenos Aires		(b) (4), (b) (6)	YES	
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**12. Was a Non-Drug Treatment given?**

Date	Location	User	Value	Reason
Feb-25-2021 10:38:52 (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
Feb-25-2021 10:38:52 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> RECOVERED/RESO LVED	Initial Entry

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

Date	Location	User	Value	Reason
Feb-25-2021 10:38:52 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**15. Serious Adverse Event Number: For Pfizer Use Only**

Date	Location	User	Value	Reason
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**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

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

**Form Status:** Data Complete, Frozen

**Site No:** 4444

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

**Subject No:** 44441550

**Subject Initials:** ---

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

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

Feb-26-2021 03:05:36 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 2021012994	Initial Entry
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**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:** 44441550

**Subject Initials:** ---

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

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

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

Date	Location	User	Value	Reason
Nov-12-2020 16:35:46 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Nov/12/2020	Initial Entry

**2. Phase of Disposition:**

Date	Location	User	Value	Reason
Nov-12-2020 16:35:46 (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-12-2020 16:35:46 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> COMPLETED	Initial Entry

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**Header Text:** c4591001

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

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

**Site No:** 4444 **Site Name:** (4444) Hospital Militar Central Cirujano  
Mayor Dr Cosme Argerich

**Subject No:** 44441550 **Subject Initials:** ---

**Generated By:** (b) (4) **Generated Time (GMT):** 29-Mar-2021 17:38

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*1. Date of Visit*

Date	Location	User	Value	Reason
Feb-05-2021 13:44:31 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Feb/5/2021	Initial Entry

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**Header Text:** c4591001

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

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

**Site No:** 4444 **Site Name:** (4444) Hospital Militar Central Cirujano  
Mayor Dr Cosme Argerich

**Subject No:** 44441550 **Subject Initials:** ---

**Generated By:** (b) (4) **Generated Time (GMT):** 29-Mar-2021 17:38

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

Date	Location	User	Value	Reason
Feb-05-2021 13:44:49 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Feb-05-2021 13:44:39 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	The response indicates participant was unblinded, however the TREATMENT UNBLINDED date is missing in the DISP visit. Please complete this date.
Feb-05-2021 13:44:39 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Participant is willin g to return for Vacc ination 3 Participant is:  eligible and NOT confirmed to hav e received only p lacebo at Vaccina	Initial Entry

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**Header Text:** c4591001

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

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

**Site No:** 4444 **Site Name:** (4444) Hospital Militar Central Cirujano  
Mayor Dr Cosme Argerich

**Subject No:** 44441550 **Subject Initials:** ---

**Generated By:** (b) (4) **Generated Time (GMT):** 29-Mar-2021 17:38

			tion 1/2	
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**Header Text:** c4591001

**Visit:** Disposition - Unscheduled

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

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

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

**Site No:** 4444

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

**Subject No:** 44441550

**Subject Initials:** ---

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

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

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**1. Date Treatment Unblinded :**

Date	Location	User	Value	Reason
Feb-05-2021 13:44:49 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Feb/5/2021	Initial Entry

**2. Primary Reason for Unblinding:**

Date	Location	User	Value	Reason
Feb-05-2021 13:44:49 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> ASSESS ELIGIBILIT Y FOR ADDITIONA L VACCINATION	Initial Entry

**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:** 44441550

**Subject Initials:** ---

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

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

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**1. Subject Status**

Date	Location	User	Value	Reason
Nov-12-2020 16:35:46 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> FOLLOW-UP	Initial Entry
Sep-23-2020 14:28:58 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> ENROLLED/RANDOMIZED	Initial Entry
Sep-23-2020 14:26:51 (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
Dec-16-2020 07:46:22 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Dec-15-2020 12:40:09 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	Santiago Corradetti (b) (4)	Query 1: Answered	Subject reported a symptom that was not

090177e196ae2ee6\Final\Final On: 01-Apr-2021 03:26 (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:** 44441550

**Subject Initials:** ---

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

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

Aires				considered as a probable COVID symptom. She referred a temporary pharyngeal itching that lasted for 2 hours and resolved spontaneously. For investigator criteria, it was incorrect to schedule a COVID illness visit.
Dec-15-2020 06:31:46 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reissued:Opened	RQ1: Response states ' It was not considered a symptom of COVID disease'. Please confirm if Illness ed diary entry of 5Dec2020 was deemed erroneous and subject had no symptoms on that day.

090177e196ae2ee6\Final\Final On: 01-Apr-2021 03:26 (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:** 44441550

**Subject Initials:** ---

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

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

Dec-14-2020 13:31:11 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6) [Redacted] [Redacted]	Query 1: Answer ed	The volunteer reports that he started with mild odynophagia on 05 DEC 2020, which resolved spontaneously without the need for medication in a period of less than 2 hours. It was not considered a symptom of COVID disease. Thank you.
Dec-14-2020 10:28:55 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	Saumitra Dubey (b) (4)	Query 1: Opened	Illness ed diary: As per Illness ed diary records, subject reported "Yes" for the question "Have you experienced any of the following?" for the COVID-19 symptoms or diagnosis on 05DEC2020. But

090177e196ae2ee6\Final\Final On: 01-Apr-2021 03:26 (GMT)

**Header Text:** c4591001

**Visit:** Subject Status - Unscheduled

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

**Site No:** 4444

**Subject No:** 44441550

**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

				corresponding COVID Illness visit not reported. Please clarify.
Nov-12-2020 16:35:46 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> Nov/12/2020	Initial Entry
Sep-23-2020 14:28:58 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> Sep/23/2020	Initial Entry
Sep-23-2020 14:26:51 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> Sep/23/2020	Initial Entry

090177e196ae2ee6\Final\Final On: 01-Apr-2021 03:26 (GMT)

**Header Text:** c4591001

**Visit:** Investigator Signature -  
Unscheduled

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

**Site No:** 4444

**Subject No:** 44441550

**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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*1. Casebook Signature*

Date	Location	User	Value	Reason
Nov-10-2020 11:54:46 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	Vanesa Fainboim (b) (4)	<b>Data Entry:</b> Click Here to Enabl e	Initial Entry

090177e196ae2ee6\Final\Final On: 01-Apr-2021 03:26 (GMT)