

**Header Text:** C4591001

**Visit:** COHORT\_SELECTION

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

**Site No:** 1231

**Subject No:** 12313879

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

**Form:** COHORT\_SELECTION

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

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

**Subject Initials:** ---

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

[eCRF Audit Trail History](#)

**Cohort Selection**

DO NOT USE THE OPTIONS STAGE 1 NONSENTINEL and STAGE 2 from this CRF. As per protocol amendment 5, STAGE 3 option is equivalent to PHASE 2/3.

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

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**Header Text:** C4591001

**Visit:** COHORT\_SELECTION

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

**Site No:** 1231

**Subject No:** 12313879

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

**Form:** MAIN INFORMED CONSENT

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

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

**Subject Initials:** ---

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

[eCRF Audit Trail History](#)

**Informed Consent**

1.	Consent Was:	OBTAINED Date Written Consent Obtained Aug/25/2020
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**Header Text:** C4591001

**Visit:** COHORT\_SELECTION

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

**Site No:** 1231

**Subject No:** 12313879

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

**Form:** DEMOGRAPHY

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

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

**Subject Initials:** ---

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

[eCRF Audit Trail History](#)

**Demography**

1.	Subject ID	[12313879]
2.	Birth Date:	(b) (6) /1993
3.	Sex:	FEMALE
4.	Ethnicity:	HISPANIC OR LATINO(A) OR OF SPANISH ORIGIN
5.	Race: (Check X all that apply):	AMERICAN INDIAN OR ALASKA NATIVE
6.	Racial Designation:	

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**Header Text:** C4591001

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

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

**Site No:** 1231

**Subject No:** 12313879

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

**Form:** DATE OF VISIT

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

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

**Subject Initials:** ---

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

[eCRF Audit Trail History](#)

**Date of Visit**

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

**Header Text:** C4591001

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

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

**Site No:** 1231

**Subject No:** 12313879

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

**Form:** INCLUSION/EXCLUSION CRITERIA

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

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

**Subject Initials:** ---

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

**Form Comments**

**Inclusion Criteria Not Met**

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

2.	Description of Exclusion Criterion Met	Not Applicable _____
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**Header Text:** C4591001

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

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

**Site No:** 1231

**Subject No:** 12313879

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

**Form:** DISPOSITION - SCREENING

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

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

**Subject Initials:** ---

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

[eCRF Audit Trail History](#)

**Disposition - Screening**

1.	Date of Completion/Discontinuation /Death	Aug/25/2020
2.	Phase of Disposition:	SCREENING
3.	Status:	COMPLETED
4.	Specify Status:	[ ]

**Header Text:** C4591001

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

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

**Site No:** 1231

**Subject No:** 12313879

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

**Form:** GENERAL MEDICAL HISTORY

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

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

**Subject Initials:** ---

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

[Form Comments](#)

**Medical History Details**

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

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**Header Text:** C4591001

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

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

**Site No:** 1231

**Subject No:** 12313879

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

**Form:** VITAL SIGNS - BASELINE

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

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

**Subject Initials:** ---

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

[eCRF Audit Trail History](#)

**Vital Signs**

1.	Date:	Aug/25/2020
2.	Weight:	[70.0]
3.	Unit:	kg
4.	Height:	[162.0]
5.	Unit:	cm
6.	Body Mass Index:	[26.7]

**Vital Signs Details**

7.a	Record Identifier:	1
	Temperature:	[36.6]
	Unit:	C
	Temperature Location:	ORAL CAVITY

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**Header Text:** C4591001

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

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

**Site No:** 1231

**Subject No:** 12313879

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

**Form:** LAB URINALYSIS - PREGNANCY TEST

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

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

**Subject Initials:** ---

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

[eCRF Audit Trail History](#)

**Lab Urinalysis**

1.	Lab Panel:	URINALYSIS
2.	Lab Sub-Panel:	PREGNANCY
3.	Collection Date:	Aug/25/2020
4.	Laboratory Name and Address (Derived)	[STUDY SITE]
5.	Specimen Type:	URINE

**Lab Result**

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

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**Header Text:** C4591001

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

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

**Site No:** 1231

**Subject No:** 12313879

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

**Form:** RANDOMIZATION

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

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

**Subject Initials:** ---

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

[eCRF Audit Trail History](#)

**Disposition**

1.	Randomization Date :	Aug/25/2020
2.	Randomization Number:	[65638]
3.	Randomization Group:	[ ]

**Header Text:** C4591001

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

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

**Site No:** 1231

**Subject No:** 12313879

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

**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

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

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

**Subject Initials:** ---

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

[eCRF Audit Trail History](#)

**Electronic Sample Tracking**

1.	Data Origin	SITE
2.	Sample Type	SERUM
3.	Sample Collected?	YES Date of Collection: Aug/25/2020
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[ ]

**Aliquot**

Please enter barcode for each aliquot.

5.a	Sample ID	[BP24Y4]
5.b	Sample ID	[BP24Y5]
5.c	Sample ID	[BP24Y6]
5.d	Sample ID	[BLDZF3]
5.e	Sample ID	[BLDZF4]
5.f	Sample ID	[BLDZF5]

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**Header Text:** C4591001

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

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

**Site No:** 1231

**Subject No:** 12313879

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

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

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

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

**Subject Initials:** ---

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

[eCRF Audit Trail History](#)

**Electronic Sample Tracking**

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB
3.	Sample Collected?	YES Date of Collection: Aug/25/2020
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[ ]

**Aliquot**

Please enter barcode for each aliquot.

5.a	Sample ID	[BP24V2]
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090177e196ae2eca\Final\Final On: 01-Apr-2021 03:23 (GMT)

**Header Text:** C4591001

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

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

**Site No:** 1231

**Subject No:** 12313879

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

**Form:** VACCINATION

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

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

**Subject Initials:** ---

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

[eCRF Audit Trail History](#)

**Vaccination**

1.	Was there a temporary delay of vaccination?	NO
2.	Treatment Name	[BLINDED THERAPY]
3.	Formulation:	INJECTION
4.	Dose Date Time:	Aug/25/2020 12:28
5.	Anatomical Location:	DELTOID MUSCLE
6.	Body Side:	LEFT
7.	Route:	INTRAMUSCULAR
8.	Actual Dose:	[ ]
9.	Unit:	
10.	Timeframe Subject Was Observed	THE PROTOCOL SPECIFIED OBSERVATION PERIOD
11.	Was the subject observed for at least the protocol specified observation period after investigational product administration?	YES

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**Header Text:** C4591001

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

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

**Site No:** 1231

**Subject No:** 12313879

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

**Form:** REACTOGENICITY DIARY

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

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

**Subject Initials:** ---

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

[eCRF Audit Trail History](#)

**Reactogenicity Diary**

1.	Select appropriate response - Reactogenicity diary collection	NO - REACTOGENICITY E-DIARY NOT COLLECTED FOR THIS SUBJECT
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**Header Text:** C4591001

**Visit:** V2\_VAX2\_L

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

**Site No:** 1231

**Subject No:** 12313879

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

**Form:** DATE OF VISIT

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

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

**Subject Initials:** ---

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

[eCRF Audit Trail History](#)

**Date of Visit**

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

**Header Text:** C4591001

**Visit:** V2\_VAX2\_L

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

**Site No:** 1231

**Subject No:** 12313879

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

**Form:** VITAL SIGNS - TEMP

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

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

**Subject Initials:** ---

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

[eCRF Audit Trail History](#)

**Vital Signs**

1.	Date:	Sep/13/2020
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**Vital Signs Details**

2.a	Record Identifier:	1
	Temperature:	[37.1]
	Unit:	C
	Temperature Location:	ORAL CAVITY



**Header Text:** C4591001

**Visit:** V2\_VAX2\_L

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

**Site No:** 1231

**Subject No:** 12313879

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

**Form:** LAB URINALYSIS - PREGNANCY TEST

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

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

**Subject Initials:** ---

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

[eCRF Audit Trail History](#)

**Lab Urinalysis**

1.	Lab Panel:	URINALYSIS
2.	Lab Sub-Panel:	PREGNANCY
3.	Collection Date:	Sep/13/2020
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:	

090177e196ae2eca\Final\Final On: 01-Apr-2021 03:23 (GMT)

**Header Text:** C4591001

**Visit:** V2\_VAX2\_L

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

**Site No:** 1231

**Subject No:** 12313879

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

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

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

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

**Subject Initials:** ---

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

[eCRF Audit Trail History](#)

**Electronic Sample Tracking**

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB
3.	Sample Collected?	YES Date of Collection: Sep/13/2020
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[ ]

**Aliquot**

Please enter barcode for each aliquot.

5.a	Sample ID	[BP1YLL]
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090177e196ae2eca\Final\Final On: 01-Apr-2021 03:23 (GMT)

**Header Text:** C4591001

**Visit:** V2\_VAX2\_L

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

**Site No:** 1231

**Subject No:** 12313879

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

**Form:** VACCINATION

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

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

**Subject Initials:** ---

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

[eCRF Audit Trail History](#)

**Vaccination**

1.	Was there a temporary delay of vaccination?	NO
2.	Treatment Name	[BLINDED THERAPY]
3.	Formulation:	INJECTION
4.	Dose Date Time:	Sep/13/2020 19:36
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

090177e196ae2eca\Final\Final On: 01-Apr-2021 03:23 (GMT)

**Header Text:** C4591001

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

**Form:** DATE OF VISIT

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

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

**Site No:** 1231

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

**Subject No:** 12313879

**Subject Initials:** ---

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

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

[eCRF Audit Trail History](#)

**Date of Visit**

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

**Header Text:** C4591001

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

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

**Site No:** 1231

**Subject No:** 12313879

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

**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

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

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

**Subject Initials:** ---

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

[eCRF Audit Trail History](#)

**Electronic Sample Tracking**

1.	Data Origin	SITE
2.	Sample Type	SERUM
3.	Sample Collected?	NO
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[Peripheral blood sampling was not performed for immunogenicity study. Sample is taken during the convalescent visit.]

**Aliquot**

Please enter barcode for each aliquot.

5.	Sample ID	[ ]
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090177e196ae2eca\Final\Final On: 01-Apr-2021 03:23 (GMT)

**Header Text:** C4591001

**Visit:** V4\_MONTH6\_L

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

**Site No:** 1231

**Subject No:** 12313879

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

**Form:** DATE OF VISIT

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

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

**Subject Initials:** ---

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

[eCRF Audit Trail History](#)

**Date of Visit**

1.	Date of Visit	Mar/16/2021
2.	Erroneous Visit	

**Header Text:** C4591001

**Visit:** V4\_MONTH6\_L

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

**Site No:** 1231

**Subject No:** 12313879

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

**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

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

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

**Subject Initials:** ---

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

[eCRF Audit Trail History](#)

**Electronic Sample Tracking**

1.	Data Origin	SITE
2.	Sample Type	SERUM
3.	Sample Collected?	YES Date of Collection: Mar/16/2021
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	[BRM9YR]
5.b	Sample ID	[BRZ2S8]
5.c	Sample ID	[BRZ2NP]

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**Header Text:** C4591001

**Visit:** V5\_MONTH12\_L

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

**Site No:** 1231

**Subject No:** 12313879

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

**Form:** DATE OF VISIT

**Form Status:** Not Started

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

**Subject Initials:** ---

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

**Date of Visit**

1.	Date of Visit	//
2.	Erroneous Visit	



**Header Text:** C4591001

**Visit:** V5\_MONTH12\_L

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

**Site No:** 1231

**Subject No:** 12313879

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

**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

**Form Status:** Not Started

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

**Subject Initials:** ---

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

**Electronic Sample Tracking**

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

**Aliquot**

Please enter barcode for each aliquot.

5.	Sample ID	[ ]
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090177e196ae2eca\Final\Final On: 01-Apr-2021 03:23 (GMT)

**Header Text:** C4591001

**Visit:** V6\_MONTH24\_L

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

**Site No:** 1231

**Subject No:** 12313879

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

**Form:** DATE OF VISIT

**Form Status:** Not Started

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

**Subject Initials:** ---

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

**Date of Visit**

1.	Date of Visit	//
2.	Erroneous Visit	

**Header Text:** C4591001

**Visit:** V6\_MONTH24\_L

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

**Site No:** 1231

**Subject No:** 12313879

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

**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

**Form Status:** Not Started

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

**Subject Initials:** ---

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

**Electronic Sample Tracking**

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

**Aliquot**

Please enter barcode for each aliquot.

5.	Sample ID	[ ]
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090177e196ae2eca\Final\Final On: 01-Apr-2021 03:23 (GMT)

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Sep/11/2020 **Form:** DATE OF VISIT - ILLNESS ONSET

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

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

**Site No:** 1231

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

**Subject No:** 12313879

**Subject Initials:** ---

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

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

[eCRF Audit Trail History](#)

**Date of Visit**

1.	Date of Visit	Sep/11/2020
2.	Erroneous Visit	

**COVID-19 Illness Visit**

3.	COVID-19 Illness Visit:	COVID_A
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**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Sep/11/2020 **Form:** SIGNS AND SYMPTOMS OF POTENTIAL COVID-19

**Form Version:** 21-Aug-2020 02:52

**Form Status:** Data Complete, Frozen, Not Complete

**Site No:** 1231

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

**Subject No:** 12313879

**Subject Initials:** ---

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

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

[eCRF Audit Trail History](#)

**Signs and Symptoms**

1.	Date of Assessment:	Sep/11/2020
2.	Date of First Symptom Started:	Aug/27/2020
3.	Symptoms Ongoing?	NO Date of Last Symptom Resolved: Sep/22/2020

**Symptoms**

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

**Symptoms - Other**

090177e196ae2eca\Final\Final On: 01-Apr-2021 03:23 (GMT)

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Sep/11/2020

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

**Form Version:** 21-Aug-2020 02:52

**Form Status:** Data Complete, Frozen, Not Complete

**Site No:** 1231

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

**Subject No:** 12313879

**Subject Initials:** ---

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

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

5.	Symptoms - Other Text:	[ ]
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**Header Text:** C4591001

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

**Form:** MICROBIOLOGY SPECIMEN

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

**Site No:** 1231

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

**Subject No:** 12313879

**Subject Initials:** ---

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

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

#	Date of Collection	Specimen Type	Specimen Collection Location	Assay Code and Description	Device Type	Form Instance
1.	Sep/11/2020	SWABBED MATERIAL	NASOPHARYNX	SEVERE ACUTE RESPIRATORY SYNDROME CORONAVIRUS 2	SARS-COV-2 DIAGNOSTIC TEST	<a href="#">Repeating Pages</a>

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Sep/11/2020 **Form:** MICROBIOLOGY SPECIMEN

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

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

**Site No:** 1231

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

**Subject No:** 12313879

**Subject Initials:** ---

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

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

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**Microbiology Specimen**

1.	Actual Date of Collection:	Sep/11/2020
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:	ATILA BIOSYSTEMS IAMP COVID-19 DETECTION KIT
7.	Test Result:	NEGATIVE
8.	Comments/Findings/Details:	[ ]
9.	Trade Name Other, Specify:	[ ]

090177e196ae2eca\Final\Final On: 01-Apr-2021 03:23 (GMT)



**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Sep/11/2020 **Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB SELF

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

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

**Site No:** 1231

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

**Subject No:** 12313879

**Subject Initials:** ---

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

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

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**Electronic Sample Tracking**

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

**Aliquot**

Please enter barcode for each aliquot.

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

090177e196ae2eca\Final\Final On: 01-Apr-2021 03:23 (GMT)

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Sep/11/2020 **Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB

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

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

**Site No:** 1231

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

**Subject No:** 12313879

**Subject Initials:** ---

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

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

[eCRF Audit Trail History](#)

**Electronic Sample Tracking**

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB
3.	Sample Collected?	YES Date of Collection: Sep/11/2020
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[ ]

**Aliquot**

Please enter barcode for each aliquot.

5.a	Sample ID	[BP1Y6H]
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090177e196ae2eca\Final\Final On: 01-Apr-2021 03:23 (GMT)

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Sep/11/2020 **Form:** HEALTH CARE UTILIZATION

**Form Version:** 21-Aug-2020 02:50

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

**Site No:** 1231

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

**Subject No:** 12313879

**Subject Initials:** ---

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

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

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**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:	NO
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
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?	NO
----	--	----

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**Header Text:** C4591001

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

**Form:** RESPIRATORY TREATMENT

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

**Site No:** 1231

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

**Subject No:** 12313879

**Subject Initials:** ---

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

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

#	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 Sep/11/2020 **Form:** RESPIRATORY TREATMENT

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

**Form Status:** Not Started

**Site No:** 1231

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

**Subject No:** 12313879

**Subject Initials:** ---

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

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

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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?	

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Sep/11/2020 **Form:** ILLNESS DETAILS

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

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

**Site No:** 1231

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

**Subject No:** 12313879

**Subject Initials:** ---

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

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

[eCRF Audit Trail History](#)

**Illness Details**

1.	Category of Clinical Event:	POTENTIAL COVID-19 ILLNESS
2.	Was a diagnosis obtained for Potential COVID-19 Illness?	NO
3.	Toxicity Grade:	1

**Header Text:** C4591001

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

**Form:** ILLNESS DETAILS - SEVERE

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

**Site No:** 1231

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

**Subject No:** 12313879

**Subject Initials:** ---

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

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

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

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**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Sep/11/2020 **Form:** ILLNESS DETAILS - SEVERE

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

**Form Status:** Not Started

**Site No:** 1231

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

**Subject No:** 12313879

**Subject Initials:** ---

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

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

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**Illness Details**

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



**Header Text:** C4591001

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

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

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

**Site No:** 1231

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

**Subject No:** 12313879

**Subject Initials:** ---

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

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

#	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>

090177e196ae2eca\Final\Final On: 01-Apr-2021 03:23 (GMT)

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Sep/11/2020 **Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY

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

**Form Status:** Not Started

**Site No:** 1231

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

**Subject No:** 12313879

**Subject Initials:** ---

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

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

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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:** 21-Aug-2020 02:51

**Site No:** 1231

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

**Subject No:** 12313879

**Subject Initials:** ---

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

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

#	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>

090177e196ae2eca\Final\Final On: 01-Apr-2021 03:23 (GMT)

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Sep/11/2020 **Form:** LOCAL LABORATORY DATA - REPEATING Hematology

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

**Form Status:** Not Started

**Site No:** 1231

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

**Subject No:** 12313879

**Subject Initials:** ---

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

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

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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:** 21-Aug-2020 02:50

**Site No:** 1231

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

**Subject No:** 12313879

**Subject Initials:** ---

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

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

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

090177e196ae2eca\Final\Final On: 01-Apr-2021 03:23 (GMT)

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Sep/11/2020 **Form:** VITAL SIGNS - COVID

**Form Version:** 21-Aug-2020 02:50

**Form Status:** Not Started

**Site No:** 1231

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

**Subject No:** 12313879

**Subject Initials:** ---

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

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

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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:	[ ]

**Header Text:** C4591001

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

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

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

**Site No:** 1231

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

**Subject No:** 12313879

**Subject Initials:** ---

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

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

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

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**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Sep/11/2020 **Form:** VITAL SIGNS - PULSE OX ROOM AIR

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

**Form Status:** Not Started

**Site No:** 1231

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

**Subject No:** 12313879

**Subject Initials:** ---

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

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

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**Vital Signs**

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

**Vital Signs Details**

2.	Record Identifier:	
	SPO2 Pulse Oximetry %	[ ]



**Header Text:** C4591001

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

**Form:** OXYGENATION PARAMETERS

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

**Site No:** 1231

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

**Subject No:** 12313879

**Subject Initials:** ---

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

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

#	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 Sep/11/2020 **Form:** OXYGENATION PARAMETERS

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

**Form Status:** Not Started

**Site No:** 1231

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

**Subject No:** 12313879

**Subject Initials:** ---

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

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

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**Oxygenation Parameters**

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

**Header Text:** C4591001

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

**Form:** CONCOMITANT MEDICATIONS - VASOPRESSORS

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

**Site No:** 1231

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

**Subject No:** 12313879

**Subject Initials:** ---

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

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

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

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**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Sep/11/2020

**Form:** CONCOMITANT MEDICATIONS - VASOPRESSORS

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

**Form Status:** Not Started

**Site No:** 1231

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

**Subject No:** 12313879

**Subject Initials:** ---

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

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

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**Concomitant Medications**

1.	What is the medication identifier?	[ ]
2.	Category:	
3.	Concomitant Medications Pre-specified:	
4.	Medication:  Provide the complete generic drug name (including salt form, where applicable). Where generic name is unknown, enter the full trade or proprietary name. Include clarifying information in the Medication text (e.g., Ingredient(s), route, use, formulation).	[ ]
5.	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:** 1231

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

**Subject No:** 12313879

**Subject Initials:** ---

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

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

#	Date of Assessment	Location of Assessment	Imaging Method	Overall Assessment	Form Instance
1.					<a href="#">Repeating Pages</a>

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**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Sep/11/2020 **Form:** IMAGING

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

**Form Status:** Not Started

**Site No:** 1231

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

**Subject No:** 12313879

**Subject Initials:** ---

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

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

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**Imaging**

1.	Date of Assessment:	//
2.	Location of Assessment:	
3.	Type of Imaging Exam:	
4.	Assessment:	

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 2 - Unscheduled Visit on Jan/06/2021      **Form:** DATE OF VISIT - ILLNESS ONSET

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

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

**Site No:** 1231

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

**Subject No:** 12313879

**Subject Initials:** ---

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

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

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**Date of Visit**

1.	Date of Visit	Jan/6/2021
2.	Erroneous Visit	

**COVID-19 Illness Visit**

3.	COVID-19 Illness Visit:	COVID_B
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**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 2 - Unscheduled Visit on **Form:** SIGNS AND SYMPTOMS OF POTENTIAL COVID-19  
Jan/06/2021

**Form Version:** 10-Dec-2020 02:29

**Form Status:** Data Complete

**Site No:** 1231

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

**Subject No:** 12313879

**Subject Initials:** ---

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

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

[eCRF Audit Trail History](#)

**Signs and Symptoms**

1.	Date of Assessment:	Jan/6/2021
2.	Date of First Symptom Started:	Jan/1/2021
3.	Symptoms Ongoing?	NO Date of Last Symptom Resolved: Jan/9/2021

**Symptoms**

4.a	Symptoms:	FEVER
	Was symptom present?	NO
4.b	Symptoms:	NEW OR INCREASED COUGH
	Was symptom present?	NO
4.c	Symptoms:	NEW OR INCREASED SHORTNESS OF BREATH
	Was symptom present?	NO
4.d	Symptoms:	CHILLS
	Was symptom present?	NO
4.e	Symptoms:	NEW OR INCREASED MUSCLE PAIN
	Was symptom present?	NO
4.f	Symptoms:	NEW LOSS OF TASTE OR SMELL
	Was symptom present?	NO
4.g	Symptoms:	NEW OR INCREASED SORE THROAT
	Was symptom present?	YES
4.h	Symptoms:	DIARRHEA
	Was symptom present?	NO
4.i	Symptoms:	VOMITING
	Was symptom present?	NO

**Symptoms - Other**

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**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 2 - Unscheduled Visit on Jan/06/2021 **Form:** SIGNS AND SYMPTOMS OF POTENTIAL COVID-19

**Form Version:** 10-Dec-2020 02:29

**Form Status:** Data Complete

**Site No:** 1231

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

**Subject No:** 12313879

**Subject Initials:** ---

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

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

5.a	Symptoms - Other Text:	[headache]
5.b	Symptoms - Other Text:	[nasal congestion]

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**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 2

**Form:** MICROBIOLOGY SPECIMEN

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

**Site No:** 1231

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

**Subject No:** 12313879

**Subject Initials:** ---

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

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

#	Date of Collection	Specimen Type	Specimen Collection Location	Assay Code and Description	Device Type	Form Instance
1.	Jan/6/2021	SWABBED MATERIAL	NASOPHARYNX	SEVERE ACUTE RESPIRATORY SYNDROME CORONAVIRUS 2	SARS-COV-2 DIAGNOSTIC TEST	<a href="#">Repeating Pages</a>

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 2 - Unscheduled Visit on **Form:** MICROBIOLOGY SPECIMEN  
Jan/06/2021

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

**Form Status:** Data Complete

**Site No:** 1231

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

**Subject No:** 12313879

**Subject Initials:** ---

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

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

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**Microbiology Specimen**

1.	Actual Date of Collection:	Jan/6/2021
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:	ATILA BIOSYSTEMS IAMP COVID-19 DETECTION KIT
7.	Test Result:	NEGATIVE
8.	Comments/Findings/Details:	[ ]
9.	Trade Name Other, Specify:	[ ]

090177e196ae2eca\Final\Final On: 01-Apr-2021 03:23 (GMT)

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 2 - Unscheduled Visit on Jan/06/2021      **Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB SELF

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

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

**Site No:** 1231

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

**Subject No:** 12313879

**Subject Initials:** ---

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

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

[eCRF Audit Trail History](#)

**Electronic Sample Tracking**

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

**Aliquot**

Please enter barcode for each aliquot.

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

**Visit:** POT\_COVID\_ILL 2 - Unscheduled Visit on Jan/06/2021 **Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB

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

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

**Site No:** 1231

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

**Subject No:** 12313879

**Subject Initials:** ---

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

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

[eCRF Audit Trail History](#)

**Electronic Sample Tracking**

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB
3.	Sample Collected?	YES Date of Collection: Jan/6/2021
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	[BPTBWV]
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090177e196ae2eca\Final\Final On: 01-Apr-2021 03:23 (GMT)

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 2 - Unscheduled Visit on **Form:** HEALTH CARE UTILIZATION  
Jan/06/2021

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

**Form Status:** Data Complete

**Site No:** 1231

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

**Subject No:** 12313879

**Subject Initials:** ---

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

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

[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:	NO
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
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?	NO
----	--	----

090177e196ae2eca\Final\Final On: 01-Apr-2021 03:23 (GMT)

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 2

**Form:** RESPIRATORY TREATMENT

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

**Site No:** 1231

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

**Subject No:** 12313879

**Subject Initials:** ---

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

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

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

090177e196ae2eca\Final\Final On: 01-Apr-2021 03:23 (GMT)

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 2 - Unscheduled Visit on **Form:** RESPIRATORY TREATMENT  
Jan/06/2021

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

**Form Status:** Not Started

**Site No:** 1231

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

**Subject No:** 12313879

**Subject Initials:** ---

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

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

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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?	



**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 2 - Unscheduled Visit on Jan/06/2021 **Form:** ILLNESS DETAILS

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

**Form Status:** Data Complete

**Site No:** 1231

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

**Subject No:** 12313879

**Subject Initials:** ---

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

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

[eCRF Audit Trail History](#)

**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: [upper airway catarrh]  Date of Diagnosis: Jan/6/2021
3.	Toxicity Grade:	1

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**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 2

**Form:** ILLNESS DETAILS - SEVERE

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

**Site No:** 1231

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

**Subject No:** 12313879

**Subject Initials:** ---

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

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

#	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 2 - Unscheduled Visit on **Form:** ILLNESS DETAILS - SEVERE  
Jan/06/2021

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

**Form Status:** Not Started

**Site No:** 1231

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

**Subject No:** 12313879

**Subject Initials:** ---

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

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

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**Illness Details**

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

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 2

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

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

**Site No:** 1231

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

**Subject No:** 12313879

**Subject Initials:** ---

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

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

#	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 2 - Unscheduled Visit on Jan/06/2021 **Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY

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

**Form Status:** Not Started

**Site No:** 1231

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

**Subject No:** 12313879

**Subject Initials:** ---

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

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

[Back to Form](#)

**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

090177e196ae2eca\Final\Final On: 01-Apr-2021 03:23 (GMT)

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 2

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

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

**Site No:** 1231

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

**Subject No:** 12313879

**Subject Initials:** ---

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

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

#	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 2 - Unscheduled Visit on Jan/06/2021 **Form:** LOCAL LABORATORY DATA - REPEATING Hematology

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

**Form Status:** Not Started

**Site No:** 1231

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

**Subject No:** 12313879

**Subject Initials:** ---

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

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

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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 2

**Form:** VITAL SIGNS - COVID

**Form Version:** 21-Aug-2020 02:50

**Site No:** 1231

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

**Subject No:** 12313879

**Subject Initials:** ---

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

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

#	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 2 - Unscheduled Visit on **Form:** VITAL SIGNS - COVID  
Jan/06/2021

**Form Version:** 21-Aug-2020 02:50

**Form Status:** Not Started

**Site No:** 1231

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

**Subject No:** 12313879

**Subject Initials:** ---

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

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

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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:	[ ]

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 2

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

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

**Site No:** 1231

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

**Subject No:** 12313879

**Subject Initials:** ---

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

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

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

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 2 - Unscheduled Visit on **Form:** VITAL SIGNS - PULSE OX ROOM AIR  
Jan/06/2021

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

**Form Status:** Not Started

**Site No:** 1231

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

**Subject No:** 12313879

**Subject Initials:** ---

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

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

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**Vital Signs**

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

**Vital Signs Details**

2.	Record Identifier:	
	SPO2 Pulse Oximetry %	[ ]

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 2

**Form:** OXYGENATION PARAMETERS

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

**Site No:** 1231

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

**Subject No:** 12313879

**Subject Initials:** ---

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

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

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

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 2 - Unscheduled Visit on **Form:** OXYGENATION PARAMETERS  
Jan/06/2021

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

**Form Status:** Not Started

**Site No:** 1231

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

**Subject No:** 12313879

**Subject Initials:** ---

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

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

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**Oxygenation Parameters**

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

090177e196ae2eca\Final\Final On: 01-Apr-2021 03:23 (GMT)

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 2

**Form:** CONCOMITANT MEDICATIONS - VASOPRESSORS

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

**Site No:** 1231

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

**Subject No:** 12313879

**Subject Initials:** ---

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

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

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

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 2 - Unscheduled Visit on  
Jan/06/2021

**Form:** CONCOMITANT MEDICATIONS - VASOPRESSORS

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

**Form Status:** Not Started

**Site No:** 1231

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

**Subject No:** 12313879

**Subject Initials:** ---

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

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

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**Concomitant Medications**

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

090177e196ae2eca\Final\Final On: 01-Apr-2021 03:23 (GMT)

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 2

**Form:** IMAGING

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

**Site No:** 1231

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

**Subject No:** 12313879

**Subject Initials:** ---

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

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

#	Date of Assessment	Location of Assessment	Imaging Method	Overall Assessment	Form Instance
1.					<a href="#">Repeating Pages</a>



**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 2 - Unscheduled Visit on **Form:** IMAGING  
Jan/06/2021

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

**Form Status:** Not Started

**Site No:** 1231

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

**Subject No:** 12313879

**Subject Initials:** ---

**Generated By:** (b) (4) [REDACTED]

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

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**Imaging**

1.	Date of Assessment:	//
2.	Location of Assessment:	
3.	Type of Imaging Exam:	
4.	Assessment:	

**Header Text:** C4591001

**Visit:** POT\_COVID\_CONVA 1 - Unscheduled Visit **Form:** DATE OF VISIT - ILLNESS CONVALESCENT  
on Oct/13/2020

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

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

**Site No:** 1231

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

**Subject No:** 12313879

**Subject Initials:** ---

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

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

[eCRF Audit Trail History](#)

**Date of Visit**

1.	Date of Visit	Oct/13/2020
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 **Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY on Oct/13/2020

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

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

**Site No:** 1231

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

**Subject No:** 12313879

**Subject Initials:** ---

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

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

[eCRF Audit Trail History](#)

**Electronic Sample Tracking**

1.	Data Origin	SITE
2.	Sample Type	SERUM
3.	Sample Collected?	YES Date of Collection: Oct/13/2020
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[ ]

**Aliquot**

Please enter barcode for each aliquot.

5.a	Sample ID	[BPT7SZ]
5.b	Sample ID	[BRXPY0]
5.c	Sample ID	[BRXPYF]

090177e196ae2eca\Final\Final On: 01-Apr-2021 03:23 (GMT)

**Header Text:** C4591001

**Visit:** POT\_COVID\_CONVA 2 - Unscheduled Visit **Form:** DATE OF VISIT - ILLNESS CONVALESCENT  
on Feb/03/2021

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

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

**Site No:** 1231

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

**Subject No:** 12313879

**Subject Initials:** ---

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

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

[eCRF Audit Trail History](#)

**Date of Visit**

1.	Date of Visit	Feb/3/2021
2.	Erroneous Visit	

**COVID-19 Illness Visit**

3.	COVID-19 Illness Visit:	COVID_B1
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**Header Text:** C4591001

**Visit:** POT\_COVID\_CONVA 2 - Unscheduled Visit **Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY on Feb/03/2021

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

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

**Site No:** 1231

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

**Subject No:** 12313879

**Subject Initials:** ---

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

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

[eCRF Audit Trail History](#)

**Electronic Sample Tracking**

1.	Data Origin	SITE
2.	Sample Type	SERUM
3.	Sample Collected?	YES Date of Collection: Feb/3/2021
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	[BPWC6T]
5.b	Sample ID	[BS43PV]
5.c	Sample ID	[BS43PD]

090177e196ae2eca\Final\Final On: 01-Apr-2021 03:23 (GMT)

**Header Text:** C4591001

**Visit:** Unplanned - New Unscheduled Visit

**Form:** DATE OF VISIT

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

**Form Status:** Not Started

**Site No:** 1231

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

**Subject No:** 12313879

**Subject Initials:** ---

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

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

**Date of Visit**

1.	Date of Visit	//
2.	Erroneous Visit	

**Header Text:** C4591001

**Visit:** Unplanned - New Unscheduled Visit

**Form:** UNPLANNED VISIT

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

**Form Status:** Not Started

**Site No:** 1231

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

**Subject No:** 12313879

**Subject Initials:** ---

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

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

**Unplanned Assessments**

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

**Header Text:** C4591001

**Visit:** End of Treatment - Unscheduled

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

**Site No:** 1231

**Subject No:** 12313879

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

**Form:** DISPOSITION - TREATMENT

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

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

**Subject Initials:** ---

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

[eCRF Audit Trail History](#)

**Disposition - Treatment**

1.	Date of Completion/Discontinuation /Death :	Oct/13/2020
2.	Phase of Disposition:	VACCINATION
3.	Status:	COMPLETED
4.	Specify Status:	[ ]



**Header Text:** C4591001

**Visit:** Follow-Up - Unscheduled

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

**Site No:** 1231

**Subject No:** 12313879

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

**Form:** DISPOSITION - FOLLOW-UP

**Form Status:** Not Started

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

**Subject Initials:** ---

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

**Disposition - Follow-Up**

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

**Header Text:** C4591001

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

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

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

**Form Status:** Not Started

**Site No:** 1231

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

**Subject No:** 12313879

**Subject Initials:** ---

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

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

**Date of Visit**

1.	Date of Visit	//
2.	Erroneous Visit	

**COVID-19 Repeat Swab**

3.	COVID-19 Repeat Swab:	
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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:** 1231

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

**Subject No:** 12313879

**Subject Initials:** ---

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

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

**Electronic Sample Tracking**

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

**Aliquot**

Please enter barcode for each aliquot.

5.	Sample ID	[ ]
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090177e196ae2eca\Final\Final On: 01-Apr-2021 03:23 (GMT)

**Header Text:** C4591001

**Visit:** Unplanned Vaccination - Unscheduled

**Form:** DATE OF VISIT

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

**Form Status:** Not Started

**Site No:** 1231

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

**Subject No:** 12313879

**Subject Initials:** ---

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

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

**Date of Visit**

1.	Date of Visit	//
2.	Erroneous Visit	

**Header Text:** C4591001

**Visit:** Unplanned Vaccination - Unscheduled

**Form:** VITAL SIGNS - TEMP

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

**Form Status:** Not Started

**Site No:** 1231

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

**Subject No:** 12313879

**Subject Initials:** ---

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

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

**Vital Signs**

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

**Vital Signs Details**

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

**Header Text:** C4591001

**Visit:** Unplanned Vaccination - Unscheduled

**Form:** LAB URINALYSIS - PREGNANCY TEST

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

**Form Status:** Not Started

**Site No:** 1231

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

**Subject No:** 12313879

**Subject Initials:** ---

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

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

**Lab Urinalysis**

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

**Lab Result**

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

090177e196ae2eca\Final\Final On: 01-Apr-2021 03:23 (GMT)

**Header Text:** C4591001

**Visit:** Unplanned Vaccination - Unscheduled

**Form:** VACCINATION

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

**Form Status:** Not Started

**Site No:** 1231

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

**Subject No:** 12313879

**Subject Initials:** ---

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

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

**Vaccination**

1.	Was there a temporary delay of vaccination?	
2.	Treatment Name	[ ]
3.	Formulation:	
4.	Dose Date Time:	//
5.	Anatomical Location:	
6.	Body Side:	
7.	Route:	
8.	Actual Dose:	[ ]
9.	Unit:	
10.	Timeframe Subject Was Observed	
11.	Was the subject observed for at least the protocol specified observation period after investigational product administration?	

090177e196ae2eca\Final\Final On: 01-Apr-2021 03:23 (GMT)

**Header Text:** C4591001

**Visit:** Unplanned Vaccination - Unscheduled

**Form:** CONTACT OUTCOME - MONTH 1

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

**Form Status:** Not Started

**Site No:** 1231

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

**Subject No:** 12313879

**Subject Initials:** ---

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

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

**Contact Outcome**

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



**Header Text:** C4591001

**Visit:** Unplanned Vaccination - Unscheduled

**Form:** CONTACT OUTCOME - MONTH 6

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

**Form Status:** Not Started

**Site No:** 1231

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

**Subject No:** 12313879

**Subject Initials:** ---

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

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

**Contact Outcome**

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

090177e196ae2eca\Final\Final On: 01-Apr-2021 03:23 (GMT)

**Header Text:** C4591001

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

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

**Form Status:** Not Started

**Site No:** 1231

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

**Subject No:** 12313879

**Subject Initials:** ---

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

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

**Date of Visit**

1.	Date of Visit	//
2.	Erroneous Visit	

**Header Text:** C4591001

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

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

**Form Status:** Not Started

**Site No:** 1231

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

**Subject No:** 12313879

**Subject Initials:** ---

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

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

**Informed Consent - Asymptomatic Surveillance**

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

**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:** 1231

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

**Subject No:** 12313879

**Subject Initials:** ---

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

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

**Electronic Sample Tracking**

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

**Aliquot**

Please enter barcode for each aliquot.

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

**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:** 1231

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

**Subject No:** 12313879

**Subject Initials:** ---

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

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

**Electronic Sample Tracking**

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

**Aliquot**

Please enter barcode for each aliquot.

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

090177e196ae2eca\Final\Final On: 01-Apr-2021 03:23 (GMT)

**Header Text:** C4591001

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

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

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

**Site No:** 1231

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

**Subject No:** 12313879

**Subject Initials:** ---

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

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

[eCRF Audit Trail History](#)

**Date of Visit**

1.	Date of Visit	Mar/16/2021
2.	Erroneous Visit	

**Header Text:** C4591001

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

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

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

**Site No:** 1231

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

**Subject No:** 12313879

**Subject Initials:** ---

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

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

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**Further Vaccination Confirmation**

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

090177e196ae2eca\Final\Final On: 01-Apr-2021 03:23 (GMT)

**Header Text:** C4591001

**Visit:** V101\_VAX3

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

**Site No:** 1231

**Subject No:** 12313879

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

**Form:** DATE OF VISIT

**Form Status:** Not Started

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

**Subject Initials:** ---

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

**Date of Visit**

1.	Date of Visit	//
2.	Erroneous Visit	



**Header Text:** C4591001

**Visit:** V101\_VAX3

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

**Site No:** 1231

**Subject No:** 12313879

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

**Form:** INFORMED CONSENT - FURTHER VACCINATION

**Form Status:** Not Started

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

**Subject Initials:** ---

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

**Informed Consent - Further Vaccination**

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

**Header Text:** C4591001

**Visit:** V101\_VAX3

**Form Version:** 28-Mar-2021 02:25

**Site No:** 1231

**Subject No:** 12313879

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

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

**Form Status:** Not Started

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

**Subject Initials:** ---

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

**Inclusion Criteria Not Met**

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

**Exclusion Criteria Met**

2.	Description of Exclusion Criterion Met	
----	---	--

**Header Text:** C4591001

**Visit:** V101\_VAX3

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

**Site No:** 1231

**Subject No:** 12313879

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

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

**Form Status:** Not Started

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

**Subject Initials:** ---

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

**Disposition - Screening for Further Vaccination**

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

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Header Text: C4591001

Visit: Logs

Form: ADVERSE EVENT REPORT

Form Version: 22-Apr-2020 21:02

Site No: 1231

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

Subject No: 12313879

Subject Initials: ---

Generated By: (b) (4)

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

#	Category	AE Identifier	Adverse Event	Start Date	Is the Adverse Event Still Ongoing	Form Instance
1.	ADVERSE EVENT	1	headache	Sep/14/2020 10:00	NO End Date Time: Sep/22/2020 17:00	<a href="#">Repeating Pages</a>
2. DELETED	ADVERSE EVENT	2	dry cough	Aug/27/2020 08:00	NO End Date Time: Sep/22/2020 17:00	<a href="#">Repeating Pages</a>
3.	ADVERSE EVENT	3	Exposure to Investigation product during pregnancy	Sep/12/2020 13:38	YES	<a href="#">Repeating Pages</a>
4.	ADVERSE EVENT	4	Injection site pain	Aug/25/2020 12:30	NO End Date Time: Aug/25/2020 14:00	<a href="#">Repeating Pages</a>
5.	ADVERSE EVENT	5	Suspected Complicated Urinary Tract Infection	Jan/31/2021 09:30	NO End Date Time: Feb/17/2021 21:00	<a href="#">Repeating Pages</a>

090177e196ae2eca\Final\Final On: 01-Apr-2021 03:23 (GMT)

**Header Text:** C4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1231

**Subject No:** 12313879

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

**Form:** ADVERSE EVENT REPORT

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

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

**Subject Initials:** ---

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

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**Adverse Event Report**

1.	Category:	ADVERSE EVENT
2.	AE ID:	[1]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[headache]
4.	Start Date Time:	Sep/14/2020 10:00
5.	Is the adverse event still ongoing?	NO End Date Time: Sep/22/2020 17:00
6.	Toxicity Grade:	3
7.	Is the adverse event serious?  If Yes, NOTIFY PFIZER IMMEDIATELY.  Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).	NO
8.	Is this adverse event the result of a study Medication Error? If Yes, record the type of medication error on the Medication Error Log.	NO
9.	Is this event related to study treatment:	NOT RELATED If Not Related to study treatment(s), this event is due to: OTHER If Other, specify: [Unknown]
10.	Latest Action Taken with Study Treatment:	NOT APPLICABLE
11.	Was a Concomitant Medication given?	YES
12.	Was a Non-Drug Treatment given?	NO

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**Header Text:** C4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1231

**Subject No:** 12313879

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

**Form:** ADVERSE EVENT REPORT

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

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

**Subject Initials:** ---

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

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	[ ]

Header Text: C4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1231

Subject No: 12313879

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Deleted, Frozen, Verified

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

Subject Initials: ---

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

\*\*\* THIS REPEATING FORM HAS BEEN DELETED \*\*\*

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**Adverse Event Report**

1.	Category:	ADVERSE EVENT
2.	AE ID:	[2]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[dry cough]
4.	Start Date Time:	Aug/27/2020 08:00
5.	Is the adverse event still ongoing?	NO End Date Time: Sep/22/2020 17:00
6.	Toxicity Grade:	+
7.	Is the adverse event serious?  If Yes, NOTIFY PFIZER IMMEDIATELY.  Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).	NO
8.	Is this adverse event the result of a study Medication Error? If Yes, record the type of medication error on the Medication Error Log.	NO
9.	Is this event related to study treatment:	NOT RELATED If Not Related to study treatment(s), this event is due to: OTHER If Other, specify: [UNKNOWN]
10.	Latest Action Taken with Study Treatment:	NOT APPLICABLE
11.	Was a Concomitant Medication given?	NO

090177e196ae2eca\Final\Final On: 01-Apr-2021 03:23 (GMT)

**Header Text:** C4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1231

**Subject No:** 12313879

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

**Form:** ADVERSE EVENT REPORT

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

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

**Subject Initials:** ---

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

**\*\*\* THIS REPEATING FORM HAS BEEN DELETED \*\*\***

12.	Was a Non-Drug Treatment given?	<del>NO</del>
13.	What was the outcome of this adverse event?:	<del>RECOVERED/RESOLVED</del>
14.	Did the adverse event cause the subject to be discontinued from the study?	<del>NO</del>
15.	Serious Adverse Event Number: For Pfizer Use Only	[ ]

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**Header Text:** C4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1231

**Subject No:** 12313879

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

**Form:** ADVERSE EVENT REPORT

**Form Status:** Data Complete, Not Complete

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

**Subject Initials:** ---

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

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**Adverse Event Report**

1.	Category:	ADVERSE EVENT	
2.	AE ID:	[3]	
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[Exposure to Investigation product during pregnancy]	
4.	Start Date Time:	Sep/12/2020 13:38	
5.	Is the adverse event still ongoing?	YES	
6.	Toxicity Grade:	Not Applicable	<a href="#">Comments</a>
7.	Is the adverse event serious?  If Yes, NOTIFY PFIZER IMMEDIATELY.  Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).	NO	
8.	Is this adverse event the result of a study Medication Error? If Yes, record the type of medication error on the Medication Error Log.	NO	
9.	Is this event related to study treatment:	NOT RELATED If Not Related to study treatment(s), this event is due to: OTHER If Other, specify: [unplanned pregnancy]	
10.	Latest Action Taken with Study Treatment:	NOT APPLICABLE	
11.	Was a Concomitant Medication given?	NO	
12.	Was a Non-Drug Treatment given?	NO	

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**Header Text:** C4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1231

**Subject No:** 12313879

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

**Form:** ADVERSE EVENT REPORT

**Form Status:** Data Complete, Not Complete

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

**Subject Initials:** ---

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

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

**Header Text:** C4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1231

**Subject No:** 12313879

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

**Form:** ADVERSE EVENT REPORT

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

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

**Subject Initials:** ---

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

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**Adverse Event Report**

1.	Category:	ADVERSE EVENT
2.	AE ID:	[4]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[Injection site pain]
4.	Start Date Time:	Aug/25/2020 12:30
5.	Is the adverse event still ongoing?	NO End Date Time: Aug/25/2020 14:00
6.	Toxicity Grade:	1
7.	Is the adverse event serious?  If Yes, NOTIFY PFIZER IMMEDIATELY.  Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).	NO
8.	Is this adverse event the result of a study Medication Error? If Yes, record the type of medication error on the Medication Error Log.	NO
9.	Is this event related to study treatment:	RELATED
10.	Latest Action Taken with Study Treatment:	NOT APPLICABLE
11.	Was a Concomitant Medication given?	NO
12.	Was a Non-Drug Treatment given?	NO
13.	What was the outcome of this adverse event?:	RECOVERED/RESOLVED

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**Header Text:** C4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1231

**Subject No:** 12313879

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

**Form:** ADVERSE EVENT REPORT

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

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

**Subject Initials:** ---

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

14.	Did the adverse event cause the subject to be discontinued from the study?	NO
15.	Serious Adverse Event Number: For Pfizer Use Only	[ ]

**Header Text:** C4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1231

**Subject No:** 12313879

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

**Form:** ADVERSE EVENT REPORT

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

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

**Subject Initials:** ---

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

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**Adverse Event Report**

1.	Category:	ADVERSE EVENT
2.	AE ID:	[5]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[Supected Complicated Urinary Tract Infection]
4.	Start Date Time:	Jan/31/2021 09:30
5.	Is the adverse event still ongoing?	NO End Date Time: Feb/17/2021 21:00
6.	Toxicity Grade:	3
7.	Is the adverse event serious?  If Yes, NOTIFY PFIZER IMMEDIATELY.  Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).	YES  Is this serious event associated with congenital anomaly or birth defect? NO  Did this serious event result in death? NO  Did this serious event require or prolong hospitalization? NO  Did this serious event result in persistent or significant disability/incapacity? NO  Is this serious event life threatening? NO  Other medically important serious event YES
8.	Is this adverse event the result of a study Medication Error? If Yes, record the type of medication error on the Medication Error Log.	NO
9.	Is this event related to study treatment:	NOT RELATED If Not Related to study treatment(s), this event is due to: OTHER If Other, specify: [unknown]

090177e196ae2eca\Final\Final On: 01-Apr-2021 03:23 (GMT)

**Header Text:** C4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1231

**Subject No:** 12313879

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

**Form:** ADVERSE EVENT REPORT

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

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

**Subject Initials:** ---

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

10.	Latest Action Taken with Study Treatment:	NOT APPLICABLE
11.	Was a Concomitant Medication given?	YES
12.	Was a Non-Drug Treatment given?	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	[2021139760]

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**Header Text:** C4591001

**Visit:** Logs

**Form:** MEDICATION ERROR

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

**Site No:** 1231

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

**Subject No:** 12313879

**Subject Initials:** ---

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

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

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

**Header Text:** C4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1231

**Subject No:** 12313879

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

**Form:** MEDICATION ERROR

**Form Status:** Not Started

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

**Subject Initials:** ---

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

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**Medication Error**

1.	Category:	
2.	Medication Error (Type of Medication Error):	[ ]
3.	Start Date:	//
4.	Is the medication error still ongoing?	
5.	Latest Action Taken with Study Treatment:	
6.	Was a Concomitant Medication given?	
7.	Was a Non-Drug Treatment given?	
8.	Did the Medication Error cause the subject to be discontinued from the study?	
9.	Was this medication error associated with any adverse events?	
10.	Serious Adverse Event Number: For Pfizer Use Only	[ ]

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**Header Text:** C4591001

**Visit:** Logs

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

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

**Site No:** 1231

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

**Subject No:** 12313879

**Subject Initials:** ---

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

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

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

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**Header Text:** C4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1231

**Subject No:** 12313879

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

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

**Form Status:** Not Started

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

**Subject Initials:** ---

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

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**Concomitant Medications**

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

090177e196ae2eca\Final\Final On: 01-Apr-2021 03:23 (GMT)

**Header Text:** C4591001

**Visit:** Logs

**Form:** CONCOMITANT MEDICATIONS - PROHIBITED

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

**Site No:** 1231

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

**Subject No:** 12313879

**Subject Initials:** ---

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

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

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

**Header Text:** C4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1231

**Subject No:** 12313879

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

**Form:** CONCOMITANT MEDICATIONS - PROHIBITED

**Form Status:** Not Started

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

**Subject Initials:** ---

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

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**Concomitant Medications**

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

090177e196ae2eca\Final\Final On: 01-Apr-2021 03:23 (GMT)

**Header Text:** C4591001

**Visit:** Logs

**Form:** RADIATION TREATMENT

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

**Site No:** 1231

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

**Subject No:** 12313879

**Subject Initials:** ---

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

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

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

**Header Text:** C4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1231

**Subject No:** 12313879

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

**Form:** RADIATION TREATMENT

**Form Status:** Not Started

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

**Subject Initials:** ---

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

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**Radiation Treatment**

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

**Header Text:** C4591001

**Visit:** Logs

**Form:** TRANSFUSIONS

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

**Site No:** 1231

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

**Subject No:** 12313879

**Subject Initials:** ---

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

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

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

090177e196ae2eca\Final\Final On: 01-Apr-2021 03:23 (GMT)

**Header Text:** C4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1231

**Subject No:** 12313879

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

**Form:** TRANSFUSIONS

**Form Status:** Not Started

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

**Subject Initials:** ---

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

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



**Header Text:** C4591001

**Visit:** UNPLANNED\_BOOSTER\_CONTACT -  
Unscheduled

**Form:** DATE OF VISIT

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

**Form Status:** Not Started

**Site No:** 1231

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

**Subject No:** 12313879

**Subject Initials:** ---

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

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

**Date of Visit**

1.	Date of Visit	//
2.	Erroneous Visit	

**Header Text:** C4591001

**Visit:** UNPLANNED\_BOOSTER\_CONTACT -  
Unscheduled

**Form:** BOOSTER DOSE TRIGGER FORM

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

**Form Status:** Not Started

**Site No:** 1231

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

**Subject No:** 12313879

**Subject Initials:** ---

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

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

**Booster Dose Trigger Form**

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

**Header Text:** C4591001

**Visit:** Disposition - Unscheduled

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

**Site No:** 1231

**Subject No:** 12313879

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

**Form:** TREATMENT UNBLINDED

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

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

**Subject Initials:** ---

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

[eCRF Audit Trail History](#)

**Treatment Unblinded**

1.	Date Treatment Unblinded :	Mar/16/2021
2.	Primary Reason for Unblinding:	ASSESS ELIGIBILITY FOR ADDITIONAL VACCINATION

**Header Text:** C4591001

**Visit:** Disposition - Unscheduled

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

**Site No:** 1231

**Subject No:** 12313879

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

**Form:** WITHDRAWAL OF CONSENT

**Form Status:** Not Started

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

**Subject Initials:** ---

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

**Withdrawal Of Consent**

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

**Header Text:** C4591001

**Visit:** Disposition - Unscheduled

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

**Site No:** 1231

**Subject No:** 12313879

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

**Form:** DEATH DETAILS CODED

**Form Status:** Not Started

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

**Subject Initials:** ---

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

**Death Details**

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

**Cause of Death**

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

**Header Text:** C4591001

**Visit:** Subject Status - Unscheduled

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

**Site No:** 1231

**Subject No:** 12313879

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

**Form:** SUBJECT STATUS

**Form Status:** Data Complete, Verified

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

**Subject Initials:** ---

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

[eCRF Audit Trail History](#)

**Subject Status**

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

**Header Text:** C4591001

**Visit:** Investigator Signature - Unscheduled

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

**Site No:** 1231

**Subject No:** 12313879

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

**Form:** CASEBOOK SIGNATURE FORM

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

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

**Subject Initials:** ---

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

[eCRF Audit Trail History](#)

**Casebook Signature Form**

1.	Casebook Signature	Click Here to Enable
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090177e196ae2eca\Final\Final On: 01-Apr-2021 03:23 (GMT)

**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:** 1231

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

**Subject No:** 12313879

**Subject Initials:** ---

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

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

[Audit Trail](#)

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

- CRF\_Sign

Name	Signature Meaning	Date	Type	Action
Fernando Polack	Approved	Mar-18-2021 11:00:07 (UTC-03:00) City of Buenos Aires	BOOK	Signed

**Affidavit:**

By my dated signature below, I, FernandoPolack, 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.

090177e196ae2eca\Final\Final On: 01-Apr-2021 03:23 (GMT)



**Header Text:** C4591001

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

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

**Site No:** 1231

**Subject No:** 12313879

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

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

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

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

**Subject Initials:** ---

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

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Item	Date	User	Comment
Form	Aug-25-2020 13:51:33 (UTC-03:00) City of Buenos Aires	(b) (4), (b) (6)	Not Applicable

090177e196ae2eca\Final\Final On: 01-Apr-2021 03:23 (GMT)

**Header Text:** C4591001

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

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

**Site No:** 1231

**Subject No:** 12313879

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

**Form:** GENERAL MEDICAL HISTORY - Comments

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

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

**Subject Initials:** ---

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

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Item	Date	User	Comment
Form	Aug-25-2020 13:52:02 (UTC-03:00) City of Buenos Aires	(b) (4), (b) (6)	Not Applicable

**Header Text:** C4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1231

**Subject No:** 12313879

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

**Form:** ADVERSE EVENT REPORT - Comments

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

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

**Subject Initials:** ---

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

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Item	Date	User	Comment
6	Nov-15-2020 10:46:36 (UTC-03:00) City of Buenos Aires	(b) (4), (b) (6)	Not Applicable
6	Nov-15-2020 10:44:30 (UTC-03:00) City of Buenos Aires	(b) (4), (b) (6)	NOT APPLICABLE

090177e196ae2eca\Final\Final On: 01-Apr-2021 03:23 (GMT)

**Header Text:** C4591001

**Visit:** Investigator Signature - Unscheduled

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

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

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

**Site No:** 1231

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

**Subject No:** 12313879

**Subject Initials:** ---

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

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

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

- CRF\_Sign

Name	Signature Meaning	Date	Type	Action
Fernando Polack	Approved	Mar-18-2021 11:00:07 (UTC-03:00) City of Buenos Aires	BOOK	Signed

**Affidavit:**

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

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

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

(b) (6)	N/A	Mar-16-2021 12:07:29 (UTC-03:00) City of Buenos Aires		Edit - All signatures invalidated
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**Affidavit:**

N/A

Tatiana Estrada	Approved	Mar-09-2021 17:50:24 (UTC-03:00) City of Buenos Aires	BOOK	Signed
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**Affidavit:**

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

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

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

(b) (6)	N/A	Feb-23-2021 12:17:36 (UTC-03:00) City of Buenos Aires		Edit - All signatures invalidated
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**Affidavit:**

N/A

(b) (6)	Approved	Feb-22-2021 19:06:21 (UTC-03:00) City of Buenos Aires	BOOK	Signed
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090177e196ae2eca\Final\Final On: 01-Apr-2021 03:23 (GMT)

**Header Text:** C4591001

**Visit:** Investigator Signature - Unscheduled

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

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

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

**Site No:** 1231

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

**Subject No:** 12313879

**Subject Initials:** ---

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

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

**Affidavit:**

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

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

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

(b) (6)	N/A	Jan-08-2021 12:19:11 (UTC-03:00) City of Buenos Aires		Edit - All signatures invalidated
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**Affidavit:**

N/A

(b) (6)	Approved	Nov-15-2020 18:20:59 (UTC-03:00) City of Buenos Aires	BOOK	Signed
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**Affidavit:**

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

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

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

(b) (6)	N/A	Nov-15-2020 10:44:30 (UTC-03:00) City of Buenos Aires		Edit - All signatures invalidated
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**Affidavit:**

N/A

(b) (6)	Approved	Nov-10-2020 18:05:45 (UTC-03:00) City of Buenos Aires	BOOK	Signed
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**Affidavit:**

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

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

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

090177e196ae2eca\Final\Final On: 01-Apr-2021 03:23 (GMT)

**Header Text:** C4591001

**Visit:** Investigator Signature - Unscheduled

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

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

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

**Site No:** 1231

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

**Subject No:** 12313879

**Subject Initials:** ---

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

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

(b) (6)	N/A	Nov-10-2020 09:05:24 (UTC-03:00) City of Buenos Aires		Edit - All signatures invalidated
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**Affidavit:**

N/A

Fernando Polack	Approved	Nov-08-2020 21:38:47 (UTC-03:00) City of Buenos Aires	BOOK	Signed
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**Affidavit:**

By my dated signature below, I, FernandoPolack, 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-03-2020 15:40:28 (UTC-03:00) City of Buenos Aires		Edit - All signatures invalidated
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**Affidavit:**

N/A

(b) (6)	Approved	Oct-30-2020 15:52:34 (UTC-03:00) City of Buenos Aires	BOOK	Signed
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**Affidavit:**

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

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

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

(b) (6)	N/A	Oct-29-2020 13:24:23 (UTC-03:00) City of Buenos Aires		Edit - All signatures invalidated
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**Affidavit:**

N/A

(b) (6)	Approved	Oct-23-2020 14:40:29 (UTC-03:00) City of Buenos Aires	BOOK	Signed
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090177e196ae2eca\Final\Final On: 01-Apr-2021 03:23 (GMT)

**Header Text:** C4591001

**Visit:** Investigator Signature - Unscheduled

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

**Site No:** 1231

**Subject No:** 12313879

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

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

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

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

**Subject Initials:** ---

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

**Affidavit:**

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

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

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

**Header Text:** C4591001

**Visit:** COHORT\_SELECTION

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

**Site No:** 1231

**Subject No:** 12313879

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

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

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

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

**Subject Initials:** ---

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

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*1. Select appropriate response - Protocol version*

Date	Location	User	Value	Reason
Aug-25-2020 13:50:42 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 24 JUL 2020	Initial Entry

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

Date	Location	User	Value	Reason
Aug-25-2020 13:50:42 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> STAGE 3 COHORTS	Initial Entry



**Header Text:** C4591001

**Visit:** COHORT\_SELECTION

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

**Site No:** 1231

**Subject No:** 12313879

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

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

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

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

**Subject Initials:** ---

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

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**I. Consent Was:**

Date	Location	User	Value	Reason
Aug-25-2020 13:50:50 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> OBTAINED Date Written Consent Obtained  Aug/25/2020	Initial Entry

090177e196ae2eca\Final\Final On: 01-Apr-2021 03:23 (GMT)

Header Text: C4591001

Visit: COHORT\_SELECTION

Form Version: 06-Jul-2020 21:55

Site No: 1231

Subject No: 12313879

Generated By: (b) (4)

Form: DEMOGRAPHY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

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**1. Subject ID**

Date	Location	User	Value	Reason
Aug-25-2020 12:14:28 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> 12313879	Item copied from previous form

**2. Birth Date:**

Date	Location	User	Value	Reason
Aug-25-2020 12:14:25 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> (b) (6) /1993	Enrollment Entry

**3. Sex:**

Date	Location	User	Value	Reason
Aug-25-2020 13:51:08 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> FEMALE	Initial Entry

**4. Ethnicity:**

Date	Location	User	Value	Reason
Aug-25-2020 13:51:08 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> HISPANIC OR LATINO(A) OR OF SPANISH ORIGIN	Initial Entry

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

Date	Location	User	Value	Reason
Aug-25-2020 13:51:08 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> AMERICAN INDIAN OR ALASKA NATIVE	Initial Entry

090177e196ae2eca\Final\Final On: 01-Apr-2021 03:23 (GMT)

**Header Text:** C4591001

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

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

**Site No:** 1231

**Subject No:** 12313879

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

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

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

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

**Subject Initials:** ---

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

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*1. Date of Visit*

Date	Location	User	Value	Reason
Aug-25-2020 13:51:19 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Aug/25/2020	Initial Entry

**Header Text:** C4591001

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

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

**Site No:** 1231

**Subject No:** 12313879

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

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

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

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

**Subject Initials:** ---

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

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

Date	Location	User	Value	Reason
Aug-25-2020 13:51:51 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Aug/25/2020	Initial Entry

**2. Phase of Disposition:**

Date	Location	User	Value	Reason
Aug-25-2020 13:51:51 (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
Aug-25-2020 13:51:51 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> COMPLETED	Initial Entry

090177e196ae2eca\Final\Final On: 01-Apr-2021 03:23 (GMT)

Header Text: C4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 21-Aug-2020 02:51

Site No: 1231

Subject No: 12313879

Generated By: (b) (4)

Form: VITAL SIGNS - BASELINE - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

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**1. Date:**

Date	Location	User	Value	Reason
Aug-25-2020 13:52:26 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Aug/25/2020	Initial Entry

**2. Weight:**

Date	Location	User	Value	Reason
Aug-25-2020 13:52:26 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> 70.0	Initial Entry

**3. Unit:**

Date	Location	User	Value	Reason
Aug-25-2020 13:52:26 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> kg	Initial Entry

**4. Height:**

Date	Location	User	Value	Reason
Aug-25-2020 13:52:26 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> 162.0	Initial Entry

**5. Unit:**

Date	Location	User	Value	Reason
Aug-25-2020 13:52:26 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> cm	Initial Entry

**6. Body Mass Index:**

Date	Location	User	Value	Reason
Aug-25-2020 13:52:26 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> 26.7	Initial Entry

**7.a**

090177e196ae2eca\Final\Final On: 01-Apr-2021 03:23 (GMT)

Header Text: C4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 21-Aug-2020 02:51

Site No: 1231

Subject No: 12313879

Generated By: (b) (4)

Form: VITAL SIGNS - BASELINE - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

Date	Location	User	Value	Reason
Aug-25-2020 13:52:26 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Record Identifier::</b> 1 <b>Temperature:</b> 36.6 <b>Temperature Unit:</b> C <b>Temperature Location:</b> ORAL CAVITY <b>n::</b> Y	Initial Entry

7.a Record Identifier:

Date	Location	User	Value	Reason
Aug-25-2020 13:52:26 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 1	Initial Entry

7.a Temperature:

Date	Location	User	Value	Reason
Aug-25-2020 13:52:26 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 36.6	Initial Entry

7.a Unit:

Date	Location	User	Value	Reason
Aug-25-2020 13:52:26 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> C	Initial Entry

7.a Temperature Location:

Date	Location	User	Value	Reason
Aug-25-2020 13:52:26 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> ORAL CAVITY	Initial Entry

090177e196ae2eca\Final\On: 01-Apr-2021 03:23 (GMT)

Header Text: C4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 21-Aug-2020 02:49

Site No: 1231

Subject No: 12313879

Generated By: (b) (4)

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

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

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**1. Lab Panel:**

Date	Location	User	Value	Reason
Aug-25-2020 13:52:35 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> URINALYSIS	Initial Entry

**2. Lab Sub-Panel:**

Date	Location	User	Value	Reason
Aug-25-2020 13:52:35 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> PREGNANCY	Initial Entry

**3. Collection Date:**

Date	Location	User	Value	Reason
Aug-25-2020 13:52:35 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Aug/25/2020	Initial Entry

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

Date	Location	User	Value	Reason
Aug-25-2020 13:52:35 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> STUDY SITE	Initial Entry

**5. Specimen Type:**

Date	Location	User	Value	Reason
Aug-25-2020 13:52:35 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> URINE	Initial Entry

**6.a**

Date	Location	User	Value	Reason
Aug-25-2020 13:52:35 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> Sponsor-Defined 113 <b>Identifier:</b> <b>Test::</b> Choriogonadotropin Beta_PX113	Initial Entry

090177e196ae2eca\Final\Final On: 01-Apr-2021 03:23 (GMT)

**Header Text:** C4591001

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

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

**Site No:** 1231

**Subject No:** 12313879

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

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

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

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

**Subject Initials:** ---

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

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

**6.a Sponsor ID:**

Date	Location	User	Value	Reason
Aug-25-2020 13:52:35 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 113	Initial Entry

**6.a Test:**

Date	Location	User	Value	Reason
Aug-25-2020 13:52:35 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Choriogonadotropin Beta_PX113	Initial Entry

**6.a Result:**

Date	Location	User	Value	Reason
Aug-25-2020 13:52:35 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NEGATIVE	Initial Entry

090177e196ae2eca\Final\Final On: 01-Apr-2021 03:23 (GMT)



**Header Text:** C4591001

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

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

**Site No:** 1231

**Subject No:** 12313879

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

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

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

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

**Subject Initials:** ---

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

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**1. Randomization Date :**

Date	Location	User	Value	Reason
Aug-25-2020 13:52:43 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Aug/25/2020	Initial Entry

**2. Randomization Number:**

Date	Location	User	Value	Reason
Aug-25-2020 13:52:43 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 65638	Initial Entry

090177e196ae2eca\Final\Final On: 01-Apr-2021 03:23 (GMT)

Header Text: C4591001

Visit: V1\_DAY1\_VAX1\_L

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1231

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

Subject No: 12313879

Subject Initials: ---

Generated By: (b) (4)

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

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**1. Data Origin**

Date	Location	User	Value	Reason
Aug-25-2020 13:52:50 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> SITE	Initial Entry

**2. Sample Type**

Date	Location	User	Value	Reason
Aug-25-2020 13:52:50 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> SERUM	Initial Entry

**3. Sample Collected?**

Date	Location	User	Value	Reason
Aug-26-2020 08:59:06 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Aug-25-2020 16:22:20 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Aug-25-2020 13:52:50 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Aug-25-2020 13:52:50 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> YES Date of Collection:  Aug/25/2020	Initial Entry

**5.a**

Date	Location	User	Value	Reason
Aug-26-2020 08:59:06 (UTC-03:00) City of	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Sample ID: BP24Y4	Initial Entry

090177e196ae2eca\Final\Final On: 01-Apr-2021 03:23 (GMT)

Header Text: C4591001

Visit: V1\_DAY1\_VAX1\_L

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1231

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

Argerich

Subject No: 12313879

Subject Initials: ---

Generated By: (b) (4)

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

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

Date	Location	User	Value	Reason
Aug-26-2020 08:59:06 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> BP24Y4	Initial Entry

5.b

Date	Location	User	Value	Reason
Aug-26-2020 08:59:15 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Sample ID: BP24Y5	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Aug-26-2020 08:59:15 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> BP24Y5	Initial Entry

5.c

Date	Location	User	Value	Reason
Aug-26-2020 08:59:21 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Sample ID: BP24Y6	Initial Entry

5.c Sample ID

Date	Location	User	Value	Reason
Aug-26-2020 08:59:21 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> BP24Y6	Initial Entry

5.d

Date	Location	User	Value	Reason
Aug-26-2020 11:23:07 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	Romina Barrera (b) (4)	<u>Data Entry:</u> Sample ID: BLDZF3	Initial Entry

090177e196ae2eca\Final\Final On: 01-Apr-2021 03:23 (GMT)

Header Text: C4591001

Visit: V1\_DAY1\_VAX1\_L

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1231

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

Subject No: 12313879

Subject Initials: ---

Generated By: (b) (4)

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

5.d Sample ID

Date	Location	User	Value	Reason
Aug-26-2020 11:23:07 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	Romina Barrera (b) (4)	<u>Data Entry:</u> BLDZF3	Initial Entry

5.e

Date	Location	User	Value	Reason
Aug-26-2020 11:23:15 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	Romina Barrera (b) (4)	<u>Data Entry:</u> Sample ID: BLDZF4	Initial Entry

5.e Sample ID

Date	Location	User	Value	Reason
Aug-26-2020 11:23:15 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	Romina Barrera (b) (4)	<u>Data Entry:</u> BLDZF4	Initial Entry

5.f

Date	Location	User	Value	Reason
Aug-26-2020 11:23:24 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	Romina Barrera (b) (4)	<u>Data Entry:</u> Sample ID: BLDZF5	Initial Entry

5.f Sample ID

Date	Location	User	Value	Reason
Aug-26-2020 11:23:24 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	Romina Barrera (b) (4)	<u>Data Entry:</u> BLDZF5	Initial Entry

090177e196ae2eca\Final\Final On: 01-Apr-2021 03:23 (GMT)

Header Text: C4591001

Visit: V1\_DAY1\_VAX1\_L

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1231

Site Name: (1231) Hospital Militar Central Cirujano Mayor Dr. Cosme Argerich

Subject No: 12313879

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 20:34

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**1. Data Origin**

Date	Location	User	Value	Reason
Aug-25-2020 13:52:57 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SITE	Initial Entry

**2. Sample Type**

Date	Location	User	Value	Reason
Aug-25-2020 13:52:57 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> NASAL_SWAB	Initial Entry

**3. Sample Collected?**

Date	Location	User	Value	Reason
Aug-26-2020 18:59:41 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Aug-25-2020 16:22:20 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Aug-25-2020 13:52:57 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Aug-25-2020 13:52:57 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES Date of Collection: Aug/25/2020	Initial Entry

**5.a**

Date	Location	User	Value	Reason
Aug-26-2020 18:59:41 (UTC-03:00) City of	ACV0PFEINFP6000	Alan Colombo (b) (4)	<b>Data Entry:</b> Sample ID: BP24V2	Initial Entry

090177e196ae2eca\Final\Final On: 01-Apr-2021 03:23 (GMT)

**Header Text:** C4591001

**Visit:** V1\_DAY1\_VAX1\_L

**Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB - eCRF Audit Trail History

**Form Version:** 22-Apr-2020 21:03

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site No:** 1231

**Site Name:** (1231) Hospital Militar Central Cirujano Mayor Dr. Cosme Argerich

**Subject No:** 12313879

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 20:34

Buenos Aires

**5.a Sample ID**

Date	Location	User	Value	Reason
Aug-26-2020 18:59:41 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	Alan Colombo (b) (4)	<b>Data Entry:</b> BP24V2	Initial Entry

Header Text: C4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 22-Apr-2020 21:04

Site No: 1231

Subject No: 12313879

Generated By: (b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1231) Hospital Militar Central Cirujano Mayor Dr. Cosme Argerich

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 20:34

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**1. Was there a temporary delay of vaccination?**

Date	Location	User	Value	Reason
Aug-25-2020 13:53:13 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NO	Initial Entry

**2. Treatment Name**

Date	Location	User	Value	Reason
Aug-25-2020 13:53:13 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> BLINDED THERAPY	Initial Entry

**3. Formulation:**

Date	Location	User	Value	Reason
Aug-25-2020 13:53:13 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> INJECTION	Initial Entry

**4. Dose Date Time:**

Date	Location	User	Value	Reason
Aug-25-2020 13:53:13 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Aug/25/2020 12:28	Initial Entry

**5. Anatomical Location:**

Date	Location	User	Value	Reason
Aug-25-2020 13:53:13 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> DELTOID MUSCLE	Initial Entry

**6. Body Side:**

Date	Location	User	Value	Reason
Aug-25-2020 13:53:13 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> LEFT	Initial Entry

**7. Route:**

090177e196ae2eca\Final\Final On: 01-Apr-2021 03:23 (GMT)

**Header Text:** C4591001

**Visit:** V1\_DAY1\_VAX1\_L

**Form Version:** 22-Apr-2020 21:04

**Site No:** 1231

**Subject No:** 12313879

**Generated By:** (b) (4)

**Form:** VACCINATION - eCRF Audit Trail History

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site Name:** (1231) Hospital Militar Central Cirujano Mayor Dr. Cosme Argerich

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 20:34

Date	Location	User	Value	Reason
Aug-25-2020 13:53:13 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> INTRAMUSCULAR	Initial Entry

**10. Timeframe Subject Was Observed**

Date	Location	User	Value	Reason
Aug-25-2020 13:53:13 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> THE PROTOCOL SPECIFIED OBSERVATION PERIOD	Initial Entry

**11. Was the subject observed for at least the protocol specified observation period after investigational product administration?**

Date	Location	User	Value	Reason
Aug-25-2020 13:53:13 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

090177e196ae2eca\Final\Final On: 01-Apr-2021 03:23 (GMT)



**Header Text:** C4591001

**Visit:** V1\_DAY1\_VAX1\_L

**Form Version:** 06-Jul-2020 21:53

**Site No:** 1231

**Subject No:** 12313879

**Generated By:** (b) (4)

**Form:** REACTOGENICITY DIARY - eCRF Audit Trail History

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site Name:** (1231) Hospital Militar Central Cirujano Mayor Dr. Cosme Argerich

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 20:34

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*1. Select appropriate response - Reactogenicity diary collection*

Date	Location	User	Value	Reason
Aug-25-2020 13:53:21 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO - REACTOGENICITY E-DIARY NOT COLLECTED FOR THIS SUBJECT	Initial Entry

Header Text: C4591001

Visit: V2\_VAX2\_L

Form Version: 22-Apr-2020 21:02

Site No: 1231

Subject No: 12313879

Generated By: (b) (4)

Form: DATE OF VISIT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1231) Hospital Militar Central Cirujano Mayor Dr. Cosme Argerich

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 20:34

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*I. Date of Visit*

Date	Location	User	Value	Reason
Sep-16-2020 09:12:10 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Closed	V2 DOV updated
Sep-14-2020 15:58:31 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (b) (4)	Query 1: Closed	Auto closed by Validation Check: VC_SV001_02
Sep-14-2020 11:55:05 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Answered	Transcription Error
Sep-14-2020 11:55:05 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Transcription Error
Sep-14-2020 11:55:05 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sep/13/2020	Transcription Error
Sep-14-2020 09:06:30 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Opened	PDQ: Date of visit at this visit is out of window (-2 day) from Date of visit (25/Aug/2020) at VID1VX1L visit. Please reconcile and update accordingly, else confirm date is correct as is.
Sep-14-2020 05:11:29 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (b) (4)	Query 1: Opened	DMW4686900;The Date of Visit at Visit V2_VAX2_L is the same as the other

090177e196ae2eca\Final\Final On: 01-Apr-2021 03:23 (GMT)

**Header Text:** C4591001

**Visit:** V2\_VAX2\_L

**Form Version:** 22-Apr-2020 21:02

**Site No:** 1231

**Subject No:** 12313879

**Generated By:** (b) (4)

**Form:** DATE OF VISIT - eCRF Audit Trail History

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site Name:** (1231) Hospital Militar Central Cirujano Mayor Dr. Cosme Argerich

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 20:34

Aires				Date of Visit at Visit COVID_A. Please review for duplication and update as appropriate.
Sep-11-2020 19:20:35 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sep/11/2020	Initial Entry

Header Text: C4591001

Visit: V2\_VAX2\_L

Form Version: 21-Aug-2020 02:51

Site No: 1231

Subject No: 12313879

Generated By: (b) (4)

Form: VITAL SIGNS - TEMP - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1231) Hospital Militar Central Cirujano Mayor Dr. Cosme Argerich

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 20:34

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**1. Date:**

Date	Location	User	Value	Reason
Sep-14-2020 11:55:34 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sep/13/2020	Initial Entry

**2.a**

Date	Location	User	Value	Reason
Sep-14-2020 11:55:34 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Record Identifier::</b> 1 <b>Temperature:</b> 37.1 <b>Temperature Unit:</b> C <b>Temperature Location::</b> ORAL CAVITY	Initial Entry

**2.a Record Identifier:**

Date	Location	User	Value	Reason
Sep-14-2020 11:55:34 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 1	Initial Entry

**2.a Temperature:**

Date	Location	User	Value	Reason
Sep-14-2020 11:55:34 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 37.1	Initial Entry

**2.a Unit:**

Date	Location	User	Value	Reason
Sep-14-2020 11:55:34 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> C	Initial Entry

**2.a Temperature Location:**

Date	Location	User	Value	Reason
Sep-14-2020 11:55:34	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>	Initial Entry

090177e196ae2eca\Final\Final On: 01-Apr-2021 03:23 (GMT)

**Header Text:** C4591001

**Visit:** V2\_VAX2\_L

**Form Version:** 21-Aug-2020 02:51

**Site No:** 1231

**Subject No:** 12313879

**Generated By:** (b) (4)

**Form:** VITAL SIGNS - TEMP - eCRF Audit Trail History

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site Name:** (1231) Hospital Militar Central Cirujano Mayor Dr. Cosme Argerich

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 20:34

(UTC-03:00) City of  
Buenos Aires

(b) (4),  
(b) (6)

ORAL CAVITY

090177e196ae2eca\Final\Final On: 01-Apr-2021 03:23 (GMT)

Header Text: C4591001

Visit: V2\_VAX2\_L

Form Version: 21-Aug-2020 02:49

Site No: 1231

Subject No: 12313879

Generated By: (b) (4)

Form: LAB URINALYSIS - PREGNANCY TEST - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1231) Hospital Militar Central Cirujano Mayor Dr. Cosme Argerich

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 20:34

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**1. Lab Panel:**

Date	Location	User	Value	Reason
Sep-14-2020 11:55:45 (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-14-2020 11:55:45 (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-14-2020 11:55:45 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sep/13/2020	Initial Entry

**4. Laboratory Name and Address (Derived)**

Date	Location	User	Value	Reason
Sep-14-2020 11:55:45 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> STUDY SITE	Initial Entry

**5. Specimen Type:**

Date	Location	User	Value	Reason
Sep-14-2020 11:55:45 (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-14-2020 11:55:45 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Sponsor-Defined 113 Identifier:</b> <b>Test::</b> Choriogonadotropin Beta_PX113	Initial Entry

090177e196ae2eca\Final\Final On: 01-Apr-2021 03:23 (GMT)

**Header Text:** C4591001

**Visit:** V2\_VAX2\_L

**Form Version:** 21-Aug-2020 02:49

**Site No:** 1231

**Subject No:** 12313879

**Generated By:** (b) (4)

**Form:** LAB URINALYSIS - PREGNANCY TEST - eCRF Audit Trail History

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site Name:** (1231) Hospital Militar Central Cirujano Mayor Dr. Cosme Argerich

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 20:34

			<b>Result::</b> NEGATIVE	
			<b>Not Done::</b>	

**6.a Sponsor ID:**

Date	Location	User	Value	Reason
Sep-14-2020 11:55:45 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 113	Initial Entry

**6.a Test:**

Date	Location	User	Value	Reason
Sep-14-2020 11:55:45 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Choriogonadotropin Beta_PX113	Initial Entry

**6.a Result:**

Date	Location	User	Value	Reason
Sep-14-2020 11:55:45 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NEGATIVE	Initial Entry

090177e196ae2eca\Final\Final On: 01-Apr-2021 03:23 (GMT)

Header Text: C4591001

Visit: V2\_VAX2\_L

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1231

Site Name: (1231) Hospital Militar Central Cirujano Mayor Dr. Cosme Argerich

Subject No: 12313879

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 20:34

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**1. Data Origin**

Date	Location	User	Value	Reason
Sep-14-2020 11:55:54 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SITE	Initial Entry

**2. Sample Type**

Date	Location	User	Value	Reason
Sep-14-2020 11:55:54 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> NASAL_SWAB	Initial Entry

**3. Sample Collected?**

Date	Location	User	Value	Reason
Sep-14-2020 12:54:26 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Sep-14-2020 11:55:54 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Sep-14-2020 11:55:54 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES Date of Collection:  Sep/13/2020	Initial Entry

**5.a**

Date	Location	User	Value	Reason
Sep-14-2020 12:54:26 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample ID:</b> BP1YLL	Initial Entry

**5.a Sample ID**

Date	Location	User	Value	Reason
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090177e196ae2eca\Final\Final On: 01-Apr-2021 03:23 (GMT)



**Header Text:** C4591001

**Visit:** V2\_VAX2\_L

**Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB - eCRF Audit Trail History

**Form Version:** 22-Apr-2020 21:03

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site No:** 1231

**Site Name:** (1231) Hospital Militar Central Cirujano Mayor Dr. Cosme Argerich

**Subject No:** 12313879

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 20:34

Sep-14-2020 12:54:26 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> BP1YLL	Initial Entry
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090177e196ae2eca\Final\Final On: 01-Apr-2021 03:23 (GMT)

Header Text: C4591001

Visit: V2\_VAX2\_L

Form Version: 22-Apr-2020 21:04

Site No: 1231

Subject No: 12313879

Generated By: (b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1231) Hospital Militar Central Cirujano Mayor Dr. Cosme Argerich

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 20:34

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**1. Was there a temporary delay of vaccination?**

Date	Location	User	Value	Reason
Sep-14-2020 11:56:12 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NO	Initial Entry

**2. Treatment Name**

Date	Location	User	Value	Reason
Sep-14-2020 11:56:12 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> BLINDED THERAPY	Initial Entry

**3. Formulation:**

Date	Location	User	Value	Reason
Sep-14-2020 11:56:12 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> INJECTION	Initial Entry

**4. Dose Date Time:**

Date	Location	User	Value	Reason
Sep-14-2020 11:56:12 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Sep/13/2020 19:36	Initial Entry

**5. Anatomical Location:**

Date	Location	User	Value	Reason
Sep-14-2020 11:56:12 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> DELTOID MUSCLE	Initial Entry

**6. Body Side:**

Date	Location	User	Value	Reason
Sep-14-2020 11:56:12 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> LEFT	Initial Entry

**7. Route:**

090177e196ae2eca\Final\Final On: 01-Apr-2021 03:23 (GMT)

**Header Text:** C4591001

**Visit:** V2\_VAX2\_L

**Form Version:** 22-Apr-2020 21:04

**Site No:** 1231

**Subject No:** 12313879

**Generated By:** (b) (4)

**Form:** VACCINATION - eCRF Audit Trail History

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site Name:** (1231) Hospital Militar Central Cirujano Mayor Dr. Cosme Argerich

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 20:34

Date	Location	User	Value	Reason
Sep-14-2020 11:56:12 (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-14-2020 11:56:12 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> THE PROTOCOL SPECIFIED OBSERVATION PERIOD	Initial Entry

**11. Was the subject observed for at least the protocol specified observation period after investigational product administration?**

Date	Location	User	Value	Reason
Sep-14-2020 11:56:12 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

090177e196ae2eca\Final\Final On: 01-Apr-2021 03:23 (GMT)

Header Text: C4591001

Visit: V3\_MONTH1\_POSTVAX2\_L

Form Version: 22-Apr-2020 21:02

Site No: 1231

Subject No: 12313879

Generated By: (b) (4)

Form: DATE OF VISIT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1231) Hospital Militar Central Cirujano Mayor Dr. Cosme Argerich

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 20:34

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*I. Date of Visit*

Date	Location	User	Value	Reason
Oct-16-2020 06:44:56 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Clo sed	Response satisfies query
Oct-15-2020 13:25:09 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Ans wered	Original value is correct
Oct-15-2020 05:38:11 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (b) (4)	Query 1: Ope ned	DMW4978908;The Date of Visit at Visit V3_MONTH1_POSTVAX2_L is the same as the other Date of Visit at Visit COVID_A1. Please review for duplication and update as appropriate.
Oct-14-2020 16:52:53 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry</b> : Oct/13 /2020	Initial Entry

090177e196ae2eca\Final\Final On: 01-Apr-2021 03:23 (GMT)

Header Text: C4591001

Visit: V3\_MONTH1\_POSTVAX2\_L

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - eCRF  
Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1231

Site Name: (1231) Hospital Militar Central Cirujano Mayor Dr. Cosme Argerich

Subject No: 12313879

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 20:34

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**1. Data Origin**

Date	Location	User	Value	Reason
Oct-14-2020 16:55:11 (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-14-2020 16:55:11 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SERUM	Initial Entry

**3. Sample Collected?**

Date	Location	User	Value	Reason
Oct-14-2020 16:55:11 (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
Oct-14-2020 16:55:11 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Peripheral blood sampling was not performed for immunogenicity study. Sample is taken during the convalescent visit.	Initial Entry

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**Header Text:** C4591001

**Visit:** V4\_MONTH6\_L

**Form Version:** 22-Apr-2020 21:02

**Site No:** 1231

**Subject No:** 12313879

**Generated By:** (b) (4)

**Form:** DATE OF VISIT - eCRF Audit Trail History

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site Name:** (1231) Hospital Militar Central Cirujano Mayor Dr. Cosme Argerich

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 20:34

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*1. Date of Visit*

Date	Location	User	Value	Reason
Mar-16-2021 13:26:39 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Mar/16/2021	Initial Entry

Header Text: C4591001

Visit: V4\_MONTH6\_L

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - eCRF  
Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1231

Site Name: (1231) Hospital Militar Central Cirujano Mayor Dr. Cosme Argerich

Subject No: 12313879

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 20:34

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**1. Data Origin**

Date	Location	User	Value	Reason
Mar-16-2021 13:26:51 (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
Mar-16-2021 13:26:51 (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
Mar-16-2021 15:16:08 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Mar-16-2021 13:26:51 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Mar-16-2021 13:26:51 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES Date of Collection: Mar/16/2021	Initial Entry

**5.a**

Date	Location	User	Value	Reason
Mar-16-2021 15:16:08 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	Alan Colombo (b) (4)	<b>Data Entry:</b> <b>Sample ID: BRM9YR</b>	Initial Entry

**5.a Sample ID**

Date	Location	User	Value	Reason
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090177e196ae2eca\Final\Final On: 01-Apr-2021 03:23 (GMT)

Header Text: C4591001

Visit: V4\_MONTH6\_L

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - eCRF  
Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1231

Site Name: (1231) Hospital Militar Central Cirujano Mayor Dr. Cosme Argerich

Subject No: 12313879

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 20:34

Mar-16-2021 15:16:08 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	Alan Colombo (b) (4)	<b>Data Entry:</b> BRM9YR	Initial Entry
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5.b

Date	Location	User	Value	Reason
Mar-16-2021 15:28:30 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample ID:</b> BRZ2S8	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Mar-16-2021 15:28:30 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BRZ2S8	Initial Entry

5.c

Date	Location	User	Value	Reason
Mar-16-2021 15:58:21 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	Alan Colombo (b) (4)	<b>Data Entry:</b> <b>Sample ID:</b> BRZ2NP	Initial Entry

5.c Sample ID

Date	Location	User	Value	Reason
Mar-16-2021 15:58:21 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	Alan Colombo (b) (4)	<b>Data Entry:</b> BRZ2NP	Initial Entry

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Header Text: C4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Sep/11/2020 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: 1231

Site Name: (1231) Hospital Militar Central Cirujano Mayor Dr. Cosme Argerich

Subject No: 12313879

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 20:34

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*1. Date of Visit*

Date	Location	User	Value	Reason
Oct-04-2020 12:08:14 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 4: Closed	Response satisfies query
Oct-03-2020 12:30:45 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 4: Answered	The patient is assessed on September 11, 2020 at 11:10 a.m. at his home by doctor (b) (6) from HMC
Sep-28-2020 00:12:03 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 4: Opened	Medical Records do not describe COVID Illnes start date 11 Sep 2020 but CRF contains information. Please, clarify it or delete it. Thanks very much.
Sep-14-2020 15:58:31 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (b) (4)	Query 3: Closed	Auto closed by Validation Check: VC_SV001_02
Sep-14-2020 11:58:19 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Answered	Original value is correct
Sep-14-2020 05:11:29 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (b) (4)	Query 3: Opened	DMW4686899;The Date of Visit at Visit COVID_A is the same as the other Date of Visit at Visit V2_VAX2_L. Please review for duplication and update as appropriate.

090177e196ae2eca\Final\Final On: 01-Apr-2021 03:23 (GMT)

**Header Text:** C4591001**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Sep/11/2020 **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:** 1231**Site Name:** (1231) Hospital Militar Central Cirujano Mayor Dr. Cosme Argerich**Subject No:** 12313879**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 20:34

Sep-13-2020 16:08:31 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Sep-13-2020 16:06:27 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Deleted	Close Auto Query
Sep-13-2020 16:05:09 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Candidate	Date of Visit is completed but Date of Assessment in the Signs and Symptoms form is missing. Please review and update as appropriate.
Sep-13-2020 16:05:09 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	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.
Sep-13-2020 16:05:09 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sep/11/2020	Initial Entry

**3. COVID-19 Illness Visit:**

Date	Location	User	Value	Reason
Sep-13-2020 16:05:09 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> COVID_A	Initial Entry

Header Text: C4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Sep/11/2020

Form: SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:52

Form Status: Data Complete, Frozen, Not Complete

Site No: 1231

Site Name: (1231) Hospital Militar Central Cirujano Mayor Dr. Cosme Argerich

Subject No: 12313879

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 20:34

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**1. Date of Assessment:**

Date	Location	User	Value	Reason
Sep-13-2020 16:06:27 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Sep/11/2020	Initial Entry

**2. Date of First Symptom Started:**

Date	Location	User	Value	Reason
Sep-13-2020 16:06:27 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Aug/27/2020	Initial Entry

**3. Symptoms Ongoing?**

Date	Location	User	Value	Reason
Oct-30-2020 01:51:45 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	Sandip Namdeorao Suryawanshi (b) (4)	Query 1: Closed	Response satisfies query
Oct-29-2020 13:24:23 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	New Information
Oct-29-2020 13:24:23 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NO Date of Last Symptom Resolved: Sep/22/2020	New Information
Oct-28-2020 11:49:44 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	DM Query: Convalescent visit occurred but Date of Last Symptom Resolved is missing. Please confirm symptoms are still ongoing. If symptoms have resolved update response for Symptom ongoing as 'No' and

090177e196ae2eca\Final\Final On: 01-Apr-2021 03:23 (GMT)

Header Text: C4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Sep/11/2020

Form: SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:52

Form Status: Data Complete, Frozen, Not Complete

Site No: 1231

Site Name: (1231) Hospital Militar Central Cirujano Mayor Dr. Cosme Argerich

Subject No: 12313879

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 20:34

				add date resolved.
Sep-13-2020 16:06:27 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

4.a

Date	Location	User	Value	Reason
Sep-13-2020 16:06:27 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptoms:</b> FEVER <b>Symptom Present:</b> NO	Initial Entry

4.a Symptoms:

Date	Location	User	Value	Reason
Sep-13-2020 16:06:27 (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
Sep-13-2020 16:06:27 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

4.b

Date	Location	User	Value	Reason
Sep-13-2020 16:06:27 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptoms:</b> NEW OR INCREASE D COUGH <b>Symptom Present:</b> YES	Initial Entry

090177e196ae2eca\Final\Final On: 01-Apr-2021 03:23 (GMT)

**Header Text:** C4591001**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Sep/11/2020**Form:** SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - eCRF Audit Trail History**Form Version:** 21-Aug-2020 02:52**Form Status:** Data Complete, Frozen, Not Complete**Site No:** 1231**Site Name:** (1231) Hospital Militar Central Cirujano Mayor Dr. Cosme Argerich**Subject No:** 12313879**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 20:34**4.b Symptoms:**

Date	Location	User	Value	Reason
Sep-13-2020 16:06:27 (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
Sep-13-2020 16:06:27 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

**4.c**

Date	Location	User	Value	Reason
Sep-13-2020 16:06:27 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Symptom NEW OR INCREASED S s: HORTNESS OF BREATH Symptom NO Present:	Initial Entry

**4.c Symptoms:**

Date	Location	User	Value	Reason
Sep-13-2020 16:06:27 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NEW OR INCREASED SHORTNESS OF BREATH	Initial Entry

**4.c Was symptom present?**

Date	Location	User	Value	Reason
Sep-13-2020 16:06:27 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**4.d**

Date	Location	User	Value	Reason
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Header Text: C4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Sep/11/2020

Form: SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:52

Form Status: Data Complete, Frozen, Not Complete

Site No: 1231

Site Name: (1231) Hospital Militar Central Cirujano Mayor Dr. Cosme Argerich

Subject No: 12313879

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 20:34

Sep-13-2020 16:06:27 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptoms:</b> CHILLS <b>Symptom Present:</b> NO	Initial Entry
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4.d Symptoms:

Date	Location	User	Value	Reason
Sep-13-2020 16:06:27 (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
Sep-13-2020 16:06:27 (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
Sep-13-2020 16:06:27 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptoms:</b> NEW OR INCREASED MUSCLE PAIN <b>Symptom P resent:</b> NO	Initial Entry

4.e Symptoms:

Date	Location	User	Value	Reason
Sep-13-2020 16:06:27 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NEW OR INCREASED MUSCLE PA IN	Initial Entry

4.e Was symptom present?

Date	Location	User	Value	Reason
Sep-13-2020 16:06:27 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

090177e196ae2eca\Final\On: 01-Apr-2021 03:23 (GMT)

Header Text: C4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Sep/11/2020

Form: SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:52

Form Status: Data Complete, Frozen, Not Complete

Site No: 1231

Site Name: (1231) Hospital Militar Central Cirujano Mayor Dr. Cosme Argerich

Subject No: 12313879

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 20:34

4.f

Date	Location	User	Value	Reason
Sep-13-2020 16:06:27 (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

4.f Symptoms:

Date	Location	User	Value	Reason
Sep-13-2020 16:06:27 (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
Sep-13-2020 16:06:27 (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
Sep-13-2020 16:08:03 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptoms:</b> NEW OR INCREASED SORE THROAT <b>Symptom Present:</b> NO	Transcription Error
Sep-13-2020 16:06:27 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptoms:</b> NEW OR INCREASED SORE THROAT <b>Symptom Present:</b> YES	Initial Entry

090177e196ae2eca\Final\Final On: 01-Apr-2021 03:23 (GMT)

**Header Text:** C4591001**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Sep/11/2020**Form:** SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - eCRF Audit Trail History**Form Version:** 21-Aug-2020 02:52**Form Status:** Data Complete, Frozen, Not Complete**Site No:** 1231**Site Name:** (1231) Hospital Militar Central Cirujano Mayor Dr. Cosme Argerich**Subject No:** 12313879**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 20:34**4.g Symptoms:**

Date	Location	User	Value	Reason
Sep-13-2020 16:06:27 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NEW OR INCREASED SORE THRO AT	Initial Entry

**4.g Was symptom present?**

Date	Location	User	Value	Reason
Sep-13-2020 16:08:03 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Transcription Error
Sep-13-2020 16:06:27 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

**4.h**

Date	Location	User	Value	Reason
Sep-13-2020 16:06:27 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptoms:</b> DIARRHEA <b>Symptom Present:</b> NO	Initial Entry

**4.h Symptoms:**

Date	Location	User	Value	Reason
Sep-13-2020 16:06:27 (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
Sep-13-2020 16:06:27 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**4.i**



**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Sep/11/2020

**Form:** SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - eCRF Audit Trail History

**Form Version:** 21-Aug-2020 02:52

**Form Status:** Data Complete, Frozen, Not Complete

**Site No:** 1231

**Site Name:** (1231) Hospital Militar Central Cirujano Mayor Dr. Cosme Argerich

**Subject No:** 12313879

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 20:34

Date	Location	User	Value	Reason
Sep-13-2020 16:06:27 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptoms:</b> VOMITING <b>Symptom Present:</b> NO	Initial Entry

**4.i Symptoms:**

Date	Location	User	Value	Reason
Sep-13-2020 16:06:27 (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
Sep-13-2020 16:06:27 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

090177e196ae2eca\Final\Final On: 01-Apr-2021 03:23 (GMT)

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Sep/11/2020 **Form:** MICROBIOLOGY SPECIMEN - Audit Trail

**Form Version:** 06-Jul-2020 21:54

**Form Status:**

**Site No:** 1231

**Site Name:** (1231) Hospital Militar Central Cirujano Mayor Dr. Cosme Argerich

**Subject No:** 12313879

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 20:34

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Date	Location	User	Value	Reason
Sep-13-2020 16:07:38 (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 Sep/11/2020 Form: MICROBIOLOGY SPECIMEN - eCRF Audit Trail History

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen, Verified

Site No: 1231

Site Name: (1231) Hospital Militar Central Cirujano Mayor Dr. Cosme Argerich

Subject No: 12313879

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 20:34

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**1. Actual Date of Collection:**

Date	Location	User	Value	Reason
Sep-13-2020 16:07:38 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sep/11/2020	Initial Entry

**2. Specimen Type:**

Date	Location	User	Value	Reason
Sep-13-2020 16:07:38 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> SWABBED MATERIAL	Initial Entry

**3. Specimen Collection Location:**

Date	Location	User	Value	Reason
Sep-13-2020 16:07:38 (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
Sep-13-2020 16:07:38 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SEVERE ACUTE RESP SYNDROME CORONAVIRUS 2	Initial Entry

**5. Device Type:**

Date	Location	User	Value	Reason
Sep-13-2020 16:07:38 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SARS-COV-2 DIAGNOSTIC TEST	Initial Entry

**6. Trade Name:**

Date	Location	User	Value	Reason
Sep-13-2020 16:07:38 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> ATILA BIOSYSTEMS IAMP COVID	Initial Entry

090177e196ae2eca\Final\Final On: 01-Apr-2021 03:23 (GMT)

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Sep/11/2020 **Form:** MICROBIOLOGY SPECIMEN - eCRF Audit Trail History

**Form Version:** 06-Jul-2020 21:54

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1231

**Site Name:** (1231) Hospital Militar Central Cirujano Mayor Dr. Cosme Argerich

**Subject No:** 12313879

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 20:34

Aires	(b) (4), (b) (6)	-19 DETECTION KIT
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**7. Test Result:**

Date	Location	User	Value	Reason
Sep-13-2020 16:07:38 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NEGATIVE	Initial Entry

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Sep/11/2020

**Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB SELF - eCRF Audit Trail History

**Form Version:** 22-Apr-2020 21:03

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1231

**Site Name:** (1231) Hospital Militar Central Cirujano Mayor Dr. Cosme Argerich

**Subject No:** 12313879

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 20:34

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**1. Data Origin**

Date	Location	User	Value	Reason
Sep-13-2020 16:08:23 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SITE	Initial Entry

**2. Sample Type**

Date	Location	User	Value	Reason
Sep-13-2020 16:08:23 (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
Sep-13-2020 16:08:23 (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
Sep-13-2020 16:08:23 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> sample collected by team physician	Initial Entry

090177e196ae2eca\Final\Final On: 01-Apr-2021 03:23 (GMT)

Header Text: C4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Sep/11/2020

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1231

Site Name: (1231) Hospital Militar Central Cirujano Mayor Dr. Cosme Argerich

Subject No: 12313879

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 20:34

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**1. Data Origin**

Date	Location	User	Value	Reason
Sep-13-2020 16:08:31 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> SITE	Initial Entry

**2. Sample Type**

Date	Location	User	Value	Reason
Sep-13-2020 16:08:31 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> NASAL_SWAB	Initial Entry

**3. Sample Collected?**

Date	Location	User	Value	Reason
Sep-15-2020 10:44:10 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Sep-14-2020 02:38:59 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Sep-13-2020 16:08:31 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Sep-13-2020 16:08:31 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> YES Date of Collection:  Sep/11/2020	Initial Entry

**5.a**

Date	Location	User	Value	Reason
Sep-15-2020 10:44:10 (UTC-03:00) City of	ACV0PFEINFP6000	Romina Barrera	<u>Data Entry:</u> Sample ID: BP1Y6H	Initial Entry

090177e196ae2eca\Final\Final On: 01-Apr-2021 03:23 (GMT)

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Sep/11/2020

**Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB - eCRF Audit Trail History

**Form Version:** 22-Apr-2020 21:03

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1231

**Site Name:** (1231) Hospital Militar Central Cirujano Mayor Dr. Cosme Argerich

**Subject No:** 12313879

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 20:34

Buenos Aires	(b) (4)
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**5.a Sample ID**

Date	Location	User	Value	Reason
Sep-15-2020 10:44:10 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	Romina Barrera (b) (4)	<u>Data Entry:</u> BP1Y6H	Initial Entry

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Header Text: C4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Sep/11/2020 Form: HEALTH CARE UTILIZATION - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:50

Form Status: Data Complete, Frozen, Verified

Site No: 1231

Site Name: (1231) Hospital Militar Central Cirujano Mayor Dr. Cosme Argerich

Subject No: 12313879

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 20:34

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*I.a*

Date	Location	User	Value	Reason
Sep-13-2020 16:09:47 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Type of Practitioner: SPECIALIST Occurrence of Visits or Contacts: NO	Initial Entry

*I.a Physician or Healthcare Professional:*

Date	Location	User	Value	Reason
Sep-13-2020 16:09:47 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> SPECIALIST	Initial Entry

*I.a Occurrence of Visits or Contacts:*

Date	Location	User	Value	Reason
Sep-13-2020 16:09:47 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

*I.b*

Date	Location	User	Value	Reason
Sep-13-2020 16:09:47 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Type of Practitioner: EMERGENCY ROOM Occurrence of Visits or Contacts: NO	Initial Entry

090177e196ae2eca\Final\Final On: 01-Apr-2021 03:23 (GMT)



**Header Text:** C4591001**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Sep/11/2020 **Form:** HEALTH CARE UTILIZATION - eCRF Audit Trail History**Form Version:** 21-Aug-2020 02:50**Form Status:** Data Complete, Frozen, Verified**Site No:** 1231**Site Name:** (1231) Hospital Militar Central Cirujano Mayor Dr. Cosme Argerich**Subject No:** 12313879**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 20:34***I.b Physician or Healthcare Professional:***

Date	Location	User	Value	Reason
Sep-13-2020 16:09:47 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> EMERGENCY ROOM	Initial Entry

***I.b Occurrence of Visits or Contacts:***

Date	Location	User	Value	Reason
Sep-13-2020 16:09:47 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

***I.c***

Date	Location	User	Value	Reason
Sep-13-2020 16:09:47 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Type of Practitioner:</b> PRIMARY CARE PHYSICIAN <b>Occurrence of Visits or Contacts:</b> NO	Initial Entry

***I.c Physician or Healthcare Professional:***

Date	Location	User	Value	Reason
Sep-13-2020 16:09:47 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> PRIMARY CARE PHYSICIAN	Initial Entry

***I.c Occurrence of Visits or Contacts:***

Date	Location	User	Value	Reason
Sep-13-2020 16:09:47 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

***I.d***

Date	Location	User	Value	Reason
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**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Sep/11/2020 **Form:** HEALTH CARE UTILIZATION - eCRF Audit Trail History

**Form Version:** 21-Aug-2020 02:50

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1231

**Site Name:** (1231) Hospital Militar Central Cirujano Mayor Dr. Cosme Argerich

**Subject No:** 12313879

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 20:34

Sep-13-2020 16:09:47 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Type of Practitioner:</b> URGENT CARE <b>Occurrence of Visits or Contacts:</b> NO	Initial Entry
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***1.d Physician or Healthcare Professional:***

Date	Location	User	Value	Reason
Sep-13-2020 16:09:47 (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
Sep-13-2020 16:09:47 (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
Sep-13-2020 16:09:47 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Type of Practitioner:</b> TELEPHONE CONSULTATION <b>Occurrence of Visits or Contacts:</b> NO	Initial Entry

090177e196ae2eca\Final\Final On: 01-Apr-2021 03:23 (GMT)

**Header Text:** C4591001**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Sep/11/2020 **Form:** HEALTH CARE UTILIZATION - eCRF Audit Trail History**Form Version:** 21-Aug-2020 02:50**Form Status:** Data Complete, Frozen, Verified**Site No:** 1231**Site Name:** (1231) Hospital Militar Central Cirujano Mayor Dr. Cosme Argerich**Subject No:** 12313879**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 20:34***1.e Physician or Healthcare Professional:***

Date	Location	User	Value	Reason
Sep-13-2020 16:09:47 (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
Sep-13-2020 16:09:47 (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
Sep-13-2020 16:09:47 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Type of Practitioner:</b> OTH R <b>Occurrence of Visits or Cont acts:</b> NO	Initial Entry

***1.f Physician or Healthcare Professional:***

Date	Location	User	Value	Reason
Sep-13-2020 16:09:47 (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
Sep-13-2020 16:09:47 (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
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**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Sep/11/2020 **Form:** HEALTH CARE UTILIZATION - eCRF Audit Trail History

**Form Version:** 21-Aug-2020 02:50

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1231

**Site Name:** (1231) Hospital Militar Central Cirujano Mayor Dr. Cosme Argerich

**Subject No:** 12313879

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 20:34

Sep-15-2020 04:02:16 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Sep-14-2020 11:50:06 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	The information is correct. The subject has not been hospitalized. The subject did not need visits or medical attention. Thank you.
Sep-13-2020 16:09:47 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	There are no visits or contacts reported and subject has not been hospitalized, please confirm whether the participant sought medical attention for this respiratory illness episode. If not, please correct data.
Sep-13-2020 16:09:47 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

090177e196ae2eca\Final\Final On: 01-Apr-2021 03:23 (GMT)

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Sep/11/2020 **Form:** ILLNESS DETAILS - eCRF Audit Trail History

**Form Version:** 06-Jul-2020 21:52

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1231

**Site Name:** (1231) Hospital Militar Central Cirujano Mayor Dr. Cosme Argerich

**Subject No:** 12313879

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 20:34

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**1. Category of Clinical Event:**

Date	Location	User	Value	Reason
Sep-14-2020 11:57:56 (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
Sep-14-2020 11:57:56 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**3. Toxicity Grade:**

Date	Location	User	Value	Reason
Sep-14-2020 11:57:56 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 1	Initial Entry

090177e196ae2eca\Final\Final On: 01-Apr-2021 03:23 (GMT)

**Header Text:** C4591001**Visit:** POT\_COVID\_ILL 2 - Unscheduled Visit on Jan/06/2021 **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:** 1231**Site Name:** (1231) Hospital Militar Central Cirujano Mayor Dr. Cosme Argerich**Subject No:** 12313879**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 20:34[Back to Form](#)**1. Date of Visit**

Date	Location	User	Value	Reason
Jan-08-2021 12:22:43 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Jan-08-2021 12:20:00 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Deleted	Close Auto Query
Jan-08-2021 12:19:09 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Candidate	Date of Visit is completed but Date of Assessment in the Signs and Symptoms form is missing. Please review and update as appropriate.
Jan-08-2021 12:19:09 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	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-08-2021 12:19:09 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Jan/6/2021	Initial Entry

**3. COVID-19 Illness Visit:**

Date	Location	User	Value	Reason
Jan-08-2021 12:19:09 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> COVID_B	Initial Entry

**Header Text:** C4591001**Visit:** POT\_COVID\_ILL 2 - Unscheduled Visit on Jan/06/2021**Form:** SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - eCRF Audit Trail History**Form Version:** 10-Dec-2020 02:29**Form Status:** Data Complete**Site No:** 1231**Site Name:** (1231) Hospital Militar Central Cirujano Mayor Dr. Cosme Argerich**Subject No:** 12313879**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 20:34[Back to Form](#)**1. Date of Assessment:**

Date	Location	User	Value	Reason
Jan-08-2021 12:20:00 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Jan/6/2021	Initial Entry

**2. Date of First Symptom Started:**

Date	Location	User	Value	Reason
Jan-08-2021 12:20:00 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Jan/1/2021	Initial Entry

**3. Symptoms Ongoing?**

Date	Location	User	Value	Reason
Jan-15-2021 12:24:01 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO Date of Last Symptom Resolved:  Jan/9/2021	New Information
Jan-08-2021 12:20:00 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

**4.a**

Date	Location	User	Value	Reason
Jan-08-2021 12:20:00 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptoms:</b> FEVER <b>Symptom Present:</b> NO	Initial Entry

**4.a Symptoms:**

Date	Location	User	Value	Reason
Jan-08-2021 12:20:00 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> FEVER	Initial Entry

Header Text: C4591001

Visit: POT\_COVID\_ILL 2 - Unscheduled Visit on Jan/06/2021

Form: SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:29

Form Status: Data Complete

Site No: 1231

Site Name: (1231) Hospital Militar Central Cirujano Mayor Dr. Cosme Argerich

Subject No: 12313879

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 20:34

Buenos Aires		(b) (4), (b) (6)		
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4.a Was symptom present?

Date	Location	User	Value	Reason
Jan-08-2021 12:20:00 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

4.b

Date	Location	User	Value	Reason
Jan-08-2021 12:20:00 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptoms:</b> NEW OR INCREASED COUGH <b>Symptom Present:</b> NO	Initial Entry

4.b Symptoms:

Date	Location	User	Value	Reason
Jan-08-2021 12:20:00 (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-08-2021 12:20:00 (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-08-2021 12:20:00 (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

090177e196ae2eca\Final\Final On: 01-Apr-2021 03:23 (GMT)



Header Text: C4591001

Visit: POT\_COVID\_ILL 2 - Unscheduled Visit on Jan/06/2021

Form: SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:29

Form Status: Data Complete

Site No: 1231

Site Name: (1231) Hospital Militar Central Cirujano Mayor Dr. Cosme Argerich

Subject No: 12313879

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 20:34

			Symptom NO Present:	
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4.c Symptoms:

Date	Location	User	Value	Reason
Jan-08-2021 12:20:00 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NEW OR INCREASED SHORTNES S OF BREATH	Initial Entry

4.c Was symptom present?

Date	Location	User	Value	Reason
Jan-08-2021 12:20:00 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

4.d

Date	Location	User	Value	Reason
Jan-08-2021 12:20:00 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Symptoms: CHILLS Symptom Present: NO	Initial Entry

4.d Symptoms:

Date	Location	User	Value	Reason
Jan-08-2021 12:20:00 (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-08-2021 12:20:00 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

4.e

090177e196ae2eca\Final\Final On: 01-Apr-2021 03:23 (GMT)

Header Text: C4591001

Visit: POT\_COVID\_ILL 2 - Unscheduled Visit on Jan/06/2021

Form: SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:29

Form Status: Data Complete

Site No: 1231

Site Name: (1231) Hospital Militar Central Cirujano Mayor Dr. Cosme Argerich

Subject No: 12313879

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 20:34

Date	Location	User	Value	Reason
Jan-08-2021 12:20:00 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptoms:</b> NEW OR INCREASED MUSCLE PAIN <b>Symptom Present:</b> NO	Initial Entry

4.e Symptoms:

Date	Location	User	Value	Reason
Jan-08-2021 12:20:00 (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-08-2021 12:20:00 (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-08-2021 12:20:00 (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

090177e196ae2eca\Final\Final On: 01-Apr-2021 03:23 (GMT)

**Header Text:** C4591001**Visit:** POT\_COVID\_ILL 2 - Unscheduled Visit on  
Jan/06/2021**Form:** SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - eCRF Audit  
Trail History**Form Version:** 10-Dec-2020 02:29**Form Status:** Data Complete**Site No:** 1231**Site Name:** (1231) Hospital Militar Central Cirujano Mayor Dr. Cosme  
Argerich**Subject No:** 12313879**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 20:34**4.f Symptoms:**

Date	Location	User	Value	Reason
Jan-08-2021 12:20:00 (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-08-2021 12:20:00 (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-08-2021 12:20:00 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptoms:</b> NEW OR INCREASED SORE THROAT <b>Symptom Present:</b> YES	Initial Entry

**4.g Symptoms:**

Date	Location	User	Value	Reason
Jan-08-2021 12:20:00 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NEW OR INCREASED SORE THR OAT	Initial Entry

**4.g Was symptom present?**

Date	Location	User	Value	Reason
Jan-08-2021 12:20:00 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

**4.h**

Date	Location	User	Value	Reason
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Header Text: C4591001

Visit: POT\_COVID\_ILL 2 - Unscheduled Visit on Jan/06/2021

Form: SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:29

Form Status: Data Complete

Site No: 1231

Site Name: (1231) Hospital Militar Central Cirujano Mayor Dr. Cosme Argerich

Subject No: 12313879

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 20:34

Jan-08-2021 12:20:00 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptoms:</b> DIARRHEA <b>Symptom Present:</b> NO	Initial Entry
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4.h Symptoms:

Date	Location	User	Value	Reason
Jan-08-2021 12:20:00 (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-08-2021 12:20:00 (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-08-2021 12:20:00 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptoms:</b> VOMITING <b>Symptom Present:</b> NO	Initial Entry

4.i Symptoms:

Date	Location	User	Value	Reason
Jan-08-2021 12:20:00 (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-08-2021 12:20:00 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

090177e196ae2eca\Final\Final On: 01-Apr-2021 03:23 (GMT)

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 2 - Unscheduled Visit on Jan/06/2021

**Form:** SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - eCRF Audit Trail History

**Form Version:** 10-Dec-2020 02:29

**Form Status:** Data Complete

**Site No:** 1231

**Site Name:** (1231) Hospital Militar Central Cirujano Mayor Dr. Cosme Argerich

**Subject No:** 12313879

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 20:34

**5.a**

Date	Location	User	Value	Reason
Jan-08-2021 12:20:31 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptoms - Other:</b> headache	Initial Entry

**5.a Symptoms - Other Text:**

Date	Location	User	Value	Reason
Jan-08-2021 12:20:31 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> headache	Initial Entry

**5.b**

Date	Location	User	Value	Reason
Jan-08-2021 12:20:54 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptoms - Other:</b> nasal congestion	Initial Entry

**5.b Symptoms - Other Text:**

Date	Location	User	Value	Reason
Jan-08-2021 12:20:54 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> nasal congestion	Initial Entry

090177e196ae2eca\Final\Final On: 01-Apr-2021 03:23 (GMT)

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 2 - Unscheduled Visit on **Form:** MICROBIOLOGY SPECIMEN - Audit Trail  
Jan/06/2021

**Form Version:** 06-Jul-2020 21:54

**Form Status:**

**Site No:** 1231

**Site Name:** (1231) Hospital Militar Central Cirujano Mayor Dr. Cosme Argerich

**Subject No:** 12313879

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 20:34

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Date	Location	User	Value	Reason
Jan-08-2021 12:21:44 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Created	

Header Text: C4591001

Visit: POT\_COVID\_ILL 2 - Unscheduled Visit on Jan/06/2021 Form: MICROBIOLOGY SPECIMEN - eCRF Audit Trail History

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete

Site No: 1231

Site Name: (1231) Hospital Militar Central Cirujano Mayor Dr. Cosme Argerich

Subject No: 12313879

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 20:34

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**1. Actual Date of Collection:**

Date	Location	User	Value	Reason
Jan-08-2021 12:21:44 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Jan/6/2021	Initial Entry

**2. Specimen Type:**

Date	Location	User	Value	Reason
Jan-08-2021 12:21:44 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> SWABBED MATERIAL	Initial Entry

**3. Specimen Collection Location:**

Date	Location	User	Value	Reason
Jan-08-2021 12:21:44 (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-08-2021 12:21:44 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SEVERE ACUTE RESP SYNDROME CORONAVIRUS 2	Initial Entry

**5. Device Type:**

Date	Location	User	Value	Reason
Jan-08-2021 12:21:44 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SARS-COV-2 DIAGNOSTIC TEST	Initial Entry

**6. Trade Name:**

Date	Location	User	Value	Reason
Jan-08-2021 12:21:44 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> ATILA BIOSYSTEMS IAMP COVI	Initial Entry

090177e196ae2eca\Final\Final On: 01-Apr-2021 03:23 (GMT)

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 2 - Unscheduled Visit on Jan/06/2021 **Form:** MICROBIOLOGY SPECIMEN - eCRF Audit Trail History

**Form Version:** 06-Jul-2020 21:54

**Form Status:** Data Complete

**Site No:** 1231

**Site Name:** (1231) Hospital Militar Central Cirujano Mayor Dr. Cosme Argerich

**Subject No:** 12313879

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 20:34

Buenos Aires	(b) (4), (b) (6)	D-19 DETECTION KIT
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**7. Test Result:**

Date	Location	User	Value	Reason
Jan-08-2021 12:21:44 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NEGATIVE	Initial Entry



**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 2 - Unscheduled Visit on Jan/06/2021

**Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB SELF - eCRF Audit Trail History

**Form Version:** 22-Apr-2020 21:03

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1231

**Site Name:** (1231) Hospital Militar Central Cirujano Mayor Dr. Cosme Argerich

**Subject No:** 12313879

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 20:34

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**1. Data Origin**

Date	Location	User	Value	Reason
Jan-08-2021 12:22:31 (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
Jan-08-2021 12:22:31 (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-08-2021 12:22:31 (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
Jan-08-2021 12:22:31 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> sample collected by a team physician	Initial Entry

090177e196ae2eca\Final\Final On: 01-Apr-2021 03:23 (GMT)

**Header Text:** C4591001**Visit:** POT\_COVID\_ILL 2 - Unscheduled Visit on  
Jan/06/2021**Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB - eCRF Audit  
Trail History**Form Version:** 22-Apr-2020 21:03**Form Status:** Data Complete, Frozen, Verified**Site No:** 1231**Site Name:** (1231) Hospital Militar Central Cirujano Mayor Dr. Cosme  
Argerich**Subject No:** 12313879**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 20:34[Back to Form](#)**1. Data Origin**

Date	Location	User	Value	Reason
Jan-08-2021 12:22:43 (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-08-2021 12:22:43 (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-11-2021 14:41:05 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Jan-11-2021 08:28:44 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Jan-08-2021 12:22:43 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Jan-08-2021 12:22:43 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES Date of Collection:  Jan/6/2021	Initial Entry

**5.a**

Date	Location	User	Value	Reason
Jan-11-2021 14:41:05 (UTC-03:00) City of	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample ID:</b> BPTBWV	Initial Entry

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 2 - Unscheduled Visit on Jan/06/2021

**Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB - eCRF Audit Trail History

**Form Version:** 22-Apr-2020 21:03

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1231

**Site Name:** (1231) Hospital Militar Central Cirujano Mayor Dr. Cosme Argerich

**Subject No:** 12313879

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 20:34

Buenos Aires

**5.a Sample ID**

Date	Location	User	Value	Reason
Jan-11-2021 14:41:05 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BPTBWV	Initial Entry

090177e196ae2eca\Final\Final On: 01-Apr-2021 03:23 (GMT)

Header Text: C4591001

Visit: POT\_COVID\_ILL 2 - Unscheduled Visit on Form: HEALTH CARE UTILIZATION - eCRF Audit Trail History  
Jan/06/2021

Form Version: 10-Dec-2020 02:26

Form Status: Data Complete

Site No: 1231

Site Name: (1231) Hospital Militar Central Cirujano Mayor Dr. Cosme Argerich

Subject No: 12313879

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 20:34

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*I.a*

Date	Location	User	Value	Reason
Jan-08-2021 12:22:58 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Type of Practitioner:</b> SPECIAL IST <b>Occurrence of Visits or Contacts:</b> NO	Initial Entry

*I.a Physician or Healthcare Professional:*

Date	Location	User	Value	Reason
Jan-08-2021 12:22:58 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> SPECIALIST	Initial Entry

*I.a Occurrence of Visits or Contacts:*

Date	Location	User	Value	Reason
Jan-08-2021 12:22:58 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

*I.b*

Date	Location	User	Value	Reason
Jan-08-2021 12:22:58 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Type of Practitioner</b> EMERGENC : Y ROOM <b>Occurrence of Visits NO or Contacts:</b>	Initial Entry

090177e196ae2eca\Final\Final On: 01-Apr-2021 03:23 (GMT)

**Header Text:** C4591001**Visit:** POT\_COVID\_ILL 2 - Unscheduled Visit on Jan/06/2021 **Form:** HEALTH CARE UTILIZATION - eCRF Audit Trail History**Form Version:** 10-Dec-2020 02:26**Form Status:** Data Complete**Site No:** 1231**Site Name:** (1231) Hospital Militar Central Cirujano Mayor Dr. Cosme Argerich**Subject No:** 12313879**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 20:34***I.b Physician or Healthcare Professional:***

Date	Location	User	Value	Reason
Jan-08-2021 12:22:58 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> EMERGENCY ROOM	Initial Entry

***I.b Occurrence of Visits or Contacts:***

Date	Location	User	Value	Reason
Jan-08-2021 12:22:58 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

***I.c***

Date	Location	User	Value	Reason
Jan-08-2021 12:22:58 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Type of Practitioner:</b> PRIMARY CARE PHYSICIAN <b>Occurrence of Visits or Contacts:</b> NO	Initial Entry

***I.c Physician or Healthcare Professional:***

Date	Location	User	Value	Reason
Jan-08-2021 12:22:58 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> PRIMARY CARE PHYSICIAN	Initial Entry

***I.c Occurrence of Visits or Contacts:***

Date	Location	User	Value	Reason
Jan-08-2021 12:22:58 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

***I.d***

Date	Location	User	Value	Reason
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**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 2 - Unscheduled Visit on **Form:** HEALTH CARE UTILIZATION - eCRF Audit Trail History  
Jan/06/2021

**Form Version:** 10-Dec-2020 02:26

**Form Status:** Data Complete

**Site No:** 1231

**Site Name:** (1231) Hospital Militar Central Cirujano Mayor Dr. Cosme Argerich

**Subject No:** 12313879

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 20:34

Jan-08-2021 12:22:58 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Type of Practitioner:</b> URGENT CARE <b>Occurrence of Visits or NO Contacts:</b>	Initial Entry
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***1.d Physician or Healthcare Professional:***

Date	Location	User	Value	Reason
Jan-08-2021 12:22:58 (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-08-2021 12:22:58 (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-08-2021 12:22:58 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Type of Practitioner:</b> TELEPHONE CONSULTATION <b>Occurrence of Visits or Contacts:</b> NO	Initial Entry

090177e196ae2eca\Final\Final On: 01-Apr-2021 03:23 (GMT)

**Header Text:** C4591001**Visit:** POT\_COVID\_ILL 2 - Unscheduled Visit on Jan/06/2021 **Form:** HEALTH CARE UTILIZATION - eCRF Audit Trail History**Form Version:** 10-Dec-2020 02:26**Form Status:** Data Complete**Site No:** 1231**Site Name:** (1231) Hospital Militar Central Cirujano Mayor Dr. Cosme Argerich**Subject No:** 12313879**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 20:34***1.e Physician or Healthcare Professional:***

Date	Location	User	Value	Reason
Jan-08-2021 12:22:58 (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-08-2021 12:22:58 (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-08-2021 12:22:58 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Type of Practitioner:</b> OTH R <b>Occurrence of Visits or Con NO</b> <b>tacts:</b>	Initial Entry

***1.f Physician or Healthcare Professional:***

Date	Location	User	Value	Reason
Jan-08-2021 12:22:58 (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-08-2021 12:22:58 (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
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**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 2 - Unscheduled Visit on **Form:** HEALTH CARE UTILIZATION - eCRF Audit Trail History  
Jan/06/2021

**Form Version:** 10-Dec-2020 02:26

**Form Status:** Data Complete

**Site No:** 1231

**Site Name:** (1231) Hospital Militar Central Cirujano Mayor Dr. Cosme Argerich

**Subject No:** 12313879

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 20:34

Jan-08-2021 12:22:58 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry
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**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 2 - Unscheduled Visit on Jan/06/2021 **Form:** ILLNESS DETAILS - eCRF Audit Trail History

**Form Version:** 06-Jul-2020 21:52

**Form Status:** Data Complete

**Site No:** 1231

**Site Name:** (1231) Hospital Militar Central Cirujano Mayor Dr. Cosme Argerich

**Subject No:** 12313879

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 20:34

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**1. Category of Clinical Event:**

Date	Location	User	Value	Reason
Jan-08-2021 12:23:38 (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-08-2021 12:23:38 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES <i>Respiratory Illness Diagnosis:</i>  upper airway catarrh  Date of Diagnosis:  Jan/6/2021	Initial Entry

**3. Toxicity Grade:**

Date	Location	User	Value	Reason
Jan-08-2021 12:23:38 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 1	Initial Entry

090177e196ae2eca\Final\Final On: 01-Apr-2021 03:23 (GMT)

**Header Text:** C4591001**Visit:** POT\_COVID\_CONVA 1 - Unscheduled Visit on Oct/13/2020 **Form:** DATE OF VISIT - ILLNESS CONVALESCENT - eCRF Audit Trail History**Form Version:** 22-Apr-2020 21:04**Form Status:** Data Complete, Frozen, Verified**Site No:** 1231**Site Name:** (1231) Hospital Militar Central Cirujano Mayor Dr. Cosme Argerich**Subject No:** 12313879**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 20:34[Back to Form](#)**1. Date of Visit**

Date	Location	User	Value	Reason
Oct-16-2020 08:00:38 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	As per site response
Oct-15-2020 13:25:38 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Original value is correct
Oct-15-2020 05:38:11 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (b) (4)	Query 1: Opened	DMW4978907;The Date of Visit at Visit COVID_A1 is the same as the other Date of Visit at Visit V3_MONTH1_POSTVAX2_L. Please review for duplication and update as appropriate.
Oct-14-2020 17:30:34 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry</b> : Oct/13/2020	Initial Entry

**3. COVID-19 Illness Visit:**

Date	Location	User	Value	Reason
Oct-14-2020 17:30:34 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> COVID_A1	Initial Entry

Header Text: C4591001

Visit: POT\_COVID\_CONVA 1 - Unscheduled Visit on Oct/13/2020

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1231

Site Name: (1231) Hospital Militar Central Cirujano Mayor Dr. Cosme Argerich

Subject No: 12313879

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 20:34

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**1. Data Origin**

Date	Location	User	Value	Reason
Oct-14-2020 17:31:50 (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-14-2020 17:31:50 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SERUM	Initial Entry

**3. Sample Collected?**

Date	Location	User	Value	Reason
Oct-15-2020 08:36:58 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Oct-15-2020 05:28:57 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Oct-14-2020 17:31:50 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Oct-14-2020 17:31:50 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES Date of Collection:  Oct/13/2020	Initial Entry

**5.a**

Date	Location	User	Value	Reason
Oct-15-2020 08:36:58 (UTC-03:00) City of	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample ID:</b> BPT7SZ	Initial Entry

090177e196ae2eca\Final\Final On: 01-Apr-2021 03:23 (GMT)

Header Text: C4591001

Visit: POT\_COVID\_CONVA 1 - Unscheduled Visit Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - eCRF  
on Oct/13/2020 Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1231

Site Name: (1231) Hospital Militar Central Cirujano Mayor Dr. Cosme Argerich

Subject No: 12313879

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 20:34

Buenos Aires

(b) (4), (b) (6)

5.a Sample ID

Date	Location	User	Value	Reason
Oct-15-2020 08:36:58 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> BPT7SZ	Initial Entry

5.b

Date	Location	User	Value	Reason
Oct-15-2020 08:40:21 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Sample ID: BRXPY0	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Oct-15-2020 08:40:21 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> BRXPY0	Initial Entry

5.c

Date	Location	User	Value	Reason
Oct-19-2020 12:34:03 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	Romina Barrera (b) (4)	<u>Data Entry:</u> Sample ID: BRXPYF	Initial Entry

5.c Sample ID

Date	Location	User	Value	Reason
Oct-19-2020 12:34:03 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	Romina Barrera (b) (4)	<u>Data Entry:</u> BRXPYF	Initial Entry

090177e196ae2eca\Final\Final On: 01-Apr-2021 03:23 (GMT)

**Header Text:** C4591001

**Visit:** POT\_COVID\_CONVA 2 - Unscheduled Visit **Form:** DATE OF VISIT - ILLNESS CONVALESCENT - eCRF Audit Trail  
on Feb/03/2021 History

**Form Version:** 22-Apr-2020 21:04

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1231

**Site Name:** (1231) Hospital Militar Central Cirujano Mayor Dr. Cosme Argerich

**Subject No:** 12313879

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 20:34

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**1. Date of Visit**

Date	Location	User	Value	Reason
Feb-04-2021 10:15:20 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Feb/3/2021	Initial Entry

**3. COVID-19 Illness Visit:**

Date	Location	User	Value	Reason
Feb-04-2021 10:15:20 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> COVID_B1	Initial Entry

090177e196ae2eca\Final\Final On: 01-Apr-2021 03:23 (GMT)

Header Text: C4591001

Visit: POT\_COVID\_CONVA 2 - Unscheduled Visit Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - eCRF  
on Feb/03/2021 Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1231

Site Name: (1231) Hospital Militar Central Cirujano Mayor Dr. Cosme Argerich

Subject No: 12313879

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 20:34

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**1. Data Origin**

Date	Location	User	Value	Reason
Feb-04-2021 10:15:36 (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-04-2021 10:15:36 (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-04-2021 16:02:32 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Feb-04-2021 11:39:25 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Feb-04-2021 10:15:36 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Feb-04-2021 10:15:36 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES Date of Collection:  Feb/3/2021	Initial Entry

**5.a**

Date	Location	User	Value	Reason
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090177e196ae2eca\Final\Final On: 01-Apr-2021 03:23 (GMT)

Header Text: C4591001

Visit: POT\_COVID\_CONVA 2 - Unscheduled Visit Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - eCRF  
on Feb/03/2021 Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1231

Site Name: (1231) Hospital Militar Central Cirujano Mayor Dr. Cosme Argerich

Subject No: 12313879

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 20:34

Feb-04-2021 16:02:32 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample ID:</b> BPWC6T	Initial Entry
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5.a Sample ID

Date	Location	User	Value	Reason
Feb-04-2021 16:02:32 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BPWC6T	Initial Entry

5.b

Date	Location	User	Value	Reason
Feb-04-2021 17:54:45 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	Agustin Morato Cabral (b) (4)	<b>Data Entry:</b> <b>Sample ID:</b> BS43PV	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Feb-04-2021 17:54:45 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	Agustin Morato Cabral (b) (4)	<b>Data Entry:</b> BS43PV	Initial Entry

5.c

Date	Location	User	Value	Reason
Feb-04-2021 18:06:46 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample ID:</b> BS43PD	Initial Entry

5.c Sample ID

Date	Location	User	Value	Reason
Feb-04-2021 18:06:46 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BS43PD	Initial Entry

090177e196ae2eca\Final\Final On: 01-Apr-2021 03:23 (GMT)

**Header Text:** C4591001

**Visit:** End of Treatment - Unscheduled

**Form Version:** 15-Sep-2020 21:55

**Site No:** 1231

**Subject No:** 12313879

**Generated By:** (b) (4)

**Form:** DISPOSITION - TREATMENT - eCRF Audit Trail History

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site Name:** (1231) Hospital Militar Central Cirujano Mayor Dr. Cosme Argerich

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 20:34

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**1. Date of Completion/Discontinuation/Death :**

Date	Location	User	Value	Reason
Oct-14-2020 16:55:39 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Oct/13/2020	Initial Entry

**2. Phase of Disposition:**

Date	Location	User	Value	Reason
Oct-14-2020 16:55:39 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> VACCINATION	Initial Entry

**3. Status:**

Date	Location	User	Value	Reason
Oct-14-2020 16:55:39 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> COMPLETED	Initial Entry

090177e196ae2eca\Final\Final On: 01-Apr-2021 03:23 (GMT)



**Header Text:** C4591001

**Visit:** Potential ReVax Initial Contact - Unscheduled **Form:** DATE OF VISIT - eCRF Audit Trail History

**Form Version:** 22-Apr-2020 21:02

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site No:** 1231

**Site Name:** (1231) Hospital Militar Central Cirujano Mayor Dr. Cosme Argerich

**Subject No:** 12313879

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 20:34

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*1. Date of Visit*

Date	Location	User	Value	Reason
Mar-17-2021 16:16:45 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Mar/16/2021	New Information
Mar-17-2021 16:12:47 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Feb/16/2021	New Information
Feb-09-2021 11:36:08 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Feb/9/2021	Initial Entry

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**Header Text:** C4591001

**Visit:** Potential ReVax Initial Contact - Unscheduled **Form:** FURTHER VACCINATION CONFIRMATION - eCRF Audit Trail History

**Form Version:** 10-Dec-2020 02:25

**Form Status:** Data Complete, Locked, Frozen

**Site No:** 1231

**Site Name:** (1231) Hospital Militar Central Cirujano Mayor Dr. Cosme Argerich

**Subject No:** 12313879

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 20:34

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*1. Select appropriate response - Is participant willing to return for Vaccination 3?*

Date	Location	User	Value	Reason
Mar-17-2021 16:13:19 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Participant is willing to return for Vaccination 3 Participant is:  eligible per other protocol allowance(s) and confirmed to have received only placebo at Vaccination 1/2	New Information
Feb-09-2021 11:36:18 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Participant is NOT willing to return for Vaccination 3 OR otherwise not eligible	Initial Entry

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**Header Text:** C4591001

**Visit:** Logs - Unscheduled

**Form Version:** 22-Apr-2020 21:02

**Site No:** 1231

**Subject No:** 12313879

**Generated By:** (b) (4)

**Form:** ADVERSE EVENT REPORT - Audit Trail

**Form Status:**

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Date	Location	User	Value	Reason
Sep-19-2020 15:49:28 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Created	

**Header Text:** C4591001

**Visit:** Logs - Unscheduled

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**Site No:** 1231

**Subject No:** 12313879

**Generated By:** (b) (4)

**Form:** ADVERSE EVENT REPORT - Audit Trail

**Form Status:**

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Date	Location	User	Value	Reason
Oct-19-2020 12:45:38 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Deleted	Transcription Error
Sep-22-2020 10:00:15 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Created	

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**Header Text:** C4591001

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**Site No:** 1231

**Subject No:** 12313879

**Generated By:** (b) (4)

**Form:** ADVERSE EVENT REPORT - Audit Trail

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Date	Location	User	Value	Reason
Oct-19-2020 12:49:18 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Created	

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**Header Text:** C4591001

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**Site No:** 1231

**Subject No:** 12313879

**Generated By:** (b) (4)

**Form:** ADVERSE EVENT REPORT - Audit Trail

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Date	Location	User	Value	Reason
Nov-10-2020 16:24:56 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Created	

**Header Text:** C4591001

**Visit:** Logs - Unscheduled

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**Site No:** 1231

**Subject No:** 12313879

**Generated By:** (b) (4)

**Form:** ADVERSE EVENT REPORT - Audit Trail

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Date	Location	User	Value	Reason
Feb-10-2021 10:30:38 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Created	

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Generated By: (b) (4)

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Form Status: Data Complete, Locked, Frozen, Verified

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**1. Category:**

Date	Location	User	Value	Reason
Sep-19-2020 15:49:28 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> ADVERSE EVENT	Initial Entry

**2. AE ID:**

Date	Location	User	Value	Reason
Sep-19-2020 15:49:28 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 1	Initial Entry

**3. Adverse Event:**

*(If possible specify diagnosis, not individual symptoms)*

Date	Location	User	Value	Reason
Sep-23-2020 01:27:54 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	Salim Bouguermouh (b) (4)	Query 1: Closed	Response satisfies query
Sep-22-2020 10:11:31 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	The adverse event is associated with an unknown cause. Thank you.
Sep-21-2020 00:22:29 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	Salim Bouguermouh (b) (4)	Query 1: Opened	Clin: Since HEADEACHE is one of the CDC-defined symptoms of COVID-19 (see protocol section 8.1), please consider whether this symptom could have been due to COVID-19 and should have triggered a potential illness visit or is due to vaccine reactogenicity
Sep-19-2020 15:49:28 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> headache	Initial Entry

**4. Start Date Time:**

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Date	Location	User	Value	Reason
Sep-19-2020 15:49:28 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sep/14/2020 10:00	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Oct-08-2020 18:26:49 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Oct-08-2020 16:23:53 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	New Information
Oct-08-2020 16:23:53 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	Martina Davalli (b) (4)	<b>Data Entry:</b> NO End Date Time: Sep/22/2020 17:00	New Information
Oct-06-2020 15:25:04 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	ClinQuery: Please confirm if AE is still ONGOING or RESOLVED. If RESOLVED, please up AE record and enter END Date.
Sep-19-2020 15:49:28 (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
Sep-19-2020 15:49:28 (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

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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
Sep-19-2020 15:49:28 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

8. Is this adverse event the result of a study Medication Error?  
If Yes, record the type of medication error on the Medication Error Log.

Date	Location	User	Value	Reason
Sep-19-2020 15:49:28 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

9. Is this event related to study treatment:

Date	Location	User	Value	Reason
Oct-22-2020 17:48:48 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Closed	Response satisfies query
Oct-22-2020 11:45:35 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Answered	Transcription Error
Oct-22-2020 11:45:35 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NOT RELATED If Not Related to study treatment(s), this event is due to:  OTHER  If Other, specify:  Unknown	Transcription Error
Oct-21-2020 18:05:51 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Opened	DM: A carriage is identified. To avoid processing errors, please remove the identified character by deleting the entry and re-entering the data (without using copy and paste).

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Sep-23-2020 08:47:39 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Sep-22-2020 09:54:09 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	New Information
Sep-22-2020 09:54:09 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NOT RELATED If Not Related to study treatment(s) , this event is due to:  OTHER  <i>If Other, specify:</i>  UNKNOWN	New Information
Sep-21-2020 08:10:58 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	DM: The response for "If Not Related to study treatment(s), this event is due to is reported as "Other", however specify is missing? kindly review and update.
Sep-19-2020 15:49:28 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NOT RELATED If Not Related to study treatment(s) , this event is due to:  OTHER	Initial Entry

**10. Latest Action Taken with Study Treatment:**

Date	Location	User	Value	Reason
Sep-19-2020 15:49:28 (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
Sep-19-2020 15:49:28 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

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(b) (4), (b) (6)

12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Sep-19-2020 15:49:28 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NO	Initial Entry

13. What was the outcome of this adverse event?:

Date	Location	User	Value	Reason
Oct-08-2020 16:33:14 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Oct-08-2020 16:33:14 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	Martina Davalli (b) (4)	<u>Data Entry:</u> RECOVERED/RESOLVED	New Information
Oct-08-2020 16:23:53 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	For AE headache: Response to "What was the outcome of this adverse event?" is 'Recovering/Resolving' but AE End Date/Time is present.
Sep-19-2020 15:49:28 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> RECOVERING/RESOLVING	Initial Entry

14. Did the adverse event cause the subject to be discontinued from the study?

Date	Location	User	Value	Reason
Sep-19-2020 15:49:28 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NO	Initial Entry

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**I. Category:**

Date	Location	User	Value	Reason
Sep-22-2020 10:00:15 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> ADVERSE EVENT	Initial Entry

**2. AE ID:**

Date	Location	User	Value	Reason
Oct-23-2020 21:27:25 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Oct-19-2020 12:45:38 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Transcription Error
Oct-17-2020 17:11:08 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	please include in CRF AE log Pregnancy per SAE report sent on 13 Oct 2020.
Sep-22-2020 10:00:15 (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
Oct-27-2020 11:58:08 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	Salim Bouguermouh (b) (4)	Query 1: Closed	Response satisfies query
Oct-19-2020 12:45:38 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Transcription Error
Oct-05-2020 01:01:06 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	Salim Bouguermouh (b) (4)	Query 1: Reissued:Opened	Clin: Per protocol section 8.3.7., COVID-19 listed symptoms COUGH does not qualify as AE and please should

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				be documented only on the COVID Illness CRF SOD form and should not be captured on the AE CRF page.
Oct-03-2020 12:26:11 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	The adverse event was associated with an unknown cause. Thank you.
Sep-27-2020 18:46:15 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	Salim Bouguermouh (b) (4)	Query 1: Reissued:Opened	Clin: Per protocol, please COVID-19 listed symptom DRY COUGH does not qualify as AE and is already documented on the COVID Illness SOD CRF form and should not be captured on the AE CRF form
Sep-27-2020 13:12:56 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	The patient presented a persistent dry cough not related to covid. It is considered EA. Thank you.
Sep-23-2020 01:28:37 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	Salim Bouguermouh (b) (4)	Query 1: Opened	Clin: Per protocol, please COVID-19 listed symptom DRY COUGH does not qualify as AE and please should be documented only on the COVID Illness CRF page and should not be captured on the AE CRF page.
Sep-22-2020 10:00:15 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> dry cough	Initial Entry

4. Start Date Time:

Date	Location	User	Value	Reason
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Sep-22-2020 10:00:37 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Sep-22-2020 10:00:37 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Aug/27/2020 08:00	Transcription Error
Sep-22-2020 10:00:15 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	For dry cough Start Date 27/Sep/2020, is a future date relative to when it was entered on 22/Sep/2020. Please correct.
Sep-22-2020 10:00:15 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sep/27/2020 08:00	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Oct-05-2020 15:54:14 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Oct-03-2020 12:24:36 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	New Information
Oct-03-2020 12:24:36 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO End Date Time: Sep/22/2020 17:00	New Information
Sep-24-2020 15:38:37 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	ClinQuery: Please confirm if AE of 'dry cough' is still ONGOING. If AE has RESOLVED, please update AE record and enter END Date.
Sep-22-2020 10:00:15 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

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6. Toxicity Grade:

Date	Location	User	Value	Reason
Sep-22-2020 10:00:15 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> 1	Initial Entry

7. Is the adverse event serious?

If Yes, NOTIFY PFIZER IMMEDIATELY.

Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).

Date	Location	User	Value	Reason
Sep-22-2020 10:00:15 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NO	Initial Entry

8. Is this adverse event the result of a study Medication Error?

If Yes, record the type of medication error on the Medication Error Log.

Date	Location	User	Value	Reason
Sep-22-2020 10:00:15 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NO	Initial Entry

9. Is this event related to study treatment:

Date	Location	User	Value	Reason
Sep-22-2020 10:00:15 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NOT RELATED If Not Related to study treatment(s), this event is due to:  OTHER  If Other, specify:  UNKNOWN	Initial Entry

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
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Generated By: (b) (4)

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Form Status: Data Complete, Deleted, Frozen, Verified

Site Name: (1231) Hospital Militar Central Cirujano Mayor Dr. Cosme Argerich

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Sep-22-2020 10:00:15 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NOT APPLICABLE	Initial Entry
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11. Was a Concomitant Medication given?

Date	Location	User	Value	Reason
Sep-22-2020 10:00:15 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NO	Initial Entry

12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Sep-22-2020 10:00:15 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NO	Initial Entry

13. What was the outcome of this adverse event?:

Date	Location	User	Value	Reason
Oct-03-2020 12:26:46 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Oct-03-2020 12:26:46 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> RECOVERED/RESOLVED	New Information
Oct-03-2020 12:24:36 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	For AE dry cough: Response to "What was the outcome of this adverse event?" is 'Not Recovered/Not Resolved' but AE End Date/Time is present.
Sep-22-2020 10:00:15 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NOT RECOVERED/NOT RESOLVED	Initial Entry

14. Did the adverse event cause the subject to be discontinued from the study?

Date	Location	User	Value	Reason
Sep-22-2020 10:00:15 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NO	Initial Entry

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**1. Category:**

Date	Location	User	Value	Reason
Oct-19-2020 12:49:18 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> ADVERSE EVENT	Initial Entry

**2. AE ID:**

Date	Location	User	Value	Reason
Oct-19-2020 12:49:18 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 3	Initial Entry

**3. Adverse Event:**

*(If possible specify diagnosis, not individual symptoms)*

Date	Location	User	Value	Reason
Oct-30-2020 22:40:30 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Closed	Response satisfies query
Oct-30-2020 13:17:37 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Answered	It has already been answered and a query has been sent to Safety.
Oct-28-2020 11:47:38 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Reissued: Opened	Clinical - please confirm a SAE safety update is submitted, containing this start date for the event Exposure during Pregnancy. Current SAE start date is 13OCT2020
Oct-28-2020 09:17:26 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	Maria Beretta (b) (4)	Query 2: Answered	According to date of last menstruation, the onset of pregnancy is 24

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				SEP 2020. Thank you
Oct-26-2020 15:40:16 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Opened	Clinical - please submit a followup Pregnancy report with the updated onset date of 24 Sep 2020.
Oct-20-2020 19:52:33 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000.InFormAdapter.Discrepancy	PFETMS Oracle (b) (4)	Query 1: Closed	Discrepancy has been closed.
Oct-20-2020 16:02:00 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Transcription Error
Oct-20-2020 16:02:00 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	Adolfo Gonzalez (b) (4)	<b>Data Entry:</b> Exposure to Investigation product during pregnancy	Transcription Error
Oct-19-2020 16:58:16 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000.InFormAdapter.Discrepancy	PFETMS Oracle (b) (4)	Query 1: Opened	Clarify EXPOSURE TO PI DURING PREGNANCY as follows...Please expand abbreviation PI and update the verbatim term. Thank you.
Oct-19-2020 12:49:18 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Exposure to PI during pregnancy	Initial Entry

**4. Start Date Time:**

Date	Location	User	Value	Reason
Feb-23-2021 18:13:29 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 5: Closed	Response satisfies query
Feb-23-2021 12:17:36 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 5: Answered	New Information

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Feb-23-2021 12:17:36 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sep/12/2020 13:38	New Information
Feb-23-2021 06:28:41 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 5: Opened	Clinical Start date is 10Sep20; however, PG Safety event (2020398348) has updated start date of 12Sep20 (estimated date of Conception). Please review, harmonize reporting, and update in the appropriate location
Feb-22-2021 15:50:28 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 5: Candidate	Clinical Start date is 10Sep20; however, PG Safety event (2020398348) has updated start date of 12Sep20 (estimated date of Conception). Please review, harmonize reporting, and update in the appropriate location
Nov-10-2020 09:52:04 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 4: Closed	Response satisfies query
Nov-10-2020 09:05:24 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 4: Answered	New Information
Nov-10-2020 09:05:24 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sep/10/2020 13:38	New Information
Nov-10-2020 08:48:43 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 4: Opened	SAE RECON: AER#2020398348 onset date was updated to 24Sep2020 in AE CRF.Per specific guidance in pregnancy, LMP could be used as date of conception if ultrasound results are not available. 10Sep2020 is the date

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				of the LMP described in the narrative.
Nov-09-2020 11:12:23 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Closed	to revised query text
Nov-08-2020 21:36:55 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Opened	SAE RECON: AER#2020398348 , onset date was updated to 24Sep2020 in AE CRF while retained as 10Sep2020 in Safety. Per Clinical 'the correct date of conception is 24Sep2020.Please submit a follow up AEM form to update SDB onset date
Nov-08-2020 15:07:48 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Closed	Response satisfies query
Nov-08-2020 12:27:29 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Answered	Changed Information
Nov-08-2020 12:27:29 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sep/24/2020 13:38	Changed Information
Nov-08-2020 11:26:10 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Reissued:Opened	CLINNICAL Based on the EDP guidance Date of onset = estimated date of conception is 24Sep2020 (not 1st day of LMP = 10Sep20). Please confirm and update AE CRF and Safety database accordingly.
Nov-06-2020 08:16:15 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Reissued:Candidate	SAE RECON: For Clinical review
Nov-05-2020 09:56:08 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sep/10/2020 13:38	New Information

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Nov-05-2020 08:33:52 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Answered	Transcription Error
Nov-05-2020 08:33:52 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sep/24/2020 13:38	Transcription Error
Nov-05-2020 03:01:24 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Reissued:Opened	SAE RECON: Based on the EDP guidance Date of onset = estimated date of conception is 24Sep2020.Please confirm and update AE CRF and Safety database accordingly.
Nov-04-2020 08:41:52 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Answered	New Information
Nov-04-2020 08:41:52 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sep/10/2020 13:38	New Information
Nov-03-2020 08:35:01 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Opened	SAE RECON: AER#2020398348 , onset date was updated to 24Sep2020 in AE CRF while retained as 13Oct2020in Safety. Per Clinical 'the correct date of conception is 24Sep2020.Please submit a follow up AEM form to update SDB onset date
Oct-26-2020 14:51:57 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Oct-21-2020 09:14:03 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Changed Information
Oct-21-2020 09:14:03 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sep/24/2020 UNK:UNK	Changed Information

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Oct-19-2020 22:31:45 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	CLINICAL Onset date for pregnancy is not positive urine test date (on 19 Sep); please update AE and send SAE safety update with onset date = Date of Conception (24 Sep)
Oct-19-2020 12:49:18 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Oct/13/2020 13:38	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Oct-19-2020 12:49:18 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

6. Toxicity Grade:

Date	Location	User	Value	Reason
Nov-15-2020 12:25:38 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Nov-15-2020 10:46:36 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry
Nov-15-2020 10:45:45 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Transcription Error
Nov-15-2020 10:45:45 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>	Transcription Error
Nov-15-2020 03:36:14 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	Balaji Prabu R (b) (4)	Query 1: Opened	Toxicity grade is not expected for pregnancy related adverse events, hence please remove the toxicity and add item level comment as NOT APPLICABLE.
Oct-19-2020 12:49:18 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 1	Initial Entry

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7. Is the adverse event serious?

If Yes, NOTIFY PFIZER IMMEDIATELY.

Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).

Date	Location	User	Value	Reason
Oct-19-2020 12:49:18 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

8. Is this adverse event the result of a study Medication Error?

If Yes, record the type of medication error on the Medication Error Log.

Date	Location	User	Value	Reason
Oct-19-2020 12:49:18 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

9. Is this event related to study treatment:

Date	Location	User	Value	Reason
Oct-19-2020 12:49:18 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NOT RELATED If Not Related to study treatment(s), this event is due to:  OTHER  If Other, specify:  unplanned pregnancy	Initial Entry

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**10. Latest Action Taken with Study Treatment:**

Date	Location	User	Value	Reason
Oct-19-2020 12:49:18 (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
Oct-19-2020 12:49:18 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**12. Was a Non-Drug Treatment given?**

Date	Location	User	Value	Reason
Oct-19-2020 12:49:18 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**13. What was the outcome of this adverse event?:**

Date	Location	User	Value	Reason
Nov-04-2020 08:21:04 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Closed	Response satisfies query
Nov-03-2020 17:44:40 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Closed	site has 'is AE still ongoing' marked Yes
Nov-03-2020 15:40:28 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 3: Opened	For AE Exposure to Investigation product during pregnancy: Response to "What was the outcome of this adverse event?" is 'Unknown' but End Date/Time is provided or "Is the adverse event still ongoing?" is marked "Yes".
Nov-03-2020 15:40:28 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Answered	New Information

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Nov-03-2020 15:40:28 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> UNKNOWN	New Information
Nov-03-2020 12:12:11 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Opened	SAE RECON: AER#2020398348, the outcome in AE CRF was reported as NOT RECOVERED/NOT RESOLVED. Based on the latest EDP guidance, outcome should be recorded as UNKNOWN. Please confirm and update accordingly.
Oct-19-2020 15:10:47 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Oct-19-2020 15:10:47 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NOT RECOVERED/NOT RESOLVED	Changed Information
Oct-19-2020 12:49:18 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	For AE Exposure to PI during pregnancy: Response to "What was the outcome of this adverse event?" is 3 but End Date/Time is missing.
Oct-19-2020 12:49:18 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> RECOVERED/RESOLVED	Initial Entry

14. Did the adverse event cause the subject to be discontinued from the study?

Date	Location	User	Value	Reason
Oct-19-2020 12:49:18 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

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**1. Category:**

Date	Location	User	Value	Reason
Nov-10-2020 16:24:56 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> ADVERSE EVENT	Initial Entry

**2. AE ID:**

Date	Location	User	Value	Reason
Nov-10-2020 16:24:56 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 4	Initial Entry

**3. Adverse Event:**

*(If possible specify diagnosis, not individual symptoms)*

Date	Location	User	Value	Reason
Nov-10-2020 16:24:56 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Injection site pain	Initial Entry

**4. Start Date Time:**

Date	Location	User	Value	Reason
Nov-10-2020 16:24:56 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Aug/25/2020 12:30	Initial Entry

**5. Is the adverse event still ongoing?**

Date	Location	User	Value	Reason
Nov-10-2020 16:24:56 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO End Date Time: Aug/25/2020 14:00	Initial Entry

**6. Toxicity Grade:**

Date	Location	User	Value	Reason
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Subject Initials: ---

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Nov-10-2020 16:24:56 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 1	Initial Entry
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7. Is the adverse event serious?

If Yes, NOTIFY PFIZER IMMEDIATELY.

Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).

Date	Location	User	Value	Reason
Nov-10-2020 16:24:56 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

8. Is this adverse event the result of a study Medication Error?

If Yes, record the type of medication error on the Medication Error Log.

Date	Location	User	Value	Reason
Nov-10-2020 16:24:56 (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
Nov-10-2020 16:24:56 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> RELATED	Initial Entry

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Nov-10-2020 16:24:56 (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
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090177e196ae2eca\Final\Final On: 01-Apr-2021 03:23 (GMT)

**Header Text:** C4591001

**Visit:** Logs - Unscheduled

**Form Version:** 22-Apr-2020 21:02

**Site No:** 1231

**Subject No:** 12313879

**Generated By:** (b) (4)

**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site Name:** (1231) Hospital Militar Central Cirujano Mayor Dr. Cosme Argerich

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 20:34

Nov-10-2020 16:24:56 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry
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**12. Was a Non-Drug Treatment given?**

Date	Location	User	Value	Reason
Nov-10-2020 16:24:56 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**13. What was the outcome of this adverse event?:**

Date	Location	User	Value	Reason
Nov-10-2020 16:24:56 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> RECOVERED/RESOLVED	Initial Entry

**14. Did the adverse event cause the subject to be discontinued from the study?**

Date	Location	User	Value	Reason
Nov-10-2020 16:24:56 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

090177e196ae2eca\Final\Final On: 01-Apr-2021 03:23 (GMT)

Header Text: C4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1231

Subject No: 12313879

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen

Site Name: (1231) Hospital Militar Central Cirujano Mayor Dr. Cosme Argerich

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 20:34

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**1. Category:**

Date	Location	User	Value	Reason
Feb-10-2021 10:30:38 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> ADVERSE EVENT	Initial Entry

**2. AE ID:**

Date	Location	User	Value	Reason
Feb-10-2021 10:30:38 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 5	Initial Entry

**3. Adverse Event:**

*(If possible specify diagnosis, not individual symptoms)*

Date	Location	User	Value	Reason
Feb-24-2021 00:25:26 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (4), (b) (6)	Query 3: Closed	Response satisfies query
Feb-23-2021 12:18:52 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Answered	Pregnancy is not an SAE, Complicated UTI instead is. Pregnancy is mentioned as patient medical history to give background on why the UTI is considered as complicated. It will not be removed.
Feb-22-2021 23:54:29 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (4), (b) (6)	Query 3: Opened	Clinical - SAE report (#2021139760) for 'Suspected UTI' reports pregnancy as a 2nd SAE event using the Event section of the SAE report. This double reports the pregnancy (reported in #2020398348); please remove from SAE event section of UTI SAE.

090177e196ae2eca\Final\Final On: 01-Apr-2021 03:23 (GMT)

**Header Text:** C4591001  
**Visit:** Logs - Unscheduled  
**Form Version:** 22-Apr-2020 21:02  
**Site No:** 1231  
**Subject No:** 12313879  
**Generated By:** (b) (4)

**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History  
**Form Status:** Data Complete, Locked, Frozen  
**Site Name:** (1231) Hospital Militar Central Cirujano Mayor Dr. Cosme Argerich  
**Subject Initials:** ---  
**Generated Time (GMT):** 29-Mar-2021 20:34

Feb-22-2021 15:54:07 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Closed	Response satisfies query
Feb-22-2021 15:51:15 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Feb-18-2021 13:31:48 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	At the moment there is no more information. It will be updated as soon as it is available. Thank you.
Feb-18-2021 13:31:06 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Answered	SAE FU was sent with this information.
Feb-16-2021 18:28:55 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Opened	Clinical - please submit a SAE update reporting the 1st day of Last Menstrual Period (10Sep20), as this is the reported start date for the pregnancy
Feb-16-2021 18:12:07 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	Clinical Please update Suspected if complicated UTI is now determined to be a definite event
Feb-10-2021 10:30:38 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Suspected Complicated Urinary Tract Infection	Initial Entry

#### 4. Start Date Time:

Date	Location	User	Value	Reason
Feb-10-2021 10:30:38 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Jan/31/2021 09:30	Initial Entry

#### 5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Feb-19-2021 11:32:48 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO End Date Time:	New Information



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Site No: 1231

Subject No: 12313879

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen

Site Name: (1231) Hospital Militar Central Cirujano Mayor Dr. Cosme Argerich

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 20:34

			Feb/17/2021 21:00	
Feb-10-2021 10:30:38 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

6. Toxicity Grade:

Date	Location	User	Value	Reason
Feb-10-2021 10:30:38 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 3	Initial Entry

7. Is the adverse event serious?

If Yes, NOTIFY PFIZER IMMEDIATELY.

Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).

Date	Location	User	Value	Reason
Feb-22-2021 23:51:37 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Closed	Response satisfies query
Feb-18-2021 13:29:31 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Answered	SAE FU was sent clarifying. Thank you.
Feb-16-2021 18:37:59 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Opened	CLINICAL - in SAE report, Race is reported as Caucasian; however, Demog CRF has Race as American Indian / Alaskan native. Please harmonize and update where required. IF Demog CRF requires update, inform and Safety will request CRF unlock
Feb-11-2021 05:21:27 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query

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**Header Text:** C4591001**Visit:** Logs - Unscheduled**Form Version:** 22-Apr-2020 21:02**Site No:** 1231**Subject No:** 12313879**Generated By:** (b) (4)**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History**Form Status:** Data Complete, Locked, Frozen**Site Name:** (1231) Hospital Militar Central Cirujano Mayor Dr. Cosme Argerich**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 20:34

Feb-10-2021 10:30:38 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	For AE Suspected Complicated Urinary Tract Infection: Response to "Is the adverse event serious?" is 'Yes' but "Serious Adverse Event Number" is blank.
Feb-10-2021 10:30:38 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<p><b>Data Entry:</b></p> <p>YES</p> <p>Is this serious event associated with congenital anomaly or birth defect?</p> <p>NO</p> <p>Did this serious event result in death?</p> <p>NO</p> <p>Did this serious event require or prolong hospitalization?</p> <p>NO</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>	Initial Entry

**8. Is this adverse event the result of a study Medication Error?***If Yes, record the type of medication error on the Medication Error Log.*

Date	Location	User	Value	Reason
Feb-10-2021 10:30:38	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>	Initial Entry

Header Text: C4591001

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Site No: 1231

Subject No: 12313879

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen

Site Name: (1231) Hospital Militar Central Cirujano Mayor Dr. Cosme Argerich

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 20:34

(UTC-03:00) City of Buenos Aires	(b) (4), (b) (6)	NO
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9. Is this event related to study treatment:

Date	Location	User	Value	Reason
Feb-10-2021 10:30:38 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NOT RELATED If Not Related to study treatment(s), this event is due to:  OTHER  If Other, specify:  unknown	Initial Entry

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Feb-10-2021 10:30:38 (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-10-2021 10:30:38 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Feb-10-2021 10:30:38 (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-19-2021 11:33:03 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Feb-19-2021 11:33:03 (UTC-03:00) City of	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> RECOVERED/RESOLVED	New Information

090177e196ae2eca\Final\Final On: 01-Apr-2021 03:23 (GMT)

**Header Text:** C4591001

**Visit:** Logs - Unscheduled

**Form Version:** 22-Apr-2020 21:02

**Site No:** 1231

**Subject No:** 12313879

**Generated By:** (b) (4)

**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History

**Form Status:** Data Complete, Locked, Frozen

**Site Name:** (1231) Hospital Militar Central Cirujano Mayor Dr. Cosme Argerich

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 20:34

Buenos Aires				
Feb-19-2021 11:32:48 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	For AE Suspected Complicated Urinary Tract Infection: Response to "What was the outcome of this adverse event?" is 'Not Recovered/Not Resolved' but AE End Date/Time is present.
Feb-10-2021 10:30:38 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NOT RECOVERED/NOT RESOLVE D	Initial Entry

**14. Did the adverse event cause the subject to be discontinued from the study?**

Date	Location	User	Value	Reason
Feb-10-2021 10:30:38 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**15. Serious Adverse Event Number: For Pfizer Use Only**

Date	Location	User	Value	Reason
Feb-11-2021 05:21:27 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 2021139760	Initial Entry

090177e196ae2eca\Final\Final On: 01-Apr-2021 03:23 (GMT)

Header Text: C4591001

Visit: Disposition - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1231

Subject No: 12313879

Generated By: (b) (4)

Form: TREATMENT UNBLINDED - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1231) Hospital Militar Central Cirujano Mayor Dr. Cosme Argerich

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 20:34

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**1. Date Treatment Unblinded :**

Date	Location	User	Value	Reason
Mar-16-2021 12:07:29 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Mar/16/2021	Initial Entry

**2. Primary Reason for Unblinding:**

Date	Location	User	Value	Reason
Mar-17-2021 13:21:36 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Mar-17-2021 09:01:14 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	The participant is finally not willing to return for vaccination 3 due to being pregnant. Thank you
Mar-16-2021 20:43:36 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (b) (4)	Query 1: Opened	DMW7768796;Primary Reason for Unblinding is "ASSESS ELIGIBILITY FOR ADDITIONAL VACCINATION", but "Participant is willing to return for Vaccination 3" is not selected in the Further Vaccination Confirmation CRF. Please review and update as appropriate.
Mar-16-2021 12:07:29 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> ASSESS ELIGIBILITY FOR ADDITIONAL VACCINATION	Initial Entry

090177e196ae2eca\Final\Final On: 01-Apr-2021 03:23 (GMT)

Header Text: C4591001

Visit: Subject Status - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1231

Subject No: 12313879

Generated By: (b) (4)

Form: SUBJECT STATUS - eCRF Audit Trail History

Form Status: Data Complete, Verified

Site Name: (1231) Hospital Militar Central Cirujano Mayor Dr. Cosme Argerich

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 20:34

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**1. Subject Status**

Date	Location	User	Value	Reason
Oct-14-2020 16:55:39 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> FOLLOW-UP	Initial Entry
Aug-25-2020 13:52:43 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> ENROLLED/RANDOMIZED	Initial Entry
Aug-25-2020 13:51:51 (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
Oct-14-2020 16:55:39 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> Oct/13/2020	Initial Entry
Aug-25-2020 13:52:43 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> Aug/25/2020	Initial Entry
Aug-25-2020 13:51:51 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> Aug/25/2020	Initial Entry

090177e196ae2eca\Final\Final On: 01-Apr-2021 03:23 (GMT)

**Header Text:** C4591001

**Visit:** Investigator Signature - Unscheduled

**Form Version:** 22-Apr-2020 21:04

**Site No:** 1231

**Subject No:** 12313879

**Generated By:** (b) (4)

**Form:** CASEBOOK SIGNATURE FORM - eCRF Audit Trail History

**Form Status:** Data Complete, Signed, Verified

**Site Name:** (1231) Hospital Militar Central Cirujano Mayor Dr. Cosme Argerich

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 20:34

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*I. Casebook Signature*

Date	Location	User	Value	Reason
Oct-22-2020 11:47:28 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Click Here to Enable	Initial Entry

090177e196ae2eca\Final\Final On: 01-Apr-2021 03:23 (GMT)