

Header Text: C4591001

Visit: COHORT_SELECTION

Form: COHORT SELECTION

Form Version: 30-Jul-2020 21:29

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1231

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

Subject No: 12313884

Subject Initials: ---

Generated By:

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

(b) (4)

[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

090177e196ae2e8f\Final\Final On: 01-Apr-2021 03:16 (GMT)

Header Text: C4591001

Visit: COHORT_SELECTION

Form Version: 22-Apr-2020 21:02

Site No: 1231

Subject No: 12313884

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
----	--------------	--

Header Text: C4591001

Visit: COHORT_SELECTION

Form: DEMOGRAPHY

Form Version: 06-Jul-2020 21:55

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1231

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

Subject No: 12313884

Subject Initials: ---

Generated By:

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

(b) (4)

[eCRF Audit Trail History](#)

Demography

1.	Subject ID	[12313884]
2.	Birth Date:	(b) (6)/1987
3.	Sex:	FEMALE
4.	Ethnicity:	HISPANIC OR LATINO(A) OR OF SPANISH ORIGIN
5.	Race: (Check X all that apply):	WHITE
6.	Racial Designation:	

090177e196ae2e8f\Final\Final On: 01-Apr-2021 03:16 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:02

Site No: 1231

Subject No: 12313884

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: 12313884

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 _____
----	--	-------------------------

Exclusion Criteria Met

2.	Description of Exclusion Criterion Met	Not Applicable _____
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090177e196ae2e8f\Final\Final On: 01-Apr-2021 03:16 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1231

Subject No: 12313884

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: 12313884

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 _____

090177e196ae2e8f\Final\Final On: 01-Apr-2021 03:16 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form: VITAL SIGNS - BASELINE

Form Version: 21-Aug-2020 02:51

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1231

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

Subject No: 12313884

Subject Initials: ---

Generated By:

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

(b) (4)

[eCRF Audit Trail History](#)

Vital Signs

1.	Date:	Aug/25/2020
2.	Weight:	[88.0]
3.	Unit:	kg
4.	Height:	[171.0]
5.	Unit:	cm
6.	Body Mass Index:	[30.1]

Vital Signs Details

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

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 21-Aug-2020 02:49

Site No: 1231

Subject No: 12313884

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:	

090177e196ae2e8f\Final\Final On: 01-Apr-2021 03:16 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1231

Subject No: 12313884

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:	[65560]
3.	Randomization Group:	[]

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1231

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

Subject No: 12313884

Subject Initials: ---

Generated By:

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

(b) (4)

[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	[BP24YJ]
5.b	Sample ID	[BP24YK]
5.c	Sample ID	[BP24YL]
5.d	Sample ID	[BLDZFD]
5.e	Sample ID	[BLDZFF]

090177e196ae2e8f\Final\Final On: 01-Apr-2021 03:16 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1231

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

Subject No: 12313884

Subject Initials: ---

Generated By:

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

(b) (4)

[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	[BP2F4D]
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Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:04

Site No: 1231

Subject No: 12313884

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 12:50
5.	Anatomical Location:	DELTOID MUSCLE
6.	Body Side:	RIGHT
7.	Route:	INTRAMUSCULAR
8.	Actual Dose:	[]
9.	Unit:	
10.	Timeframe Subject Was Observed	THE PROTOCOL SPECIFIED OBSERVATION PERIOD
11.	Was the subject observed for at least the protocol specified observation period after investigational product administration?	YES

090177e196ae2e8f\Final\Final On: 01-Apr-2021 03:16 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 06-Jul-2020 21:53

Site No: 1231

Subject No: 12313884

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: 12313884

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/16/2020
2.	Erroneous Visit	

Header Text: C4591001

Visit: V2_VAX2_L

Form Version: 15-Sep-2020 21:54

Site No: 1231

Subject No: 12313884

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/16/2020
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Vital Signs Details

2.a	Record Identifier:	1
	Temperature:	[36.8]
	Unit:	C
	Temperature Location:	ORAL CAVITY

090177e196ae2e8f\Final\Final On: 01-Apr-2021 03:16 (GMT)

Header Text: C4591001

Visit: V2_VAX2_L

Form Version: 21-Aug-2020 02:49

Site No: 1231

Subject No: 12313884

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/16/2020
4.	Laboratory Name and Address (Derived)	[STUDY SITE]
5.	Specimen Type:	URINE

Lab Result

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

090177e196ae2e8f\Final\Final On: 01-Apr-2021 03:16 (GMT)

Header Text: C4591001

Visit: V2_VAX2_L

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1231

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

Subject No: 12313884

Subject Initials: ---

Generated By:

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

(b) (4)

[eCRF Audit Trail History](#)

Electronic Sample Tracking

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB
3.	Sample Collected?	YES Date of Collection: Sep/16/2020
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[]

Aliquot

Please enter barcode for each aliquot.

5.a	Sample ID	[BP2B7R]
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Header Text: C4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:04

Site No: 1231

Subject No: 12313884

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/16/2020 09:42
5.	Anatomical Location:	DELTOID MUSCLE
6.	Body Side:	RIGHT
7.	Route:	INTRAMUSCULAR
8.	Actual Dose:	[]
9.	Unit:	
10.	Timeframe Subject Was Observed	THE PROTOCOL SPECIFIED OBSERVATION PERIOD
11.	Was the subject observed for at least the protocol specified observation period after investigational product administration?	YES

090177e196ae2e8f\Final\Final On: 01-Apr-2021 03:16 (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: 12313884

Subject Initials: ---

Generated By:

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

(b) (4)

[eCRF Audit Trail History](#)

Date of Visit

1.	Date of Visit	Oct/14/2020
2.	Erroneous Visit	

Header Text: C4591001

Visit: V3_MONTH1_POSTVAX2_L **Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

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

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

Subject No: 12313884 **Subject Initials:** ---

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

(b) (4)

[eCRF Audit Trail History](#)

Electronic Sample Tracking

1.	Data Origin	SITE
2.	Sample Type	SERUM
3.	Sample Collected?	YES Date of Collection: Oct/14/2020
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	[BRXRV5]
5.b	Sample ID	[BP1NFJ]
5.c	Sample ID	[BRXRW1]

090177e196ae2e8f\Final\Final On: 01-Apr-2021 03:16 (GMT)

Header Text: C4591001

Visit: V4_MONTH6_L

Form Version: 22-Apr-2020 21:02

Site No: 1231

Subject No: 12313884

Generated By:

(b) (4)

Form: DATE OF VISIT

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](#)

Date of Visit

1.	Date of Visit	Mar/20/2021
2.	Erroneous Visit	

Header Text: C4591001**Visit:** V4_MONTH6_L**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY**Form Version:** 22-Apr-2020 21:03**Form Status:** Data Complete, Frozen, Verified**Site No:** 1231**Site Name:** (1231) Hospital Militar Central Cirujano Mayor Dr. Cosme Argerich**Subject No:** 12313884**Subject Initials:** ---**Generated By:****Generated Time (GMT):** 29-Mar-2021 20:34

(b) (4)

[eCRF Audit Trail History](#)**Electronic Sample Tracking**

1.	Data Origin	SITE
2.	Sample Type	SERUM
3.	Sample Collected?	YES Date of Collection: Mar/20/2021
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	[BR1YLD]
5.b	Sample ID	[BS1P57]
5.c	Sample ID	[BS1TXN]

Header Text: C4591001

Visit: V5_MONTH12_L

Form Version: 22-Apr-2020 21:02

Site No: 1231

Subject No: 12313884

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: 12313884

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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090177e196ae2e8f\Final\Final On: 01-Apr-2021 03:16 (GMT)

Header Text: C4591001

Visit: V6_MONTH24_L

Form Version: 22-Apr-2020 21:02

Site No: 1231

Subject No: 12313884

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: 12313884

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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Header Text: C4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Sep/27/2020

Form Version: 22-Apr-2020 21:03

Site No: 1231

Subject No: 12313884

Generated By:

(b) (4)

Form: DATE OF VISIT - ILLNESS ONSET

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](#)

Date of Visit

1.	Date of Visit	Sep/27/2020
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/27/2020

Form Version: 15-Sep-2020 21:55

Site No: 1231

Subject No: 12313884

Generated By:

(b) (4)

Form: SIGNS AND SYMPTOMS OF POTENTIAL
COVID-19

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](#)

Signs and Symptoms

1.	Date of Assessment:	Sep/27/2020
2.	Date of First Symptom Started:	Sep/25/2020
3.	Symptoms Ongoing?	NO Date of Last Symptom Resolved: Oct/1/2020

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

090177e196ae2e8f\Final\Final On: 01-Apr-2021 03:16 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Sep/27/2020

Form Version: 15-Sep-2020 21:55

Site No: 1231

Subject No: 12313884

Generated By:

(b) (4)

Form: SIGNS AND SYMPTOMS OF POTENTIAL
COVID-19

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

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		
5.a	Symptoms - Other Text:	[rhinorrhea]

090177e196ae2e8f\Final\Final On: 01-Apr-2021 03:16 (GMT)

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: 12313884

Subject Initials: ---

Generated By:

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

(b) (4)

#	Date of Collection	Specimen Type	Specimen Collection Location	Assay Code and Description	Device Type	Form Instance
1.	Sep/26/2020	SWABBED MATERIAL	NASOPHARYNX	SEVERE ACUTE RESPIRATORY SYNDROME CORONAVIRUS 2	SARS-COV-2 DIAGNOSTIC TEST	Repeating Pages

090177e196ae2e8f\Final\Final On: 01-Apr-2021 03:16 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Sep/27/2020

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: 12313884

Subject Initials: ---

Generated By:

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

(b) (4)

[Back to Form](#)
[eCRF Audit Trail History](#)
[Form Audit Trail](#)

Microbiology Specimen

1.	Actual Date of Collection:	Sep/26/2020
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:	[]

090177e196ae2e8f\Final\Final On: 01-Apr-2021 03:16 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Sep/27/2020

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: 12313884

Subject Initials: ---

Generated By:

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

(b) (4)

[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 team physician]

Aliquot

Please enter barcode for each aliquot.

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

090177e196ae2e8f\Final\Final On: 01-Apr-2021 03:16 (GMT)

Header Text: C4591001**Visit:** POT_COVID_ILL 1 -
Unscheduled Visit on Sep/27/2020**Form Version:** 22-Apr-2020 21:03**Site No:** 1231**Subject No:** 12313884**Generated By:**

(b) (4)

Form: ELECTRONIC SAMPLE TRACKING - NASAL
SWAB**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](#)**Electronic Sample Tracking**

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB
3.	Sample Collected?	YES Date of Collection: Sep/27/2020
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	[BPWSKB]
5.b	Sample ID	[BPWSKB]

Header Text: C4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Sep/27/2020

Form: HEALTH CARE UTILIZATION

Form Version: 15-Sep-2020 21:53

Form Status: Data Complete, Frozen, Verified

Site No: 1231

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

Subject No: 12313884

Subject Initials: ---

Generated By:

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

(b) (4)

[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

090177e196ae2e8f\Final\Final On: 01-Apr-2021 03:16 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Sep/27/2020

Form: HEALTH CARE UTILIZATION

Form Version: 15-Sep-2020 21:53

Form Status: Data Complete, Frozen, Verified

Site No: 1231

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

Subject No: 12313884

Subject Initials: ---

Generated By:

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

(b) (4)

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

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: 12313884

Subject Initials: ---

Generated By:

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

(b) (4)

#	Treatment Identifier	Con Non-Drug Treatments Pre-specified	Treatm ent	Treatm ent	Start D ate	Form Instanc e
1.						Repeating Pages

Header Text: C4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Sep/27/2020

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: 12313884

Subject Initials: ---

Generated By:

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

(b) (4)

[Back to Form](#)

Respiratory Treatment

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

090177e196ae2e8f\Final\Final On: 01-Apr-2021 03:16 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Sep/27/2020

Form Version: 06-Jul-2020 21:52

Site No: 1231

Subject No: 12313884

Generated By:

(b) (4)

Form: ILLNESS DETAILS

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](#)

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

090177e196ae2e8f\Final\Final On: 01-Apr-2021 03:16 (GMT)

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: 12313884

Subject Initials: ---

Generated By:

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

(b) (4)

#	Category of Clinical Event:	Subcategory of Clinical Event	Diagnosis Obtained	Toxicity Grade	Form Instance
1.					Repeating Pages

Header Text: C4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Sep/27/2020

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: 12313884

Subject Initials: ---

Generated By:

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

(b) (4)

[Back to Form](#)

Illness Details

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

090177e196ae2e8f\Final\Final On: 01-Apr-2021 03:16 (GMT)

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: 12313884

Subject Initials: ---

Generated By:

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

(b) (4)

#	Category for Lab Test	Vendor Name	Collection Date:	Specimen Type	Lab Result			Form Instance
1.					Sponsor-Defined Identifier	Test:	Result:	Repeating Pages

Header Text: C4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Sep/27/2020

Form Version: 21-Aug-2020 02:49

Site No: 1231

Subject No: 12313884

Generated By:

(b) (4)

Form: LOCAL LABORATORY DATA - REPEATING
CHEMISTRY

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

[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

090177e196ae2e8f\Final\Final On: 01-Apr-2021 03:16 (GMT)

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: 12313884

Subject Initials: ---

Generated By:

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

(b) (4)

#	Category for Lab Test	Vendor Name (DERIVED)	Collection Date	Specimen Type	Lab Result			Form Instance
1.					Sponsor-Defined Identifier	Test:	Result:	Repeating Pages

090177e196ae2e8f\Final\Final On: 01-Apr-2021 03:16 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Sep/27/2020

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: 12313884

Subject Initials: ---

Generated By:

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

(b) (4)

[Back to Form](#)

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

090177e196ae2e8f\Final\Final On: 01-Apr-2021 03:16 (GMT)

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: 12313884

Subject Initials: ---

Generated By:

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

(b) (4)

#	Date:	Vital Signs Details			Form Instance
1.		Record Identifier:	Systolic:	Diastolic:	Repeating Pages

Header Text: C4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Sep/27/2020

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: 12313884

Subject Initials: ---

Generated By:

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

(b) (4)

[Back to Form](#)

Vital Signs

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

Vital Signs Details

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

090177e196ae2e8f\Final\Final On: 01-Apr-2021 03:16 (GMT)

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: 12313884

Subject Initials: ---

Generated By:

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

(b) (4)

#	Date:	Vital Signs Details		Form Instance
1.		Record Identifier:	Oxygen Saturation	Repeating Pages

Header Text: C4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Sep/27/2020

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: 12313884

Subject Initials: ---

Generated By:

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

(b) (4)

[Back to Form](#)

Vital Signs

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

Vital Signs Details

2.	Record Identifier:	
	SPO2 Pulse Oximetry %	[]

090177e196ae2e8f\Final\Final On: 01-Apr-2021 03:16 (GMT)

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: 12313884

Subject Initials: ---

Generated By:

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

(b) (4)

#	Date Time of Assessment	Arterial Blood Gases PaO2	FiO2 (Fraction of Inhaled Oxygen)	Form Instance
1.				Repeating Pages

Header Text: C4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Sep/27/2020

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: 12313884

Subject Initials: ---

Generated By:

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

(b) (4)

[Back to Form](#)

Oxygenation Parameters

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

090177e196ae2e8f\Final\Final On: 01-Apr-2021 03:16 (GMT)

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: 12313884

Subject Initials: ---

Generated By:

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

(b) (4)

#	Sponsor-Defined Identifier	Category for Medication	Concomitant Medications Pre-specified	Name of Medication	Start Date	Form Instance
1.						Repeating Pages

Header Text: C4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Sep/27/2020

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: 12313884

Subject Initials: ---

Generated By:

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

(b) (4)

[Back to Form](#)

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?	

090177e196ae2e8f\Final\Final On: 01-Apr-2021 03:16 (GMT)

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: 12313884

Subject Initials: ---

Generated By:

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

(b) (4)

#	Date of Assessment	Location of Assessment	Imaging Method	Overall Assessment	Form Instance
1.					Repeating Pages

Header Text: C4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Sep/27/2020

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: 12313884

Subject Initials: ---

Generated By:

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

(b) (4)

[Back to Form](#)

Imaging

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

090177e196ae2e8f\Final\Final On: 01-Apr-2021 03:16 (GMT)

Header Text: C4591001

Visit: POT_COVID_CONVA 1 -
Unscheduled Visit on Oct/30/2020

Form Version: 22-Apr-2020 21:04

Site No: 1231

Subject No: 12313884

Generated By:

(b) (4)

Form: DATE OF VISIT - ILLNESS CONVALESCENT

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](#)

Date of Visit

1.	Date of Visit	Oct/30/2020
2.	Erroneous Visit	

COVID-19 Illness Visit

3.	COVID-19 Illness Visit:	COVID_A1
----	-------------------------	----------

090177e196ae2e8f\Final\Final On: 01-Apr-2021 03:16 (GMT)

Header Text: C4591001

Visit: POT_COVID_CONVA 1 -
Unscheduled Visit on Oct/30/2020

Form Version: 22-Apr-2020 21:03

Site No: 1231

Subject No: 12313884

Generated By:

(b) (4)

Form: ELECTRONIC SAMPLE TRACKING -
IMMUNOGENICITY

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](#)

Electronic Sample Tracking

1.	Data Origin	SITE
2.	Sample Type	SERUM
3.	Sample Collected?	YES Date of Collection: Oct/30/2020
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	[BPWDPP]
5.b	Sample ID	[BJ5N9B]
5.c	Sample ID	[BJ5NC2]

090177e196ae2e8f\Final\Final On: 01-Apr-2021 03:16 (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: 12313884 **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: 12313884 **Subject Initials:** ---

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

(b) (4)

Unplanned Assessments

1.	Assessments	
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Header Text: C4591001

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

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

Site No: 1231

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

Subject No: 12313884

Subject Initials: ---

Generated By:

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

(b) (4)

[eCRF Audit Trail History](#)

Disposition - Treatment

1.	Date of Completion/Discontinuation/Death :	Oct/14/2020
2.	Phase of Disposition:	VACCINATION
3.	Status:	COMPLETED
4.	Specify Status:	[]

090177e196ae2e8f\Final\Final On: 01-Apr-2021 03:16 (GMT)

Header Text: C4591001

Visit: Follow-Up - Unscheduled

Form Version: 15-Sep-2020 21:53

Site No: 1231

Subject No: 12313884

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 **Form:** DATE OF VISIT - REPEAT SWAB
- New Unscheduled Visit

Form Version: 10-Oct-2020 15:57

Form Status: Not Started

Site No: 1231

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

Subject No: 12313884

Subject Initials: ---

Generated By:

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

(b) (4)

Date of Visit

1.	Date of Visit	//
2.	Erroneous Visit	

COVID-19 Repeat Swab

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

Header Text: C4591001

Visit: POT_COVID_REPEAT_SWAB - New Unscheduled Visit **Form:** ELECTRONIC SAMPLE TRACKING - REPEAT SWAB

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

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

Subject No: 12313884 **Subject Initials:** ---

Generated By: (b) (4) **Generated Time (GMT):** 29-Mar-2021 20:34

Electronic Sample Tracking

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

Aliquot

Please enter barcode for each aliquot.

5.	Sample ID	[]
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Header Text: C4591001

Visit: 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: 12313884

Subject Initials: ---

Generated By:

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

(b) (4)

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: 12313884

Subject Initials: ---

Generated By:

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

(b) (4)

Vital Signs

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

Vital Signs Details

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

090177e196ae2e8f\Final\Final On: 01-Apr-2021 03:16 (GMT)

Header Text: C4591001**Visit:** Unplanned Vaccination -
Unscheduled**Form:** LAB URINALYSIS - PREGNANCY TEST**Form Version:** 20-Feb-2021 02:14**Form Status:** Not Started**Site No:** 1231**Site Name:** (1231) Hospital Militar Central Cirujano
Mayor Dr. Cosme Argerich**Subject No:** 12313884**Subject Initials:** ---**Generated By:****Generated Time (GMT):** 29-Mar-2021 20:34

(b) (4)

Lab Urinalysis

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

Lab Result

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

Header Text: C4591001

Visit: Unplanned Vaccination -
Unscheduled

Form: VACCINATION

Form Version: 10-Dec-2020 02:26

Form Status: Not Started

Site No: 1231

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

Subject No: 12313884

Subject Initials: ---

Generated By:

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

(b) (4)

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?	

090177e196ae2e8f\Final\Final On: 01-Apr-2021 03:16 (GMT)

Header Text: C4591001

Visit: Unplanned Vaccination -
Unscheduled

Form Version: 10-Oct-2020 15:57

Site No: 1231

Subject No: 12313884

Generated By:

(b) (4)

Form: CONTACT OUTCOME - MONTH 1

Form Status: Not Started

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

Subject Initials: ---

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

Contact Outcome

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

Header Text: C4591001

Visit: Unplanned Vaccination -
Unscheduled

Form: CONTACT OUTCOME - MONTH 6

Form Version: 10-Oct-2020 16:01

Form Status: Not Started

Site No: 1231

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

Subject No: 12313884

Subject Initials: ---

Generated By:

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

(b) (4)

Contact Outcome

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

Header Text: C4591001

Visit: V201_SURVEIL_CONSENT - **Form:** DATE OF VISIT
Unscheduled

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

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

Subject No: 12313884 **Subject Initials:** ---

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

(b) (4)

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: 12313884

Subject Initials: ---

Generated By:

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

(b) (4)

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:** 12313884**Subject Initials:** ---**Generated By:****Generated Time (GMT):** 29-Mar-2021 20:34

(b) (4)

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: 12313884

Subject Initials: ---

Generated By:

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

(b) (4)

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	[]
----	-----------	-----

090177e196ae2e8f\Final\Final On: 01-Apr-2021 03:16 (GMT)

Header Text: C4591001

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

Unscheduled

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen, Verified

Site No: 1231

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

Subject No: 12313884

Subject Initials: ---

Generated By:

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

(b) (4)

[eCRF Audit Trail History](#)

Date of Visit		
1.	Date of Visit	Jan/19/2021
2.	Erroneous Visit	

Header Text: C4591001

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

Form Version: 10-Dec-2020 02:25

Form Status: Data Complete, Frozen, Verified

Site No: 1231

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

Subject No: 12313884

Subject Initials: ---

Generated By:

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

(b) (4)

[eCRF Audit Trail History](#)

Further Vaccination Confirmation

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

Header Text: C4591001

Visit: 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: 12313884

Subject Initials: ---

Generated By:

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

(b) (4)

#	Category	AE Identifier	Adverse Event	Start Date	Is the Adverse Event Still Ongoing	Form Instance
1.	ADVERSE EVENT	1	right axillary adenopathy	Sep/18/2020 12:00	NO End Date Time: Sep/22/2020 17:00	Repeating Pages

090177e196ae2e8f\Final\Final On: 01-Apr-2021 03:16 (GMT)

Header Text: C4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Locked, Frozen

Site No: 1231

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

Subject No: 12313884

Subject Initials: ---

Generated By:

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

(b) (4)

[Back to Form](#)

[eCRF Audit Trail History](#)

[Form Audit Trail](#)

Adverse Event Report

1.	Category:	ADVERSE EVENT
2.	AE ID:	[1]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[right axillary adenopathy]
4.	Start Date Time:	Sep/18/2020 12:00
5.	Is the adverse event still ongoing?	NO End Date Time: Sep/22/2020 17:00
6.	Toxicity Grade:	1

090177e196ae2e8f\Final\Final On: 01-Apr-2021 03:16 (GMT)

Header Text: C4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1231

Subject No: 12313884

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

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

090177e196ae2e8f\Final\Final On: 01-Apr-2021 03:16 (GMT)

Header Text: C4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Locked, Frozen

Site No: 1231

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

Subject No: 12313884

Subject Initials: ---

Generated By:

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

(b) (4)

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

090177e196ae2e8f\Final\Final On: 01-Apr-2021 03:16 (GMT)

Header Text: C4591001

Visit: Logs

Form: MEDICATION ERROR

Form Version: 17-Jul-2020 21:54

Site No: 1231

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

Subject No: 12313884

Subject Initials: ---

Generated By:

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

(b) (4)

#	Category	Medication Error	Start Date	Is the medication error Still Ongoing	Study Medication Errors Action	Form Instance
1.						Repeating Pages

Header Text: C4591001

Visit: Logs - Unscheduled

Form: MEDICATION ERROR

Form Version: 17-Jul-2020 21:54

Form Status: Not Started

Site No: 1231

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

Subject No: 12313884

Subject Initials: ---

Generated By:

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

(b) (4)

[Back to Form](#)

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	[]

090177e196ae2e8f\Final\Final On: 01-Apr-2021 03:16 (GMT)

Header Text: C4591001

Visit: Logs

Form: CONCOMITANT MEDICATIONS - NON STUDY VACCINATIONS

Form Version: 22-Apr-2020 21:03

Site No: 1231

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

Subject No: 12313884

Subject Initials: ---

Generated By:

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

(b) (4)

#	Sponsor-Defined Identifier	Category for Medication	Concomitant Medications Pre-specified	Name of Medication	Start Date	Form Instance
1.						Repeating Pages

090177e196ae2e8f\Final\Final On: 01-Apr-2021 03:16 (GMT)

Header Text: C4591001

Visit: Logs - Unscheduled

Form: CONCOMITANT MEDICATIONS - NON STUDY VACCINATIONS

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1231

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

Subject No: 12313884

Subject Initials: ---

Generated By:

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

(b) (4)

[Back to Form](#)

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:	//

090177e196ae2e8f\Final\Final On: 01-Apr-2021 03:16 (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: 12313884

Subject Initials: ---

Generated By:

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

(b) (4)

#	Sponsor-Defined Identifier	Category for Medication	Concomitant Medications Pre-specified	Name of Medication	Dose Description	Form Instance
1.						Repeating Pages

090177e196ae2e8f\Final\Final On: 01-Apr-2021 03:16 (GMT)

Header Text: C4591001

Visit: Logs - Unscheduled

Form: CONCOMITANT MEDICATIONS - PROHIBITED

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1231

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

Subject No: 12313884

Subject Initials: ---

Generated By:

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

(b) (4)

[Back to Form](#)

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?	

090177e196ae2e8f\Final\Final On: 01-Apr-2021 03:16 (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: 12313884

Subject Initials: ---

Generated By:

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

(b) (4)

#	Category	Treatment Identifier	Con Non-Drug Treatments Pre-specified	Treatment	Start Date	Form Instance
1.						Repeating Pages

Header Text: C4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1231

Subject No: 12313884

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

[Back to Form](#)

Radiation Treatment

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

090177e196ae2e8f\Final\Final On: 01-Apr-2021 03:16 (GMT)

Header Text: C4591001

Visit: Logs

Form: TRANSFUSIONS

Form Version: 22-Apr-2020 21:03

Site No: 1231

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

Subject No: 12313884

Subject Initials: ---

Generated By:

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

(b) (4)

#	Transfusion Type	Date of Transfusion	Form Instance
1.			Repeating Pages

Header Text: C4591001

Visit: Logs - Unscheduled

Form: TRANSFUSIONS

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1231

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

Subject No: 12313884

Subject Initials: ---

Generated By:

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

(b) (4)

[Back to Form](#)

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: 12313884

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: 12313884

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: 12313884

Generated By:

(b) (4)

Form: TREATMENT UNBLINDED

Form Status: Data Complete, Frozen, Verified

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

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Treatment Unblinded

1.	Date Treatment Unblinded :	Jan/19/2021
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: 12313884

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: 12313884

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: SUBJECT STATUS

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Verified

Site No: 1231

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

Subject No: 12313884

Subject Initials: ---

Generated By:

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

(b) (4)

[eCRF Audit Trail History](#)

Subject Status

1.	Subject Status	FOLLOW-UP
2.	Subject Status Date	Oct/14/2020

Header Text: C4591001

Visit: Investigator Signature -
Unscheduled

Form Version: 22-Apr-2020 21:04

Site No: 1231

Subject No: 12313884

Generated By:

(b) (4)

Form: CASEBOOK SIGNATURE FORM

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](#)

Casebook Signature Form

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

Header Text: C4591001

Visit: Investigator Signature -
Unscheduled

Form: CASEBOOK SIGNATURE FORM

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Verified

Site No: 1231

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

Subject No: 12313884

Subject Initials: ---

Generated By:

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

(b) (4)

[Audit Trail](#)

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

- CRF_Sign
- CRF_Sign_1

Name	Signature Meaning	Date	Type	Action
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Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form: INCLUSION/EXCLUSION CRITERIA -
Comments

Form Version: 30-Jul-2020 21:29

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1231

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

Subject No: 12313884

Subject Initials: ---

Generated By:

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

(b) (4)

[Back to Form](#)

Item	Date	User	Comment
Form	Aug-25-2020 15:00:39 (UTC-03:00) City of Buenos Aires	(b) (4), (b) (6)	Not Applicable

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1231

Subject No: 12313884

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

[Back to Form](#)

Item	Date	User	Comment
Form	Aug-25-2020 15:01:04 (UTC-03:00) City of Buenos Aires	(b) (4), (b) (6)	Not Applicable

Header Text: C4591001

Visit: Investigator Signature -
Unscheduled

Form: CASEBOOK SIGNATURE FORM - Signature
History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Verified

Site No: 1231

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

Subject No: 12313884

Subject Initials: ---

Generated By:

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

(b) (4)

[Back to Form](#)

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

- CRF_Sign
- CRF_Sign_1

Name	Signature Meaning	Date	Type	Action
Martina Davalli	N/A	Mar-20-2021 13:09:36 (UTC-03:00) City of Buenos Aires		Edit - All signatures invalidated

Affidavit:

N/A

(b) (6)	Approved	Jan-20-2021 20:44:08 (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.

090177e196ae2e8f\Final\Final On: 01-Apr-2021 03:16 (GMT)

Header Text: C4591001

Visit: Investigator Signature -
Unscheduled

Form: CASEBOOK SIGNATURE FORM - Signature
History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Verified

Site No: 1231

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

Subject No: 12313884

Subject Initials: ---

Generated By:

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

(b) (4)

(b) (6)	N/A	Jan-19-2021 13:39:49 (UTC-03:00) City of Buenos Aires		Edit - All signatures invalidated
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Affidavit:

N/A

(b) (6)	Approved	Nov-03-2020 17:21:24 (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-03-2020 09:05:45 (UTC-03:00) City of Buenos Aires		Edit - All signatures invalidated
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Affidavit:

N/A

Fernando Polack	Approved	Oct-31-2020 13:18:27 (UTC-03:00) City of Buenos Aires	BOOK	Signed
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090177e196ae2e8f\Final\Final On: 01-Apr-2021 03:16 (GMT)

Header Text: C4591001

Visit: Investigator Signature -
Unscheduled

Form: CASEBOOK SIGNATURE FORM - Signature
History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Verified

Site No: 1231

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

Subject No: 12313884

Subject Initials: ---

Generated By:

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

(b) (4)

Affidavit:

By my dated signature below, I, Fernando Polack, 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.

Alan Colombo	N/A	Oct-30-2020 18:25:56 (UTC-03:00) City of Buenos Aires		Edit - All signatures invalidated
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Affidavit:

N/A

Fernando Polack	Approved	Oct-30-2020 18:11:53 (UTC-03:00) City of Buenos Aires	BOOK	Signed
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090177e196ae2e8f\Final\Final On: 01-Apr-2021 03:16 (GMT)

Header Text: C4591001

Visit: Investigator Signature -
Unscheduled

Form: CASEBOOK SIGNATURE FORM - Signature
History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Verified

Site No: 1231

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

Subject No: 12313884

Subject Initials: ---

Generated By:

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

(b) (4)

Affidavit:

By my dated signature below, I, Fernando Polack, 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-30-2020 13:45:58 (UTC-03:00) City of Buenos Aires		Edit - All signatures invalidated
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Affidavit:

N/A

(b) (6)	Approved	Oct-23-2020 14:41:14 (UTC-03:00) City of Buenos Aires	BOOK	Signed
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090177e196ae2e8f\Final\Final On: 01-Apr-2021 03:16 (GMT)

Header Text: C4591001

Visit: Investigator Signature -
Unscheduled

Form Version: 22-Apr-2020 21:04

Site No: 1231

Subject No: 12313884

Generated By:

(b) (4)

Form: CASEBOOK SIGNATURE FORM - Signature
History

Form Status: Data Complete, Verified

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

Subject Initials: ---

Generated Time (GMT): 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: COHORT SELECTION - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:29

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1231

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

Subject No: 12313884

Subject Initials: ---

Generated By:

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

(b) (4)

[Back to Form](#)

1. Select appropriate response - Protocol version

Date	Location	User	Value	Reason
Aug-25-2020 14:59:04 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 24 JUL 2020	Transcription Error
Aug-25-2020 14:58:51 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 30 JUN 2020	Initial Entry

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

Date	Location	User	Value	Reason
Aug-25-2020 14:58:51 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: STAGE 3 COHORTS	Initial Entry

090177e196ae2e8f\Final\Final On: 01-Apr-2021 03:16 (GMT)

Header Text: C4591001

Visit: COHORT_SELECTION

Form: MAIN INFORMED CONSENT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1231

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

Subject No: 12313884

Subject Initials: ---

Generated By:

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

(b) (4)

[Back to Form](#)

1. Consent Was:

Date	Location	User	Value	Reason
Aug-25-2020 14:59:12 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: OBTAINED Date Written Consent Obtained Aug/25/2020	Initial Entry

090177e196ae2e8f\Final\Final On: 01-Apr-2021 03:16 (GMT)

Header Text: C4591001

Visit: COHORT_SELECTION

Form Version: 06-Jul-2020 21:55

Site No: 1231

Subject No: 12313884

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

[Back to Form](#)

1. Subject ID

Date	Location	User	Value	Reason
Aug-25-2020 12:21:01 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 12313884	Item copied from previous form

2. Birth Date:

Date	Location	User	Value	Reason
Aug-25-2020 12:20:55 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: (b) (6)/1987	Enrollment Entry

3. Sex:

Date	Location	User	Value	Reason
Aug-25-2020 14:59:24 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: FEMALE	Initial Entry

4. Ethnicity:

Date	Location	User	Value	Reason
Aug-25-2020	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Initial Entry

090177e196ae2e8f\Final\Final On: 01-Apr-2021 03:16 (GMT)

Header Text: C4591001

Visit: COHORT_SELECTION

Form: DEMOGRAPHY - eCRF Audit Trail History

Form Version: 06-Jul-2020 21:55

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1231

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

Subject No: 12313884

Subject Initials: ---

Generated By:

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

(b) (4)

14:59:24 (UTC-03:00) City of Buenos Aires		(b) (4), (b) (6)	HISPANIC OR LA TINO(A) OR OF S PANISH ORIGIN	
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5. Race: (Check X all that apply):

Date	Location	User	Value	Reason
Aug-25-2020 14:59:24 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: WHITE	Initial Entry

090177e196ae2e8f\Final\Final On: 01-Apr-2021 03:16 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:02

Site No: 1231

Subject No: 12313884

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

[Back to Form](#)

1. Date of Visit

Date	Location	User	Value	Reason
Aug-25-2020 14:59:32 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Aug/25/2020	Initial Entry

090177e196ae2e8f\Final\Final On: 01-Apr-2021 03:16 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1231

Subject No: 12313884

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

[Back to Form](#)

1. Date of Completion/Discontinuation/Death

Date	Location	User	Value	Reason
Aug-25-2020 15:00:51 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Aug/25/2020	Initial Entry

2. Phase of Disposition:

Date	Location	User	Value	Reason
Aug-25-2020 15:00:51 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SCREENING	Initial Entry

3. Status:

Date	Location	User	Value	Reason
Aug-25-2020 15:00:51 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: COMPLETED	Initial Entry

090177e196ae2e8f\Final\Final On: 01-Apr-2021 03:16 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form: VITAL SIGNS - BASELINE - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:51

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1231

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

Subject No: 12313884

Subject Initials: ---

Generated By:

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

(b) (4)

[Back to Form](#)

1. Date:

Date	Location	User	Value	Reason
Aug-25-2020 15:01:31 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Aug/25/2020	Initial Entry

2. Weight:

Date	Location	User	Value	Reason
Aug-25-2020 15:01:31 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 88.0	Initial Entry

3. Unit:

Date	Location	User	Value	Reason
Aug-25-2020 15:01:31 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: kg	Initial Entry

4. Height:

Date	Location	User	Value	Reason
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090177e196ae2e8f\Final\Final On: 01-Apr-2021 03:16 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form: VITAL SIGNS - BASELINE - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:51

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1231

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

Subject No: 12313884

Subject Initials: ---

Generated By:

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

(b) (4)

Aug-25-2020 15:01:31 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 171.0	Initial Entry
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5. Unit:

Date	Location	User	Value	Reason
Aug-25-2020 15:01:31 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: cm	Initial Entry

6. Body Mass Index:

Date	Location	User	Value	Reason
Aug-25-2020 15:01:31 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 30.1	Initial Entry

7.a

Date	Location	User	Value	Reason
Aug-25-2020 15:01:31 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Record I 1 dentifier: : Temperat 37.0 ure:	Initial Entry

090177e196ae2e8f\Final\Final On: 01-Apr-2021 03:16 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form: VITAL SIGNS - BASELINE - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:51

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1231

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

Subject No: 12313884

Subject Initials: ---

Generated By:

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

(b) (4)

			Temperat C ure Unit: Temperat ORAL ure Locat CAVI ion:: TY	
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7.a Record Identifier:

Date	Location	User	Value	Reason
Aug-25-2020 15:01:31 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 1	Initial Entry

7.a Temperature:

Date	Location	User	Value	Reason
Aug-25-2020 15:01:31 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 37.0	Initial Entry

7.a Unit:

Date	Location	User	Value	Reason
Aug-25-2020 15:01:31 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: C	Initial Entry

090177e196ae2e8f\Final\Final On: 01-Apr-2021 03:16 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form: VITAL SIGNS - BASELINE - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:51

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1231

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

Subject No: 12313884

Subject Initials: ---

Generated By:

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

(b) (4)

7.a Temperature Location:

Date	Location	User	Value	Reason
Aug-25-2020 15:01:31 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: ORAL CAVITY	Initial Entry

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

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

Form Version: 21-Aug-2020 02:49

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1231

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

Subject No: 12313884

Subject Initials: ---

Generated By:

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

(b) (4)

[Back to Form](#)

1. Lab Panel:

Date	Location	User	Value	Reason
Aug-25-2020 15:01:40 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: URINALYSIS	Initial Entry

2. Lab Sub-Panel:

Date	Location	User	Value	Reason
Aug-25-2020 15:01:40 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: PREGNANCY	Initial Entry

3. Collection Date:

Date	Location	User	Value	Reason
Aug-25-2020 15:01:40 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Aug/25/2020	Initial Entry

4. Laboratory Name and Address (Derived)

Date	Location	User	Value	Reason
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090177e196ae2e8f\Final\Final On: 01-Apr-2021 03:16 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

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

Form Version: 21-Aug-2020 02:49

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1231

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

Subject No: 12313884

Subject Initials: ---

Generated By:

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

(b) (4)

Aug-25-2020 15:01:40 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: STUDY SITE	Initial Entry
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5. Specimen Type:

Date	Location	User	Value	Reason
Aug-25-2020 15:01:40 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: URINE	Initial Entry

6.a

Date	Location	User	Value	Reason
Aug-25-2020 15:01:40 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sponsor- 113 Defined I dentifier: Test:: Choriogon adotropin Beta_PX11 3 Result:: NEGATIV E Not Done ::	Initial Entry

6.a Sponsor ID:

090177e196ae2e8f\Final\Final On: 01-Apr-2021 03:16 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

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

Form Version: 21-Aug-2020 02:49

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1231

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

Subject No: 12313884

Subject Initials: ---

Generated By:

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

(b) (4)

Date	Location	User	Value	Reason
Aug-25-2020 15:01:40 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 113	Initial Entry

6.a Test:

Date	Location	User	Value	Reason
Aug-25-2020 15:01:40 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Choriogonadotropin Beta_PX113	Initial Entry

6.a Result:

Date	Location	User	Value	Reason
Aug-25-2020 15:01:40 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NEGATIVE	Initial Entry

090177e196ae2e8f\Final\Final On: 01-Apr-2021 03:16 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1231

Subject No: 12313884

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

[Back to Form](#)

1. Randomization Date :

Date	Location	User	Value	Reason
Aug-25-2020 15:01:47 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Aug/25/2020	Initial Entry

2. Randomization Number:

Date	Location	User	Value	Reason
Aug-25-2020 15:01:47 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 65560	Initial Entry

090177e196ae2e8f\Final\Final On: 01-Apr-2021 03:16 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1231

Subject No: 12313884

Generated By:

(b) (4)

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

[Back to Form](#)

1. Data Origin

Date	Location	User	Value	Reason
Aug-25-2020 15:01:55 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Aug-25-2020 15:01:55 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SERUM	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Aug-26-2020 09:01:57 (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)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	'Sample Collected?' is Yes, however

090177e196ae2e8f\Final\Final On: 01-Apr-2021 03:16 (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: 12313884

Subject Initials: ---

Generated By:

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

(b) (4)

City of Buenos Aires		(b) (4), (b) (6)		no barcodes are entered. Please review and correct as appropriate.
Aug-25-2020 15:01:55 (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 15:01:55 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Date of Collection: Aug/25/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Aug-26-2020 09:01:57 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BP24YJ	Initial Entry

5.a Sample ID

090177e196ae2e8f\Final\Final On: 01-Apr-2021 03:16 (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: 12313884

Subject Initials: ---

Generated By:

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

(b) (4)

Date	Location	User	Value	Reason
Aug-26-2020 09:01:57 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BP24YJ	Initial Entry

5.b

Date	Location	User	Value	Reason
Aug-26-2020 09:02:06 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID BP24Y : K	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Aug-26-2020 09:02:06 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BP24YK	Initial Entry

5.c

Date	Location	User	Value	Reason
Aug-26-2020 09:02:12 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID BP24Y : L	Initial Entry

090177e196ae2e8f\Final\Final On: 01-Apr-2021 03:16 (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: 12313884

Subject Initials: ---

Generated By:

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

(b) (4)

5.c Sample ID

Date	Location	User	Value	Reason
Aug-26-2020 09:02:12 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BP24YL	Initial Entry

5.d

Date	Location	User	Value	Reason
Aug-26-2020 11:27:22 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	Romina Barrera (b) (4)	Data Entry: Sample I BLDZF D: D	Initial Entry

5.d Sample ID

Date	Location	User	Value	Reason
Aug-26-2020 11:27:22 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	Romina Barrera (b) (4)	Data Entry: BLDZFD	Initial Entry

5.e

Date	Location	User	Value	Reason
Aug-26-2020 11:27:32 (UTC-03:00) City	ACV0PFEINFP6000	Romina Barrera (b) (4)	Data Entry: Sample ID BLDZF : F	Initial Entry

090177e196ae2e8f\Final\Final On: 01-Apr-2021 03:16 (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: 12313884

Subject Initials: ---

Generated By:

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

(b) (4)

of Buenos Aires

5.e Sample ID

Date	Location	User	Value	Reason
Aug-26-2020 11:27:32 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	Romina Barrera (b) (4)	Data Entry: BLDZFF	Initial Entry

090177e196ae2e8f\Final\Final On: 01-Apr-2021 03:16 (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: 12313884

Subject Initials: ---

Generated By:

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

(b) (4)

[Back to Form](#)

1. Data Origin

Date	Location	User	Value	Reason
Aug-25-2020 15:02:02 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Aug-25-2020 15:02:02 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: NASAL_SWAB	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Aug-26-2020 19:05:42 (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)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	'Sample Collected?' is Yes, however

090177e196ae2e8f\Final\Final On: 01-Apr-2021 03:16 (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: 12313884

Subject Initials: ---

Generated By:

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

(b) (4)

City of Buenos Aires		(b) (4), (b) (6)		no barcodes are entered. Please review and correct as appropriate.
Aug-25-2020 15:02:02 (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 15:02:02 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Date of Collection: Aug/25/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Aug-26-2020 19:05:42 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	Alan Colombo (b) (4)	Data Entry: Sample ID: BP2F4 D: D	Initial Entry

5.a Sample ID

090177e196ae2e8f\Final\Final On: 01-Apr-2021 03:16 (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: 12313884

Subject Initials: ---

Generated By:

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

(b) (4)

Date	Location	User	Value	Reason
Aug-26-2020 19:05:42 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	Alan Colombo (b) (4)	Data Entry: BP2F4D	Initial Entry

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:04

Site No: 1231

Subject No: 12313884

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

[Back to Form](#)

1. Was there a temporary delay of vaccination?

Date	Location	User	Value	Reason
Aug-25-2020 15:02:15 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2. Treatment Name

Date	Location	User	Value	Reason
Aug-25-2020 15:02:15 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: BLINDED THERAPY	Initial Entry

3. Formulation:

Date	Location	User	Value	Reason
Aug-25-2020 15:02:15 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: INJECTION	Initial Entry

4. Dose Date Time:

Date	Location	User	Value	Reason
Aug-25-2020	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Initial Entry

090177e196ae2e8f\Final\Final On: 01-Apr-2021 03:16 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:04

Site No: 1231

Subject No: 12313884

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

15:02:15
(UTC-03:00) City
of Buenos Aires

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

Aug/25/2020 12:5
0

5. Anatomical Location:

Date	Location	User	Value	Reason
Aug-25-2020 15:02:15 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: DELTOID MUSCLE	Initial Entry

6. Body Side:

Date	Location	User	Value	Reason
Aug-25-2020 15:02:15 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: RIGHT	Initial Entry

7. Route:

Date	Location	User	Value	Reason
Aug-25-2020 15:02:15 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: INTRAMUSCULAR	Initial Entry

10. Timeframe Subject Was Observed

Date	Location	User	Value	Reason
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090177e196ae2e8f\Final\Final On: 01-Apr-2021 03:16 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form: VACCINATION - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1231

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

Subject No: 12313884

Subject Initials: ---

Generated By:

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

(b) (4)

Aug-25-2020 15:02:15 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: THE PROTOCOL SPE CIFIED OBSERVATIO N PERIOD	Initial Entry
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11. Was the subject observed for at least the protocol specified observation period after investigational product administration?

Date	Location	User	Value	Reason
Aug-25-2020 15:02:15 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

090177e196ae2e8f\Final\Final On: 01-Apr-2021 03:16 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form: REACTOGENICITY DIARY - eCRF Audit Trail History

Form Version: 06-Jul-2020 21:53

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1231

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

Subject No: 12313884

Subject Initials: ---

Generated By:

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

(b) (4)

[Back to Form](#)

1. Select appropriate response - Reactogenicity diary collection

Date	Location	User	Value	Reason
Aug-25-2020 15:02:47 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 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: 12313884

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

[Back to Form](#)

1. Date of Visit

Date	Location	User	Value	Reason
Sep-17-2020 15:50:43 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sep/16/2020	Initial Entry

090177e196ae2e8f\Final\Final On: 01-Apr-2021 03:16 (GMT)

Header Text: C4591001

Visit: V2_VAX2_L

Form Version: 15-Sep-2020 21:54

Site No: 1231

Subject No: 12313884

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

[Back to Form](#)

1. Date:

Date	Location	User	Value	Reason
Sep-17-2020 15:51:02 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sep/16/2020	Initial Entry

2.a

Date	Location	User	Value	Reason
Sep-17-2020 15:51:02 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Record Identifier: 1 Temperature: 36.8 Temperature Unit: Temperature Location: ORAL CAVITY	Initial Entry

2.a Record Identifier:

Date	Location	User	Value	Reason
Sep-17-2020 15:51:02 (UTC-03:00) City	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 1	Initial Entry

090177e196ae2e8f\Final\Final On: 01-Apr-2021 03:16 (GMT)

Header Text: C4591001

Visit: V2_VAX2_L

Form: VITAL SIGNS - TEMP - eCRF Audit Trail History

Form Version: 15-Sep-2020 21:54

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1231

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

Subject No: 12313884

Subject Initials: ---

Generated By:

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

(b) (4)

of Buenos Aires	(b) (4), (b) (6)
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2.a Temperature:

Date	Location	User	Value	Reason
Sep-17-2020 15:51:02 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 36.8	Initial Entry

2.a Unit:

Date	Location	User	Value	Reason
Sep-17-2020 15:51:02 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: C	Initial Entry

2.a Temperature Location:

Date	Location	User	Value	Reason
Sep-17-2020 15:51:02 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: ORAL CAVITY	Initial Entry

090177e196ae2e8f\Final\Final On: 01-Apr-2021 03:16 (GMT)

Header Text: C4591001

Visit: V2_VAX2_L

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

Form Version: 21-Aug-2020 02:49

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1231

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

Subject No: 12313884

Subject Initials: ---

Generated By:

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

(b) (4)

[Back to Form](#)

1. Lab Panel:

Date	Location	User	Value	Reason
Sep-17-2020 15:51:14 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: URINALYSIS	Initial Entry

2. Lab Sub-Panel:

Date	Location	User	Value	Reason
Sep-17-2020 15:51:14 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: PREGNANCY	Initial Entry

3. Collection Date:

Date	Location	User	Value	Reason
Sep-17-2020 15:51:14 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sep/16/2020	Initial Entry

4. Laboratory Name and Address (Derived)

Date	Location	User	Value	Reason
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090177e196ae2e8f\Final\Final On: 01-Apr-2021 03:16 (GMT)

Header Text: C4591001

Visit: V2_VAX2_L

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

Form Version: 21-Aug-2020 02:49

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1231

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

Subject No: 12313884

Subject Initials: ---

Generated By:

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

(b) (4)

Sep-17-2020 15:51:14 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: STUDY SITE	Initial Entry
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5. Specimen Type:

Date	Location	User	Value	Reason
Sep-17-2020 15:51:14 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: URINE	Initial Entry

6.a

Date	Location	User	Value	Reason
Sep-17-2020 15:51:14 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sponsor- 113 Defined I dentifier: Test:: Choriogon adotropin Beta_PX11 3 Result:: NEGATIV E Not Done ::	Initial Entry

6.a Sponsor ID:

090177e196ae2e8f\Final\Final On: 01-Apr-2021 03:16 (GMT)

Header Text: C4591001

Visit: V2_VAX2_L

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

Form Version: 21-Aug-2020 02:49

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1231

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

Subject No: 12313884

Subject Initials: ---

Generated By:

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

(b) (4)

Date	Location	User	Value	Reason
Sep-17-2020 15:51:14 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 113	Initial Entry

6.a Test:

Date	Location	User	Value	Reason
Sep-17-2020 15:51:14 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Choriogonadotropin B eta_PX113	Initial Entry

6.a Result:

Date	Location	User	Value	Reason
Sep-17-2020 15:51:14 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NEGATIVE	Initial Entry

090177e196ae2e8f\Final\Final On: 01-Apr-2021 03:16 (GMT)

Header Text: C4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:03

Site No: 1231

Subject No: 12313884

Generated By:

(b) (4)

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

[Back to Form](#)

1. Data Origin

Date	Location	User	Value	Reason
Sep-16-2020 12:29:39 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Sep-16-2020 12:29:39 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: NASAL_SWAB	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Sep-16-2020 12:29:57 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Sep-16-2020 12:29:39 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes

090177e196ae2e8f\Final\Final On: 01-Apr-2021 03:16 (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: 12313884

Subject Initials: ---

Generated By:

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

(b) (4)

				are entered. Please review and correct as appropriate.
Sep-16-2020 12:29:39 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	Romina Barrera (b) (4)	Data Entry: YES Date of Collection: Sep/16/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Sep-16-2020 12:29:57 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	Romina Barrera (b) (4)	Data Entry: Sample ID BP2B7 : R	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Sep-16-2020 12:29:57 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	Romina Barrera (b) (4)	Data Entry: BP2B7R	Initial Entry

090177e196ae2e8f\Final\Final On: 01-Apr-2021 03:16 (GMT)

Header Text: C4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:04

Site No: 1231

Subject No: 12313884

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

[Back to Form](#)

1. Was there a temporary delay of vaccination?

Date	Location	User	Value	Reason
Sep-17-2020 15:51:44 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2. Treatment Name

Date	Location	User	Value	Reason
Sep-17-2020 15:51:44 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: BLINDED THERAPY	Initial Entry

3. Formulation:

Date	Location	User	Value	Reason
Sep-17-2020 15:51:44 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: INJECTION	Initial Entry

4. Dose Date Time:

Date	Location	User	Value	Reason
Sep-17-2020	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Initial Entry

090177e196ae2e8f\Final\Final On: 01-Apr-2021 03:16 (GMT)

Header Text: C4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:04

Site No: 1231

Subject No: 12313884

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

15:51:44
(UTC-03:00) City
of Buenos Aires

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

Sep/16/2020 09:42

5. Anatomical Location:

Date	Location	User	Value	Reason
Sep-17-2020 15:51:44 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: DELTOID MUSCLE	Initial Entry

6. Body Side:

Date	Location	User	Value	Reason
Sep-17-2020 15:51:44 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: RIGHT	Initial Entry

7. Route:

Date	Location	User	Value	Reason
Sep-17-2020 15:51:44 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: INTRAMUSCULAR	Initial Entry

10. Timeframe Subject Was Observed

Date	Location	User	Value	Reason
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090177e196ae2e8f\Final\Final On: 01-Apr-2021 03:16 (GMT)

Header Text: C4591001

Visit: V2_VAX2_L

Form: VACCINATION - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1231

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

Subject No: 12313884

Subject Initials: ---

Generated By:

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

(b) (4)

Sep-17-2020 15:51:44 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: THE PROTOCOL SPE CIFIED OBSERVATIO N PERIOD	Initial Entry
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11. Was the subject observed for at least the protocol specified observation period after investigational product administration?

Date	Location	User	Value	Reason
Sep-17-2020 15:51:44 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

090177e196ae2e8f\Final\Final On: 01-Apr-2021 03:16 (GMT)

Header Text: C4591001

Visit: V3_MONTH1_POSTVAX2_L

Form: DATE OF VISIT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1231

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

Subject No: 12313884

Subject Initials: ---

Generated By:

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

(b) (4)

[Back to Form](#)

1. Date of Visit

Date	Location	User	Value	Reason
Oct-14-2020 19:05:53 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Oct/14/2020	Initial Entry

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: 12313884 **Subject Initials:** ---

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

(b) (4)

[Back to Form](#)

1. Data Origin

Date	Location	User	Value	Reason
Oct-14-2020 12:36:28 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Oct-14-2020 12:36:28 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SERUM	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Oct-14-2020 12:36:45 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Oct-14-2020 12:36:28 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes

090177e196ae2e8f\Final\Final On: 01-Apr-2021 03:16 (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: 12313884 Subject Initials: ---

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

(b) (4)

				are entered. Please review and correct as appropriate.
Oct-14-2020 12:36:28 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Date of Collection : Oct/14/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Oct-14-2020 12:36:45 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample I BRXRV D: 5	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Oct-14-2020 12:36:45 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BRXRV5	Initial Entry

5.b

Date	Location	User	Value	Reason
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090177e196ae2e8f\Final\Final On: 01-Apr-2021 03:16 (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: 12313884 Subject Initials: ---

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

(b) (4)

Oct-14-2020 13:11:22 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	Agustin Morato Cabral (b) (4)	Data Entry: Sample ID BP1NF : J	Initial Entry
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5.b Sample ID

Date	Location	User	Value	Reason
Oct-14-2020 13:11:22 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	Agustin Morato Cabral (b) (4)	Data Entry: BP1NFJ	Initial Entry

5.c

Date	Location	User	Value	Reason
Oct-14-2020 13:55:07 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample I BRXRW D: 1	Initial Entry

5.c Sample ID

Date	Location	User	Value	Reason
Oct-14-2020 13:55:07 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BRXRW1	Initial Entry

090177e196ae2e8f\Final\Final On: 01-Apr-2021 03:16 (GMT)

Header Text: C4591001

Visit: V4_MONTH6_L

Form Version: 22-Apr-2020 21:02

Site No: 1231

Subject No: 12313884

Generated By:

(b) (4)

Form: DATE OF VISIT - 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

[Back to Form](#)

1. Date of Visit

Date	Location	User	Value	Reason
Mar-20-2021 13:09:36 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	Martina Davalli (b) (4)	Data Entry: Mar/20/2021	Initial Entry

Header Text: C4591001

Visit: V4_MONTH6_L

Form Version: 22-Apr-2020 21:03

Site No: 1231

Subject No: 12313884

Generated By:

(b) (4)

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - 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

[Back to Form](#)

1. Data Origin

Date	Location	User	Value	Reason
Mar-20-2021 13:09:50 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Mar-20-2021 13:09:50 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SERUM	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Mar-20-2021 16:59:23 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Mar-20-2021 13:09:50 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes

090177e196ae2e8f\Final\Final On: 01-Apr-2021 03:16 (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, Frozen, Verified

Site No: 1231

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

Subject No: 12313884

Subject Initials: ---

Generated By:

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

(b) (4)

				are entered. Please review and correct as appropriate.
Mar-20-2021 13:09:50 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	Martina Davalli (b) (4)	Data Entry: YES Date of Collection : Mar/20/2021	Initial Entry

5.a

Date	Location	User	Value	Reason
Mar-20-2021 16:59:23 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6) [Redacted] [Redacted]	Data Entry: Sample I BR1YL D: D	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Mar-20-2021 16:59:23 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6) [Redacted] [Redacted]	Data Entry: BR1YLD	Initial Entry

5.b

Date	Location	User	Value	Reason
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090177e196ae2e8f\Final\Final On: 01-Apr-2021 03:16 (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, Frozen, Verified

Site No: 1231

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

Subject No: 12313884

Subject Initials: ---

Generated By:

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

(b) (4)

Mar-20-2021 17:18:08 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID BS1P5 : 7	Initial Entry
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5.b Sample ID

Date	Location	User	Value	Reason
Mar-20-2021 17:18:08 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BS1P57	Initial Entry

5.c

Date	Location	User	Value	Reason
Mar-20-2021 17:35:26 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample I BS1TX D: N	Initial Entry

5.c Sample ID

Date	Location	User	Value	Reason
Mar-20-2021 17:35:26 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BS1TXN	Initial Entry

090177e196ae2e8f\Final\Final On: 01-Apr-2021 03:16 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Sep/27/2020

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: 12313884

Subject Initials: ---

Generated By:

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

(b) (4)

[Back to Form](#)

1. Date of Visit

Date	Location	User	Value	Reason
Sep-28-2020 13:42:12 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Deleted	Close Auto Query
Sep-28-2020 09:10:52 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Sep-27-2020 18:43:19 (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-27-2020 18:43:19 (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

090177e196ae2e8f\Final\Final On: 01-Apr-2021 03:16 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Sep/27/2020

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: 12313884

Subject Initials: ---

Generated By:

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

(b) (4)

				Swab Self and Nasal Swab are missing. Please review and update as appropriate.
Sep-27-2020 18:43:19 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sep/27/2020	Initial Entry

3. COVID-19 Illness Visit:

Date	Location	User	Value	Reason
Sep-27-2020 18:43:19 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: COVID_A	Initial Entry

090177e196ae2e8f\Final\Final On: 01-Apr-2021 03:16 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Sep/27/2020

Form Version: 15-Sep-2020 21:55

Site No: 1231

Subject No: 12313884

Generated By:

(b) (4)

Form: SIGNS AND SYMPTOMS OF POTENTIAL
COVID-19 - 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

[Back to Form](#)

1. Date of Assessment:

Date	Location	User	Value	Reason
Sep-28-2020 13:42:12 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sep/27/2020	Initial Entry

2. Date of First Symptom Started:

Date	Location	User	Value	Reason
Sep-28-2020 13:42:12 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sep/25/2020	Initial Entry

3. Symptoms Ongoing?

Date	Location	User	Value	Reason
Nov-03-2020 12:55:03 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Nov-03-2020 09:05:45 (UTC-03:00)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	New Information

090177e196ae2e8f\Final\Final On: 01-Apr-2021 03:16 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Sep/27/2020

Form Version: 15-Sep-2020 21:55

Site No: 1231

Subject No: 12313884

Generated By:

(b) (4)

Form: SIGNS AND SYMPTOMS OF POTENTIAL
COVID-19 - 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

City of Buenos Aires				
Nov-03-2020 09:05:45 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO Date of Last Symptom Resolved : Oct/1/2020	New Information
Nov-02-2020 23:56:46 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	DM: 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 add date resolved.
Sep-28-2020 13:42:12 (UTC-03:00)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

090177e196ae2e8f\Final\Final On: 01-Apr-2021 03:16 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Sep/27/2020

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

Form Version: 15-Sep-2020 21:55

Form Status: Data Complete, Frozen, Verified

Site No: 1231

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

Subject No: 12313884

Subject Initials: ---

Generated By:

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

(b) (4)

City of Buenos
Aires

4.a

Date	Location	User	Value	Reason
Sep-28-2020 13:42:12 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptoms: FEVE R Symptom Pre NO sent:	Initial Entry

4.a Symptoms:

Date	Location	User	Value	Reason
Sep-28-2020 13:42:12 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: FEVER	Initial Entry

4.a Was symptom present?

Date	Location	User	Value	Reason
Sep-28-2020 13:42:12 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

4.b

090177e196ae2e8f\Final\Final On: 01-Apr-2021 03:16 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Sep/27/2020

Form Version: 15-Sep-2020 21:55

Site No: 1231

Subject No: 12313884

Generated By:

(b) (4)

Form: SIGNS AND SYMPTOMS OF POTENTIAL
COVID-19 - 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

Date	Location	User	Value	Reason
Sep-28-2020 13:42:12 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom: NEW OR INCREASED COUGH Symptom Present: YES	Initial Entry

4.b Symptoms:

Date	Location	User	Value	Reason
Sep-28-2020 13:42:12 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NEW OR INCREASED COUGH	Initial Entry

4.b Was symptom present?

Date	Location	User	Value	Reason
Sep-28-2020 13:42:12 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

4.c

Date	Location	User	Value	Reason
Sep-28-2020	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Initial Entry

090177e196ae2e8f\Final\Final On: 01-Apr-2021 03:16 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Sep/27/2020

Form Version: 15-Sep-2020 21:55

Site No: 1231

Subject No: 12313884

Generated By:

(b) (4)

Form: SIGNS AND SYMPTOMS OF POTENTIAL
COVID-19 - 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

13:42:12 (UTC-03:00) City of Buenos Aires		(b) (4), (b) (6)	Symp toms: NEW OR INC REASED SH ORTNESS OF BREATH	
			Symp tom P resen t:	

4.c Symptoms:

Date	Location	User	Value	Reason
Sep-28-2020 13:42:12 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NEW OR INCREASE D SHORTNESS OF B REATH	Initial Entry

4.c Was symptom present?

Date	Location	User	Value	Reason
Sep-28-2020 13:42:12 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

4.d

Date	Location	User	Value	Reason
Sep-28-2020 13:42:12	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptoms: CHIL	Initial Entry

090177e196ae2e8f\Final\Final On: 01-Apr-2021 03:16 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Sep/27/2020

Form Version: 15-Sep-2020 21:55

Site No: 1231

Subject No: 12313884

Generated By:

(b) (4)

Form: SIGNS AND SYMPTOMS OF POTENTIAL
COVID-19 - 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

(UTC-03:00) City of Buenos Aires	(b) (4), (b) (6)	LS	Symptom Present:	NO
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4.d Symptoms:

Date	Location	User	Value	Reason
Sep-28-2020 13:42:12 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: CHILLS	Initial Entry

4.d Was symptom present?

Date	Location	User	Value	Reason
Sep-28-2020 13:42:12 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

4.e

Date	Location	User	Value	Reason
Sep-28-2020 13:42:12 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptoms: NEW OR INCREASED MUSCLE PAIN	Initial Entry

090177e196ae2e8f\Final\Final On: 01-Apr-2021 03:16 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Sep/27/2020

Form Version: 15-Sep-2020 21:55

Site No: 1231

Subject No: 12313884

Generated By:

(b) (4)

Form: SIGNS AND SYMPTOMS OF POTENTIAL
COVID-19 - 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

			Symptom Present:	
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4.e Symptoms:

Date	Location	User	Value	Reason
Sep-28-2020 13:42:12 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NEW OR INCREASE D MUSCLE PAIN	Initial Entry

4.e Was symptom present?

Date	Location	User	Value	Reason
Sep-28-2020 13:42:12 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

4.f

Date	Location	User	Value	Reason
Sep-28-2020 13:42:12 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptoms: NEW LOSS OF TASTE OR SMELL Symptom Present: NO	Initial Entry

090177e196ae2e8f\Final\Final On: 01-Apr-2021 03:16 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Sep/27/2020

Form Version: 15-Sep-2020 21:55

Site No: 1231

Subject No: 12313884

Generated By:

(b) (4)

Form: SIGNS AND SYMPTOMS OF POTENTIAL
COVID-19 - 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

4.f Symptoms:

Date	Location	User	Value	Reason
Sep-28-2020 13:42:12 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NEW LOSS OF TASTE OR SMELL	Initial Entry

4.f Was symptom present?

Date	Location	User	Value	Reason
Sep-28-2020 13:42:12 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

4.g

Date	Location	User	Value	Reason
Sep-28-2020 13:42:12 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom: NEW OR INCREASED SORE THROAT Symptom Present: YES	Initial Entry

090177e196ae2e8f\Final\Final On: 01-Apr-2021 03:16 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Sep/27/2020

Form Version: 15-Sep-2020 21:55

Site No: 1231

Subject No: 12313884

Generated By:

(b) (4)

Form: SIGNS AND SYMPTOMS OF POTENTIAL
COVID-19 - 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

4.g Symptoms:

Date	Location	User	Value	Reason
Sep-28-2020 13:42:12 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NEW OR INCREASE D SORE THROAT	Initial Entry

4.g Was symptom present?

Date	Location	User	Value	Reason
Sep-28-2020 13:42:12 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

4.h

Date	Location	User	Value	Reason
Sep-28-2020 13:42:12 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptoms: DIARR HEA Symptom P NO resent:	Initial Entry

090177e196ae2e8f\Final\Final On: 01-Apr-2021 03:16 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Sep/27/2020

Form Version: 15-Sep-2020 21:55

Site No: 1231

Subject No: 12313884

Generated By:

(b) (4)

Form: SIGNS AND SYMPTOMS OF POTENTIAL
COVID-19 - 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

4.h Symptoms:

Date	Location	User	Value	Reason
Sep-28-2020 13:42:12 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: DIARRHEA	Initial Entry

4.h Was symptom present?

Date	Location	User	Value	Reason
Sep-28-2020 13:42:12 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

4.i

Date	Location	User	Value	Reason
Sep-28-2020 13:42:12 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptoms: VOMIT ING Symptom P NO resent:	Initial Entry

090177e196ae2e8f\Final\Final On: 01-Apr-2021 03:16 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Sep/27/2020

Form Version: 15-Sep-2020 21:55

Site No: 1231

Subject No: 12313884

Generated By:

(b) (4)

Form: SIGNS AND SYMPTOMS OF POTENTIAL
COVID-19 - 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

4.i Symptoms:

Date	Location	User	Value	Reason
Sep-28-2020 13:42:12 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: VOMITING	Initial Entry

4.i Was symptom present?

Date	Location	User	Value	Reason
Sep-28-2020 13:42:12 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

5.a

Date	Location	User	Value	Reason
Sep-28-2020 13:43:01 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptoms - rhinorr Other: hea	Initial Entry

5.a Symptoms - Other Text:

Date	Location	User	Value	Reason
Sep-28-2020 13:43:01 (UTC-03:00) City	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: rhinorrhea	Initial Entry

090177e196ae2e8f\Final\Final On: 01-Apr-2021 03:16 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Sep/27/2020

Form Version: 15-Sep-2020 21:55

Site No: 1231

Subject No: 12313884

Generated By:

(b) (4)

Form: SIGNS AND SYMPTOMS OF POTENTIAL
COVID-19 - 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

of Buenos Aires				
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090177e196ae2e8f\Final\Final On: 01-Apr-2021 03:16 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Sep/27/2020

Form Version: 06-Jul-2020 21:54

Site No: 1231

Subject No: 12313884

Generated By:

(b) (4)

Form: MICROBIOLOGY SPECIMEN - Audit Trail

Form Status:

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

Subject Initials: ---

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

[Back to Form](#)

Date	Location	User	Value	Reason
Sep-30-2020 14:27:55 (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/27/2020

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: 12313884

Subject Initials: ---

Generated By:

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

(b) (4)

[Back to Form](#)

1. Actual Date of Collection:

Date	Location	User	Value	Reason
Sep-30-2020 14:32:19 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sep/26/2020	Transcription Error
Sep-30-2020 14:27:55 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sep/27/2020	Initial Entry

2. Specimen Type:

Date	Location	User	Value	Reason
Sep-30-2020 14:27:55 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: SWABBED MATERI AL	Initial Entry

3. Specimen Collection Location:

Date	Location	User	Value	Reason
Sep-30-2020 14:27:55 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NASOPHARYNX	Initial Entry

090177e196ae2e8f\Final\Final On: 01-Apr-2021 03:16 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Sep/27/2020

Form Version: 06-Jul-2020 21:54

Site No: 1231

Subject No: 12313884

Generated By:

(b) (4)

Form: MICROBIOLOGY SPECIMEN - 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

4. Assay Code and Description:

Date	Location	User	Value	Reason
Sep-30-2020 14:27:55 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SEVERE ACUTE RES P SYNDROME CORO NAVIRUS 2	Initial Entry

5. Device Type:

Date	Location	User	Value	Reason
Sep-30-2020 14:27:55 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SARS-COV-2 DIAGN OSTIC TEST	Initial Entry

6. Trade Name:

Date	Location	User	Value	Reason
Sep-30-2020 14:27:55 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: ATILA BIOSYSTEM S IAMP COVID-19 D ETECTION KIT	Initial Entry

7. Test Result:

Date	Location	User	Value	Reason
Sep-30-2020 14:27:55 (UTC-03:00) City	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NEGATIVE	Initial Entry

090177e196ae2e8f\Final\Final On: 01-Apr-2021 03:16 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Sep/27/2020

Form Version: 06-Jul-2020 21:54

Site No: 1231

Subject No: 12313884

Generated By:

(b) (4)

Form: MICROBIOLOGY SPECIMEN - 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

of Buenos Aires

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

090177e196ae2e8f\Final\Final On: 01-Apr-2021 03:16 (GMT)

Header Text: C4591001**Visit:** POT_COVID_ILL 1 -
Unscheduled Visit on Sep/27/2020**Form Version:** 22-Apr-2020 21:03**Site No:** 1231**Subject No:** 12313884**Generated By:**

(b) (4)

Form: ELECTRONIC SAMPLE TRACKING - NASAL
SWAB SELF - 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[Back to Form](#)**1. Data Origin**

Date	Location	User	Value	Reason
Sep-30-2020 14:28:20 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Sep-30-2020 14:28:20 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: NASAL_SWAB_SELF	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Sep-30-2020 14:28:20 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) [REDACTED] (4), [REDACTED] (b) (6) [REDACTED]	Data Entry: NO	Initial Entry

4. If no sample was collected or sample was not collected according to protocol, please provide reason:

Date	Location	User	Value	Reason
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Header Text: C4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Sep/27/2020

Form Version: 22-Apr-2020 21:03

Site No: 1231

Subject No: 12313884

Generated By:

(b) (4)

Form: ELECTRONIC SAMPLE TRACKING - NASAL
SWAB SELF - 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

Sep-30-2020 14:28:20 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: sample collected by te am physician	Initial Entry
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Header Text: C4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Sep/27/2020

Form Version: 22-Apr-2020 21:03

Site No: 1231

Subject No: 12313884

Generated By:

(b) (4)

Form: ELECTRONIC SAMPLE TRACKING - NASAL
SWAB - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

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

Subject Initials: ---

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

[Back to Form](#)

1. Data Origin

Date	Location	User	Value	Reason
Sep-28-2020 09:10:52 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Sep-28-2020 09:10:52 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: NASAL_SWAB	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Sep-28-2020 09:11:06 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Sep-28-2020 09:10:52 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes

090177e196ae2e8f\Final\Final On: 01-Apr-2021 03:16 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Sep/27/2020

Form Version: 22-Apr-2020 21:03

Site No: 1231

Subject No: 12313884

Generated By:

(b) (4)

Form: ELECTRONIC SAMPLE TRACKING - NASAL
SWAB - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

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

Subject Initials: ---

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

				are entered. Please review and correct as appropriate.
Sep-28-2020 09:10:52 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Date of Collectio n: Sep/27/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Sep-27-2020 18:44:11 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample I BPWSK D: B	Transcription Error (DELETED)
Sep-27-2020 18:43:48 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample I BPWSK D: B	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Sep-27-2020 18:44:11 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BPWSKB	Transcription Error (DELETED)

090177e196ae2e8f\Final\Final On: 01-Apr-2021 03:16 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Sep/27/2020

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: 12313884

Subject Initials: ---

Generated By:

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

(b) (4)

Sep-27-2020 18:43:48 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BPWSKB	Initial Entry
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5.b

Date	Location	User	Value	Reason
Sep-28-2020 09:11:06 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample I BPWSK D: B	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Sep-28-2020 09:11:06 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BPWSKB	Initial Entry

090177e196ae2e8f\Final\Final On: 01-Apr-2021 03:16 (GMT)

Header Text: C4591001**Visit:** POT_COVID_ILL 1 -
Unscheduled Visit on Sep/27/2020**Form Version:** 15-Sep-2020 21:53**Site No:** 1231**Subject No:** 12313884**Generated By:**

(b) (4)

Form: HEALTH CARE UTILIZATION - 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[Back to Form](#)*I.a*

Date	Location	User	Value	Reason
Sep-30-2020 14:28:34 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Type of Practitioner: SPECIALIST T Occurrence of Visits or Contacts: NO	Initial Entry

I.a Physician or Healthcare Professional:

Date	Location	User	Value	Reason
Sep-30-2020 14:28:34 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: SPECIALIST	Initial Entry

I.a Occurrence of Visits or Contacts:

Date	Location	User	Value	Reason
Oct-02-2020 11:35:46 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query

Header Text: C4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Sep/27/2020

Form: HEALTH CARE UTILIZATION - eCRF Audit
Trail History

Form Version: 15-Sep-2020 21:53

Form Status: Data Complete, Frozen, Verified

Site No: 1231

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

Subject No: 12313884

Subject Initials: ---

Generated By:

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

(b) (4)

Oct-01-2020 12:49:44 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	The form was completed. Thank you
Sep-30-2020 20:35:46 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	please complete this page with available information
Sep-30-2020 14:28:34 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

1.b

Date	Location	User	Value	Reason
Sep-30-2020 14:28:34 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Type of Pr EMERG actitioner: ENCY ROOM Occurrenc NO e of Visits o r Contacts:	Initial Entry

090177e196ae2e8f\Final\Final On: 01-Apr-2021 03:16 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Sep/27/2020

Form: HEALTH CARE UTILIZATION - eCRF Audit
Trail History

Form Version: 15-Sep-2020 21:53

Form Status: Data Complete, Frozen, Verified

Site No: 1231

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

Subject No: 12313884

Subject Initials: ---

Generated By:

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

(b) (4)

1.b Physician or Healthcare Professional:

Date	Location	User	Value	Reason
Sep-30-2020 14:28:34 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: EMERGENCY ROOM	Initial Entry

1.b Occurrence of Visits or Contacts:

Date	Location	User	Value	Reason
Sep-30-2020 14:28:34 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

1.c

Date	Location	User	Value	Reason
Sep-30-2020 14:28:34 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Type of Practitioner: PRIMARY CARE PHYSICIAN Occurrence of Visits or Contacts: NO	Initial Entry

090177e196ae2e8f\Final\Final On: 01-Apr-2021 03:16 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Sep/27/2020

Form: HEALTH CARE UTILIZATION - eCRF Audit
Trail History

Form Version: 15-Sep-2020 21:53

Form Status: Data Complete, Frozen, Verified

Site No: 1231

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

Subject No: 12313884

Subject Initials: ---

Generated By:

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

(b) (4)

1.c Physician or Healthcare Professional:

Date	Location	User	Value	Reason
Sep-30-2020 14:28:34 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: PRIMARY CARE PH YSICIAN	Initial Entry

1.c Occurrence of Visits or Contacts:

Date	Location	User	Value	Reason
Sep-30-2020 14:28:34 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

1.d

Date	Location	User	Value	Reason
Sep-30-2020 14:28:34 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Type of Prac URGE titioner: NT C ARE Occurrence NO of Visits or Contacts:	Initial Entry

090177e196ae2e8f\Final\Final On: 01-Apr-2021 03:16 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Sep/27/2020

Form: HEALTH CARE UTILIZATION - eCRF Audit
Trail History

Form Version: 15-Sep-2020 21:53

Form Status: Data Complete, Frozen, Verified

Site No: 1231

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

Subject No: 12313884

Subject Initials: ---

Generated By:

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

(b) (4)

1.d Physician or Healthcare Professional:

Date	Location	User	Value	Reason
Sep-30-2020 14:28:34 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: URGENT CARE	Initial Entry

1.d Occurrence of Visits or Contacts:

Date	Location	User	Value	Reason
Sep-30-2020 14:28:34 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

1.e

Date	Location	User	Value	Reason
Sep-30-2020 14:28:34 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Type of P TELEPH ractitione ONE CO r: NSULTA TION Occurren NO ce of Visit s or Cont acts:	Initial Entry

090177e196ae2e8f\Final\Final On: 01-Apr-2021 03:16 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Sep/27/2020

Form: HEALTH CARE UTILIZATION - eCRF Audit
Trail History

Form Version: 15-Sep-2020 21:53

Form Status: Data Complete, Frozen, Verified

Site No: 1231

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

Subject No: 12313884

Subject Initials: ---

Generated By:

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

(b) (4)

1.e Physician or Healthcare Professional:

Date	Location	User	Value	Reason
Sep-30-2020 14:28:34 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: TELEPHONE CONS ULTATION	Initial Entry

1.e Occurrence of Visits or Contacts:

Date	Location	User	Value	Reason
Sep-30-2020 14:28:34 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

1.f

Date	Location	User	Value	Reason
Sep-30-2020 14:28:34 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Type of Practiti OT oner: HE R Occurrence of NO Visits or Conta cts:	Initial Entry

090177e196ae2e8f\Final\Final On: 01-Apr-2021 03:16 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Sep/27/2020

Form Version: 15-Sep-2020 21:53

Site No: 1231

Subject No: 12313884

Generated By:

(b) (4)

Form: HEALTH CARE UTILIZATION - 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

1.f Physician or Healthcare Professional:

Date	Location	User	Value	Reason
Sep-30-2020 14:28:34 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: OTHER	Initial Entry

1.f Occurrence of Visits or Contacts:

Date	Location	User	Value	Reason
Sep-30-2020 14:28:34 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

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

Date	Location	User	Value	Reason
Oct-01-2020 12:49:03 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

090177e196ae2e8f\Final\Final On: 01-Apr-2021 03:16 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Sep/27/2020

Form Version: 06-Jul-2020 21:52

Site No: 1231

Subject No: 12313884

Generated By:

(b) (4)

Form: ILLNESS DETAILS - 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

[Back to Form](#)

1. Category of Clinical Event:

Date	Location	User	Value	Reason
Sep-30-2020 14:28:48 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: POTENTIAL COVID- 19 ILLNESS	Initial Entry

2. Was a diagnosis obtained for Potential COVID-19 Illness?

Date	Location	User	Value	Reason
Sep-30-2020 14:28:48 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

3. Toxicity Grade:

Date	Location	User	Value	Reason
Sep-30-2020 14:28:48 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 1	Initial Entry

090177e196ae2e8f\Final\Final On: 01-Apr-2021 03:16 (GMT)

Header Text: C4591001

Visit: POT_COVID_CONVA 1 -
Unscheduled Visit on Oct/30/2020

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: 12313884

Subject Initials: ---

Generated By:

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

(b) (4)

[Back to Form](#)

1. Date of Visit

Date	Location	User	Value	Reason
Oct-30-2020 13:45:58 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Oct/30/2020	Initial Entry

3. COVID-19 Illness Visit:

Date	Location	User	Value	Reason
Oct-30-2020 13:45:58 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: COVID_A1	Initial Entry

090177e196ae2e8f\Final\Final On: 01-Apr-2021 03:16 (GMT)

Header Text: C4591001

Visit: POT_COVID_CONVA 1 -
Unscheduled Visit on Oct/30/2020

Form Version: 22-Apr-2020 21:03

Site No: 1231

Subject No: 12313884

Generated By:

(b) (4)

Form: ELECTRONIC SAMPLE TRACKING -
IMMUNOGENICITY - 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

[Back to Form](#)

1. Data Origin

Date	Location	User	Value	Reason
Oct-30-2020 13:46:13 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Oct-30-2020 13:46:13 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SERUM	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Oct-30-2020 17:40:09 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Oct-30-2020 13:46:13 (UTC-03:00)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidat e	'Sample Collected?' is Yes, however

090177e196ae2e8f\Final\Final On: 01-Apr-2021 03:16 (GMT)

Header Text: C4591001

Visit: POT_COVID_CONVA 1 -
Unscheduled Visit on Oct/30/2020

Form Version: 22-Apr-2020 21:03

Site No: 1231

Subject No: 12313884

Generated By:

(b) (4)

Form: ELECTRONIC SAMPLE TRACKING -
IMMUNOGENICITY - 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

City of Buenos Aires				no barcodes are entered. Please review and correct as appropriate.
Oct-30-2020 13:46:13 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Date of Collection: Oct/30/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Oct-30-2020 17:40:09 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	Alan Colombo (b) (4)	Data Entry: Sample ID: BPWDPP	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Oct-30-2020 17:40:09 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	Alan Colombo (b) (4)	Data Entry: BPWDPP	Initial Entry

5.b

090177e196ae2e8f\Final\Final On: 01-Apr-2021 03:16 (GMT)

Header Text: C4591001

Visit: POT_COVID_CONVA 1 -
Unscheduled Visit on Oct/30/2020

Form Version: 22-Apr-2020 21:03

Site No: 1231

Subject No: 12313884

Generated By:

(b) (4)

Form: ELECTRONIC SAMPLE TRACKING -
IMMUNOGENICITY - 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

Date	Location	User	Value	Reason
Oct-30-2020 18:09:05 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	Alan Colombo (b) (4)	Data Entry: Sample I BJ5N9 D: B	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Oct-30-2020 18:09:05 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	Alan Colombo (b) (4)	Data Entry: BJ5N9B	Initial Entry

5.c

Date	Location	User	Value	Reason
Oct-30-2020 18:25:56 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	Alan Colombo (b) (4)	Data Entry: Sample I BJ5NC D: 2	Initial Entry

5.c Sample ID

Date	Location	User	Value	Reason
Oct-30-2020 18:25:56 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	Alan Colombo (b) (4)	Data Entry: BJ5NC2	Initial Entry

090177e196ae2e8f\Final\Final On: 01-Apr-2021 03:16 (GMT)

Header Text: C4591001

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

Form Version: 15-Sep-2020 21:55

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1231

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

Subject No: 12313884

Subject Initials: ---

Generated By:

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

(b) (4)

[Back to Form](#)

1. Date of Completion/Discontinuation/Death :

Date	Location	User	Value	Reason
Oct-14-2020 19:06:24 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Oct/14/2020	Initial Entry

2. Phase of Disposition:

Date	Location	User	Value	Reason
Oct-14-2020 19:06:24 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: VACCINATION	Initial Entry

3. Status:

Date	Location	User	Value	Reason
Oct-14-2020 19:06:24 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: COMPLETED	Initial Entry

090177e196ae2e8f\Final\Final On: 01-Apr-2021 03:16 (GMT)

Header Text: C4591001

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

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

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

Subject No: 12313884 **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-19-2021 13:39:49 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Jan/19/2021	Initial Entry

090177e196ae2e8f\Final\Final On: 01-Apr-2021 03:16 (GMT)

Header Text: C4591001

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

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

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

Subject No: 12313884 **Subject Initials:** ---

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

(b) (4)

[Back to Form](#)

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

Date	Location	User	Value	Reason
Jan-19-2021 13:41:10 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Jan-19-2021 13:39:56 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	The response indicates participant was unblinded, however the TREATMENT UNBLINDED date is missing in the DISP visit. Please complete this date.
Jan-19-2021 13:39:56 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Participant is willing to return for Vaccination 3 Participant is: eligible and NOT confirm	Initial Entry

090177e196ae2e8f\Final\Final On: 01-Apr-2021 03:16 (GMT)

Header Text: C4591001

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

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

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

Subject No: 12313884 **Subject Initials:** ---

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

(b) (4)

			ed to have re ceived only p lacebo at Vac cination 1/2	
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Header Text: C4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1231

Subject No: 12313884

Generated By:

(b) (4)

Form: ADVERSE EVENT REPORT - Audit Trail

Form Status:

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

Subject Initials: ---

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

[Back to Form](#)

Date	Location	User	Value	Reason
Oct-12-2020 08:16:03 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Created	

Header Text: C4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Locked, Frozen

Site No: 1231

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

Subject No: 12313884

Subject Initials: ---

Generated By:

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

(b) (4)

[Back to Form](#)

1. Category:

Date	Location	User	Value	Reason
Oct-12-2020 08:16:03 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: ADVERSE EVENT	Initial Entry

2. AE ID:

Date	Location	User	Value	Reason
Oct-12-2020 08:16:03 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 1	Initial Entry

3. Adverse Event:

(If possible specify diagnosis, not individual symptoms)

Date	Location	User	Value	Reason
Oct-12-2020 08:16:03 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: right axillary adenopathy	Initial Entry

4. Start Date Time:

Date	Location	User	Value	Reason
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090177e196ae2e8f\Final\Final On: 01-Apr-2021 03:16 (GMT)

Header Text: C4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Locked, Frozen

Site No: 1231

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

Subject No: 12313884

Subject Initials: ---

Generated By:

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

(b) (4)

Oct-12-2020 08:16:03 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sep/18/2020 12:00	Initial Entry
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5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Oct-12-2020 08:16:03 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO End Date Time: Sep/22/2020 17:00	Initial Entry

6. Toxicity Grade:

Date	Location	User	Value	Reason
Oct-12-2020 08:16:03 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 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).

090177e196ae2e8f\Final\Final On: 01-Apr-2021 03:16 (GMT)

Header Text: C4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Locked, Frozen

Site No: 1231

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

Subject No: 12313884

Subject Initials: ---

Generated By:

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

(b) (4)

Date	Location	User	Value	Reason
Oct-12-2020 08:16:03 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 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-12-2020 08:16:03 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

9. Is this event related to study treatment:

Date	Location	User	Value	Reason
Oct-12-2020 08:16:03 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NOT RELATED If Not Related to study treatment(s), this event is due to: OTHER <i>If Other, specify:</i> Unknown	Initial Entry

090177e196ae2e8f\Final\Final On: 01-Apr-2021 03:16 (GMT)

Header Text: C4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Locked, Frozen

Site No: 1231

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

Subject No: 12313884

Subject Initials: ---

Generated By:

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

(b) (4)

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Oct-12-2020 08:16:03 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NOT APPLICABLE	Initial Entry

11. Was a Concomitant Medication given?

Date	Location	User	Value	Reason
Oct-12-2020 08:16:03 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Oct-12-2020 08:16:03 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

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

Date	Location	User	Value	Reason
Oct-12-2020 08:16:03 (UTC-03:00) City	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: RECOVERED/RESO LVED	Initial Entry

090177e196ae2e8f\Final\Final On: 01-Apr-2021 03:16 (GMT)

Header Text: C4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Locked, Frozen

Site No: 1231

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

Subject No: 12313884

Subject Initials: ---

Generated By:

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

(b) (4)

of Buenos Aires

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

Date	Location	User	Value	Reason
Oct-12-2020 08:16:03 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

090177e196ae2e8f\Final\Final On: 01-Apr-2021 03:16 (GMT)

Header Text: C4591001

Visit: Disposition - Unscheduled

Form: TREATMENT UNBLINDED - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1231

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

Subject No: 12313884

Subject Initials: ---

Generated By:

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

(b) (4)

[Back to Form](#)

1. Date Treatment Unblinded :

Date	Location	User	Value	Reason
Jan-19-2021 13:41:10 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Jan/19/2021	Initial Entry

2. Primary Reason for Unblinding:

Date	Location	User	Value	Reason
Jan-19-2021 13:41:10 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: ASSESS ELIGIBILITY FOR ADDITIONAL VACCINATION	Initial Entry

090177e196ae2e8f\Final\Final On: 01-Apr-2021 03:16 (GMT)

Header Text: C4591001

Visit: Subject Status - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1231

Subject No: 12313884

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

[Back to Form](#)

1. Subject Status

Date	Location	User	Value	Reason
Oct-14-2020 19:06:24 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: FOLLOW-UP	Initial Entry
Aug-25-2020 15:01:47 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: ENROLLED/RANDOMIZED	Initial Entry
Aug-25-2020 15:00:51 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SCREENED	Initial Entry

2. Subject Status Date

Date	Location	User	Value	Reason
Oct-14-2020 19:06:24 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Oct/14/2020	Initial Entry
Aug-25-2020 15:01:47 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Aug/25/2020	Initial Entry

090177e196ae2e8f\Final\Final On: 01-Apr-2021 03:16 (GMT)

Header Text: C4591001

Visit: Subject Status - Unscheduled

Form: SUBJECT STATUS - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Verified

Site No: 1231

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

Subject No: 12313884

Subject Initials: ---

Generated By:

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

(b) (4)

Aug-25-2020 15:00:51 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Aug/25/2020	Initial Entry
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Header Text: C4591001

Visit: Investigator Signature -
Unscheduled

Form Version: 22-Apr-2020 21:04

Site No: 1231

Subject No: 12313884

Generated By:

(b) (4)

Form: CASEBOOK SIGNATURE FORM - eCRF Audit
Trail History

Form Status: Data Complete, Verified

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

Subject Initials: ---

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

[Back to Form](#)

1. Casebook Signature

Date	Location	User	Value	Reason
Oct-21-2020 21:40:40 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Click Here to Enable	Initial Entry