

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: 12312868

Subject Initials: ---

Generated By:

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

(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	30 JUN 2020
2.	Select appropriate response - What cohort does the subject belong to?	STAGE 3 COHORTS

090177e196ae2e73\Final\Final On: 01-Apr-2021 03:14 (GMT)

Header Text: C4591001

Visit: COHORT_SELECTION

Form Version: 22-Apr-2020 21:02

Site No: 1231

Subject No: 12312868

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 20:20

[eCRF Audit Trail History](#)

Informed Consent

1.	Consent Was:	OBTAINED Date Written Consent Obtained Aug/21/2020
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Header Text: C4591001

Visit: COHORT_SELECTION

Form: DEMOGRAPHY

Form Version: 06-Jul-2020 21:55

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1231

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

Subject No: 12312868

Subject Initials: ---

Generated By:

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

(b) (4)

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Demography

1.	Subject ID	[12312868]
2.	Birth Date:	(b) (6)/1977
3.	Sex:	FEMALE
4.	Ethnicity:	HISPANIC OR LATINO(A) OR OF SPANISH ORIGIN
5.	Race: (Check X all that apply):	WHITE
6.	Racial Designation:	

090177e196ae2e73\Final\Final On: 01-Apr-2021 03:14 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:02

Site No: 1231

Subject No: 12312868

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 20:20

[eCRF Audit Trail History](#)

Date of Visit

1.	Date of Visit	Aug/21/2020
2.	Erroneous Visit	

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 21-Aug-2020 02:50

Site No: 1231

Subject No: 12312868

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 20:20

[eCRF Audit Trail History](#)

Study eligibility requires subjects to meet all inclusion criteria (YES) and Not meet exclusion criteria (NO).

Inclusion Criteria

1.a	Inclusion Number:	1
	Criterion Description:	Male or female participants between the ages of 18 and 55 years, inclusive, 65 and 85 years, inclusive, or 18 and 85 years, inclusive, at randomization (dependent upon study stage)
	Criterion met?	YES
	Criterion ID: (For Pfizer use only)	IN01A00
1.b	Inclusion Number:	2
	Criterion Description:	Participants who are willing and able to comply with all scheduled visits, vaccination plan, laboratory tests, lifestyle considerations, and other study procedures
	Criterion met?	YES
	Criterion ID: (For Pfizer use only)	IN02A00

090177e196ae2e73\Final\Final On: 01-Apr-2021 03:14 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 21-Aug-2020 02:50

Site No: 1231

Subject No: 12312868

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 20:20

1.c	Inclusion Number:	3
	Criterion Description:	Healthy participants who are determined by medical history, physical examination, and clinical judgment of the investigator to be eligible for inclusion in the study
	Criterion met?	YES
	Criterion ID: (For Pfizer use only)	IN03A00

1.d	Inclusion Number:	4
	Criterion Description:	Capable of giving personal signed informed consent, which includes compliance with the requirements and restrictions listed in the ICD and in this protocol
	Criterion met?	YES
	Criterion ID: (For Pfizer use only)	IN04A00

Exclusion Criteria

2.a	Exclusion Number:	1
	Criterion Description:	Other medical or psychiatric condition incl. recent (within past year) or active suicidal ideation/behavior/lab abnormality that may increase the risk of study participation
	Criterion met?	NO
	Criterion ID: (For Pfizer use only)	EX01A00

090177e196ae2e73\Final\Final On: 01-Apr-2021 03:14 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 21-Aug-2020 02:50

Site No: 1231

Subject No: 12312868

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 20:20

2.b	Exclusion Number:	2
	Criterion Description:	Known infection with human immunodeficiency virus (HIV), hepatitis C virus (HCV), or hepatitis B virus (HBV)
	Criterion met?	NO
	Criterion ID: (For Pfizer use only)	EX02A00
2.c	Exclusion Number:	3
	Criterion Description:	History of severe adverse reaction associated with a vaccine and/or severe allergic reaction (eg, anaphylaxis) to any component of the study intervention(s)
	Criterion met?	NO
	Criterion ID: (For Pfizer use only)	EX03A00
2.d	Exclusion Number:	4
	Criterion Description:	Receipt of medications intended to prevent COVID-19
	Criterion met?	NO
	Criterion ID: (For Pfizer use only)	EX04A00

090177e196ae2e73\Final\Final On: 01-Apr-2021 03:14 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 21-Aug-2020 02:50

Site No: 1231

Subject No: 12312868

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 20:20

2.e	Exclusion Number:	8
	Criterion Description:	Immunocompromised individuals with known or suspected immunodeficiency, as determined by history and/or laboratory/physical examination
	Criterion met?	NO
	Criterion ID: (For Pfizer use only)	EX08A00
2.f	Exclusion Number:	10
	Criterion Description:	Bleeding diathesis or condition associated with prolonged bleeding that would, in the opinion of the investigator, contraindicate intramuscular injection
	Criterion met?	NO
	Criterion ID: (For Pfizer use only)	EX10A00
2.g	Exclusion Number:	11
	Criterion Description:	Women who are pregnant or breastfeeding
	Criterion met?	NO
	Criterion ID: (For Pfizer use only)	EX11A00

090177e196ae2e73\Final\Final On: 01-Apr-2021 03:14 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 21-Aug-2020 02:50

Site No: 1231

Subject No: 12312868

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 20:20

2.h	Exclusion Number:	12
	Criterion Description:	Previous vaccination with any coronavirus vaccine
	Criterion met?	NO
	Criterion ID: (For Pfizer use only)	EX12A00
2.i	Exclusion Number:	13
	Criterion Description:	Subjects who receive immunosuppressive therapy, such as cytotoxic agents or systemic corticosteroids
	Criterion met?	NO
	Criterion ID: (For Pfizer use only)	EX13A01
2.j	Exclusion Number:	15
	Criterion Description:	Receipt of blood/plasma products or immunoglobulin, from 60 days before study intervention administration or planned receipt throughout the study
	Criterion met?	NO
	Criterion ID: (For Pfizer use only)	EX14A01

090177e196ae2e73\Final\Final On: 01-Apr-2021 03:14 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 21-Aug-2020 02:50

Site No: 1231

Subject No: 12312868

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 20:20

2.k	Exclusion Number:	16
	Criterion Description:	Participation in other studies involving study intervention within 28 days prior to study entry and/or during study participation
	Criterion met?	NO
	Criterion ID: (For Pfizer use only)	EX15A01
2.l	Exclusion Number:	17
	Criterion Description:	Previous participation in other studies involving study intervention containing lipid nanoparticles
	Criterion met?	NO
	Criterion ID: (For Pfizer use only)	EX16A01
2.m	Exclusion Number:	22
	Criterion Description:	Investigator site staff or Pfizer employees directly involved in the conduct of the study, site staff otherwise supervised by the investigator, and their respective family members
	Criterion met?	NO
	Criterion ID: (For Pfizer use only)	EX21A01

090177e196ae2e73\Final\Final On: 01-Apr-2021 03:14 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1231

Subject No: 12312868

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 20:20

[eCRF Audit Trail History](#)

Disposition - Screening

1.	Date of Completion/Discontinuation /Death	Aug/21/2020
2.	Phase of Disposition:	SCREENING
3.	Status:	COMPLETED
4.	Specify Status:	[]

090177e196ae2e73\Final\Final On: 01-Apr-2021 03:14 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1231

Subject No: 12312868

Generated By:

(b) (4)

Form: GENERAL MEDICAL 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 20:20

[Form Comments](#)

[eCRF Audit Trail History](#)

Medical History Details

1.a	Line/MH Number:	[1]
	Disease/Syndrome /Surgery/Non-Drug Allergies/Drug Allergies:	[Depressive disorder]
	Start Date:	Mar/15/2020
	Ongoing:	YES

090177e196ae2e73\Final\Final On: 01-Apr-2021 03:14 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 21-Aug-2020 02:51

Site No: 1231

Subject No: 12312868

Generated By:

(b) (4)

Form: VITAL SIGNS - BASELINE

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Vital Signs

1.	Date:	Aug/21/2020
2.	Weight:	[70.8]
3.	Unit:	kg
4.	Height:	[162.0]
5.	Unit:	cm
6.	Body Mass Index:	[27.0]

Vital Signs Details

7.a	Record Identifier:	1
	Temperature:	[36.3]
	Unit:	C
	Temperature Location:	ORAL CAVITY

090177e196ae2e73\Final\Final On: 01-Apr-2021 03:14 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 21-Aug-2020 02:49

Site No: 1231

Subject No: 12312868

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 20:20

[eCRF Audit Trail History](#)

Lab Urinalysis

1.	Lab Panel:	URINALYSIS
2.	Lab Sub-Panel:	PREGNANCY
3.	Collection Date:	Aug/21/2020
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:	

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1231

Subject No: 12312868

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 20:20

[eCRF Audit Trail History](#)

Disposition

1.	Randomization Date :	Aug/21/2020
2.	Randomization Number:	[60566]
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:** 12312868**Subject Initials:** ---**Generated By:****Generated Time (GMT):** 29-Mar-2021 20:20

(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/21/2020
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	[BJ4965]
5.b	Sample ID	[BJ4966]
5.c	Sample ID	[BJ4967]
5.d	Sample ID	[BHY5PP]
5.e	Sample ID	[BHY5PR]
5.f	Sample ID	[BHY5PS]

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1231

Subject No: 12312868

Generated By:

(b) (4)

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Electronic Sample Tracking

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB
3.	Sample Collected?	YES Date of Collection: Aug/21/2020
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	[BHY5VN]
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090177e196ae2e73\Final\Final On: 01-Apr-2021 03:14 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:04

Site No: 1231

Subject No: 12312868

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 20:20

[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/21/2020 13:40
5.	Anatomical Location:	DELTOID MUSCLE
6.	Body Side:	LEFT
7.	Route:	INTRAMUSCULAR
8.	Actual Dose:	[]
9.	Unit:	
10.	Timeframe Subject Was Observed	THE PROTOCOL SPECIFIED OBSERVATION PERIOD
11.	Was the subject observed for at least the protocol specified observation period after investigational product administration?	YES

090177e196ae2e73\Final\Final On: 01-Apr-2021 03:14 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 06-Jul-2020 21:53

Site No: 1231

Subject No: 12312868

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 20:20

[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: 12312868

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 20:20

[eCRF Audit Trail History](#)

Date of Visit

1.	Date of Visit	Oct/8/2020
2.	Erroneous Visit	

Header Text: C4591001

Visit: V2_VAX2_L

Form Version: 10-Oct-2020 16:01

Site No: 1231

Subject No: 12312868

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 20:20

[eCRF Audit Trail History](#)

Vital Signs

1.	Date:	Oct/8/2020
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Vital Signs Details

2.a	Record Identifier:	1
	Temperature:	[36.3]
	Unit:	C
	Temperature Location:	ORAL CAVITY

090177e196ae2e73\Final\Final On: 01-Apr-2021 03:14 (GMT)

Header Text: C4591001

Visit: V2_VAX2_L

Form Version: 21-Aug-2020 02:49

Site No: 1231

Subject No: 12312868

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 20:20

[eCRF Audit Trail History](#)

Lab Urinalysis

1.	Lab Panel:	URINALYSIS
2.	Lab Sub-Panel:	PREGNANCY
3.	Collection Date:	Oct/8/2020
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:	

090177e196ae2e73\Final\Final On: 01-Apr-2021 03:14 (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: 12312868

Subject Initials: ---

Generated By:

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

(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: Oct/8/2020
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	[]
5.b	Sample ID	[BPXWYD]

090177e196ae2e73\Final\Final On: 01-Apr-2021 03:14 (GMT)

Header Text: C4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:04

Site No: 1231

Subject No: 12312868

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 20:20

[eCRF Audit Trail History](#)

Vaccination

1.	Was there a temporary delay of vaccination?	YES Date of First Delay: Sep/10/2020 Reason(s) for Temporary Delay of Vaccination RECENT SYSTEMIC CORTICOSTEROID TREATMENT
2.	Treatment Name	[BLINDED THERAPY]
3.	Formulation:	INJECTION
4.	Dose Date Time:	Oct/8/2020 11:26
5.	Anatomical Location:	DELTOID MUSCLE
6.	Body Side:	LEFT
7.	Route:	INTRAMUSCULAR
8.	Actual Dose:	[]
9.	Unit:	
10.	Timeframe Subject Was Observed	THE PROTOCOL SPECIFIED OBSERVATION PERIOD
11.	Was the subject observed for at least the protocol specified observation period after investigational product administration?	YES

090177e196ae2e73\Final\Final On: 01-Apr-2021 03:14 (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

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Subject Initials: ---

Generated By:

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

(b) (4)

[eCRF Audit Trail History](#)

Date of Visit

1.	Date of Visit	Nov/11/2020
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:** 12312868**Subject Initials:** ---**Generated By:****Generated Time (GMT):** 29-Mar-2021 20:20

(b) (4)

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

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

Aliquot

Please enter barcode for each aliquot.

5.a	Sample ID	[BJ4F0H]
5.b	Sample ID	[BJ4F1T]
5.c	Sample ID	[BP1P9L]

Header Text: C4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Sep/11/2020

Form Version: 22-Apr-2020 21:03

Site No: 1231

Subject No: 12312868

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 20:20

[eCRF Audit Trail History](#)

Date of Visit

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

COVID-19 Illness Visit

3.	COVID-19 Illness Visit:	COVID_A
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090177e196ae2e73\Final\Final On: 01-Apr-2021 03:14 (GMT)

Header Text: C4591001**Visit:** POT_COVID_ILL 1 -
Unscheduled Visit on Sep/11/2020**Form Version:** 21-Aug-2020 02:52**Site No:** 1231**Subject No:** 12312868**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 20:20[eCRF Audit Trail History](#)**Signs and Symptoms**

1.	Date of Assessment:	Sep/11/2020
2.	Date of First Symptom Started:	Sep/6/2020
3.	Symptoms Ongoing?	NO Date of Last Symptom Resolved: Sep/16/2020

Symptoms

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

Header Text: C4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Sep/11/2020

Form Version: 21-Aug-2020 02:52

Site No: 1231

Subject No: 12312868

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 20:20

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:	[otalgia]

090177e196ae2e73\Final\Final On: 01-Apr-2021 03:14 (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: 12312868

Subject Initials: ---

Generated By:

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

(b) (4)

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

090177e196ae2e73\Final\Final On: 01-Apr-2021 03:14 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Sep/11/2020

Form: MICROBIOLOGY SPECIMEN

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen, Verified

Site No: 1231

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

Subject No: 12312868

Subject Initials: ---

Generated By:

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

(b) (4)

[Back to Form](#)

[eCRF Audit Trail History](#)

[Form Audit Trail](#)

Microbiology Specimen

1.	Actual Date of Collection:	Sep/11/2020
2.	Specimen Type:	SWABBED MATERIAL
3.	Specimen Collection Location:	NASOPHARYNX
4.	Assay Code and Description:	SEVERE ACUTE RESP SYNDROME CORONAVIRUS 2
5.	Device Type:	SARS-COV-2 DIAGNOSTIC TEST
6.	Trade Name:	ATILA BIOSYSTEMS IAMP COVID-19 DETECTION KIT
7.	Test Result:	NEGATIVE
8.	Comments/Findings /Details:	[]
9.	Trade Name Other, Specify:	[]

090177e196ae2e73\Final\Final On: 01-Apr-2021 03:14 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Sep/11/2020

Form Version: 22-Apr-2020 21:03

Site No: 1231

Subject No: 12312868

Generated By:

(b) (4)

Form: ELECTRONIC SAMPLE TRACKING - NASAL
SWAB SELF

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 20:20

[eCRF Audit Trail History](#)

Electronic Sample Tracking

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

Aliquot

Please enter barcode for each aliquot.

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

Header Text: C4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Sep/11/2020

Form Version: 22-Apr-2020 21:03

Site No: 1231

Subject No: 12312868

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 20:20

[eCRF Audit Trail History](#)

Electronic Sample Tracking

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

Aliquot

Please enter barcode for each aliquot.

5.a	Sample ID	[BP1Y6D]
-----	-----------	----------

090177e196ae2e73\Final\Final On: 01-Apr-2021 03:14 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Sep/11/2020

Form Version: 21-Aug-2020 02:50

Site No: 1231

Subject No: 12312868

Generated By:

(b) (4)

Form: HEALTH CARE UTILIZATION

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 20:20

[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

090177e196ae2e73\Final\Final On: 01-Apr-2021 03:14 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Sep/11/2020

Form: HEALTH CARE UTILIZATION

Form Version: 21-Aug-2020 02:50

Form Status: Data Complete, Frozen, Verified

Site No: 1231

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

Subject No: 12312868

Subject Initials: ---

Generated By:

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

(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

090177e196ae2e73\Final\Final On: 01-Apr-2021 03:14 (GMT)

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: 12312868

Subject Initials: ---

Generated By:

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

(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/11/2020

Form: RESPIRATORY TREATMENT

Form Version: 06-Jul-2020 21:53

Form Status: Not Started

Site No: 1231

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

Subject No: 12312868

Subject Initials: ---

Generated By:

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

(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?	

090177e196ae2e73\Final\Final On: 01-Apr-2021 03:14 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Sep/11/2020

Form Version: 06-Jul-2020 21:52

Site No: 1231

Subject No: 12312868

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 20:20

[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:	2

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: 12312868

Subject Initials: ---

Generated By:

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

(b) (4)

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

090177e196ae2e73\Final\Final On: 01-Apr-2021 03:14 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Sep/11/2020

Form: ILLNESS DETAILS - SEVERE

Form Version: 17-Jul-2020 21:55

Form Status: Not Started

Site No: 1231

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

Subject No: 12312868

Subject Initials: ---

Generated By:

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

(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:	

090177e196ae2e73\Final\Final On: 01-Apr-2021 03:14 (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: 12312868

Subject Initials: ---

Generated By:

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

(b) (4)

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

090177e196ae2e73\Final\Final On: 01-Apr-2021 03:14 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Sep/11/2020

Form: LOCAL LABORATORY DATA - REPEATING
CHEMISTRY

Form Version: 21-Aug-2020 02:49

Form Status: Not Started

Site No: 1231

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

Subject No: 12312868

Subject Initials: ---

Generated By:

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

(b) (4)

[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

090177e196ae2e73\Final\Final On: 01-Apr-2021 03:14 (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: 12312868

Subject Initials: ---

Generated By:

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

(b) (4)

#	Category f or Lab Tes t	Vendor Nam e (DERIVED)	Collecti on Date :	Specim en Type	Lab Result			Form Instan ce
1.					Sponsor-Defi ned Identifie r	Te st:	Res ult:	Repeating Pages

090177e196ae2e73\Final\Final On: 01-Apr-2021 03:14 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Sep/11/2020

Form: LOCAL LABORATORY DATA - REPEATING
Hematology

Form Version: 21-Aug-2020 02:51

Form Status: Not Started

Site No: 1231

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

Subject No: 12312868

Subject Initials: ---

Generated By:

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

(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

090177e196ae2e73\Final\Final On: 01-Apr-2021 03:14 (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: 12312868

Subject Initials: ---

Generated By:

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

(b) (4)

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

090177e196ae2e73\Final\Final On: 01-Apr-2021 03:14 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Sep/11/2020

Form: VITAL SIGNS - COVID

Form Version: 21-Aug-2020 02:50

Form Status: Not Started

Site No: 1231

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

Subject No: 12312868

Subject Initials: ---

Generated By:

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

(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:	[]

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: 12312868

Subject Initials: ---

Generated By:

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

(b) (4)

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

090177e196ae2e73\Final\Final On: 01-Apr-2021 03:14 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Sep/11/2020

Form: VITAL SIGNS - PULSE OX ROOM AIR

Form Version: 21-Aug-2020 02:51

Form Status: Not Started

Site No: 1231

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

Subject No: 12312868

Subject Initials: ---

Generated By:

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

(b) (4)

[Back to Form](#)

Vital Signs

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

Vital Signs Details

2.	Record Identifier:	
	SPO2 Pulse Oximetry %	[]

Header Text: C4591001

Visit: POT_COVID_ILL 1

Form: OXYGENATION PARAMETERS

Form Version: 06-Jul-2020 21:52

Site No: 1231

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

Subject No: 12312868

Subject Initials: ---

Generated By:

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

(b) (4)

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

090177e196ae2e73\Final\Final On: 01-Apr-2021 03:14 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Sep/11/2020

Form: OXYGENATION PARAMETERS

Form Version: 06-Jul-2020 21:52

Form Status: Not Started

Site No: 1231

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

Subject No: 12312868

Subject Initials: ---

Generated By:

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

(b) (4)

[Back to Form](#)

Oxygenation Parameters

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

090177e196ae2e73\Final\Final On: 01-Apr-2021 03:14 (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: 12312868

Subject Initials: ---

Generated By:

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

(b) (4)

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

090177e196ae2e73\Final\Final On: 01-Apr-2021 03:14 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Sep/11/2020

Form Version: 06-Jul-2020 21:55

Site No: 1231

Subject No: 12312868

Generated By:

(b) (4)

Form: CONCOMITANT MEDICATIONS -
VASOPRESSORS

Form Status: Not Started

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

Subject Initials: ---

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

[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?	

090177e196ae2e73\Final\Final On: 01-Apr-2021 03:14 (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: 12312868

Subject Initials: ---

Generated By:

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

(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/11/2020

Form: IMAGING

Form Version: 06-Jul-2020 21:53

Form Status: Not Started

Site No: 1231

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

Subject No: 12312868

Subject Initials: ---

Generated By:

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

(b) (4)

[Back to Form](#)

Imaging

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

Header Text: C4591001

Visit: POT_COVID_ILL 2 -
Unscheduled Visit on Oct/17/2020

Form Version: 22-Apr-2020 21:03

Site No: 1231

Subject No: 12312868

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 20:20

[eCRF Audit Trail History](#)

Date of Visit

1.	Date of Visit	Oct/17/2020
2.	Erroneous Visit	

COVID-19 Illness Visit

3.	COVID-19 Illness Visit:	COVID_B
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090177e196ae2e73\Final\Final On: 01-Apr-2021 03:14 (GMT)

Header Text: C4591001**Visit:** POT_COVID_ILL 2 -
Unscheduled Visit on Oct/17/2020**Form Version:** 10-Oct-2020 16:02**Site No:** 1231**Subject No:** 12312868**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 20:20[eCRF Audit Trail History](#)**Signs and Symptoms**

1.	Date of Assessment:	Oct/17/2020
2.	Date of First Symptom Started:	Oct/14/2020
3.	Symptoms Ongoing?	NO Date of Last Symptom Resolved: Oct/20/2020

Symptoms

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

Header Text: C4591001

Visit: POT_COVID_ILL 2 -
Unscheduled Visit on Oct/17/2020

Form Version: 10-Oct-2020 16:02

Site No: 1231

Subject No: 12312868

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 20:20

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.	Symptoms - Other Text:	[]

090177e196ae2e73\Final\Final On: 01-Apr-2021 03:14 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 2

Form: MICROBIOLOGY SPECIMEN

Form Version: 06-Jul-2020 21:54

Site No: 1231

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

Subject No: 12312868

Subject Initials: ---

Generated By:

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

(b) (4)

#	Date of Collection	Specimen Type	Specimen Collection Location	Assay Code and Description	Device Type	Form Instance
1.	Oct/17/2020	SWABBED MATERIAL	NASOPHARYNX	SEVERE ACUTE RESPIRATORY SYNDROME CORONAVIRUS 2	SARS-COV-2 DIAGNOSTIC TEST	Repeating Pages

090177e196ae2e73\Final\Final On: 01-Apr-2021 03:14 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 2 -
Unscheduled Visit on Oct/17/2020

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: 12312868

Subject Initials: ---

Generated By:

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

(b) (4)

[Back to Form](#)

[eCRF Audit Trail History](#)

[Form Audit Trail](#)

Microbiology Specimen

1.	Actual Date of Collection:	Oct/17/2020
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:	[]

090177e196ae2e73\Final\Final On: 01-Apr-2021 03:14 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 2 -
Unscheduled Visit on Oct/17/2020

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: 12312868

Subject Initials: ---

Generated By:

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

(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 a team physician]

Aliquot

Please enter barcode for each aliquot.

5.	Sample ID	[]
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Header Text: C4591001

Visit: POT_COVID_ILL 2 -
Unscheduled Visit on Oct/17/2020

Form Version: 22-Apr-2020 21:03

Site No: 1231

Subject No: 12312868

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 20:20

[eCRF Audit Trail History](#)

Electronic Sample Tracking

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB
3.	Sample Collected?	YES Date of Collection: Oct/17/2020
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	[BPT7VK]
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090177e196ae2e73\Final\Final On: 01-Apr-2021 03:14 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 2 -
Unscheduled Visit on Oct/17/2020

Form Version: 10-Oct-2020 15:59

Site No: 1231

Subject No: 12312868

Generated By:

(b) (4)

Form: HEALTH CARE UTILIZATION

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 20:20

[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

090177e196ae2e73\Final\Final On: 01-Apr-2021 03:14 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 2 -
Unscheduled Visit on Oct/17/2020

Form: HEALTH CARE UTILIZATION

Form Version: 10-Oct-2020 15:59

Form Status: Data Complete, Frozen, Verified

Site No: 1231

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

Subject No: 12312868

Subject Initials: ---

Generated By:

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

(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

090177e196ae2e73\Final\Final On: 01-Apr-2021 03:14 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 2

Form: RESPIRATORY TREATMENT

Form Version: 06-Jul-2020 21:53

Site No: 1231

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

Subject No: 12312868

Subject Initials: ---

Generated By:

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

(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 2 -
Unscheduled Visit on Oct/17/2020

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: 12312868

Subject Initials: ---

Generated By:

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

(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?	

090177e196ae2e73\Final\Final On: 01-Apr-2021 03:14 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 2 -
Unscheduled Visit on Oct/17/2020

Form Version: 06-Jul-2020 21:52

Site No: 1231

Subject No: 12312868

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 20:20

[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

090177e196ae2e73\Final\Final On: 01-Apr-2021 03:14 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 2

Form: ILLNESS DETAILS - SEVERE

Form Version: 17-Jul-2020 21:55

Site No: 1231

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

Subject No: 12312868

Subject Initials: ---

Generated By:

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

(b) (4)

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

090177e196ae2e73\Final\Final On: 01-Apr-2021 03:14 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 2 -
Unscheduled Visit on Oct/17/2020

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: 12312868

Subject Initials: ---

Generated By:

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

(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:	

090177e196ae2e73\Final\Final On: 01-Apr-2021 03:14 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 2

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY

Form Version: 21-Aug-2020 02:49

Site No: 1231

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

Subject No: 12312868

Subject Initials: ---

Generated By:

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

(b) (4)

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

090177e196ae2e73\Final\Final On: 01-Apr-2021 03:14 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 2 -
Unscheduled Visit on Oct/17/2020

Form: LOCAL LABORATORY DATA - REPEATING
CHEMISTRY

Form Version: 21-Aug-2020 02:49

Form Status: Not Started

Site No: 1231

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

Subject No: 12312868

Subject Initials: ---

Generated By:

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

(b) (4)

[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

090177e196ae2e73\Final\Final On: 01-Apr-2021 03:14 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 2

Form: LOCAL LABORATORY DATA - REPEATING Hematology

Form Version: 21-Aug-2020 02:51

Site No: 1231

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

Subject No: 12312868

Subject Initials: ---

Generated By:

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

(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

090177e196ae2e73\Final\Final On: 01-Apr-2021 03:14 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 2 -
Unscheduled Visit on Oct/17/2020

Form Version: 21-Aug-2020 02:51

Site No: 1231

Subject No: 12312868

Generated By:

(b) (4)

Form: LOCAL LABORATORY DATA - REPEATING
Hematology

Form Status: Not Started

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

Subject Initials: ---

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

[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

090177e196ae2e73\Final\Final On: 01-Apr-2021 03:14 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 2

Form: VITAL SIGNS - COVID

Form Version: 21-Aug-2020 02:50

Site No: 1231

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

Subject No: 12312868

Subject Initials: ---

Generated By:

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

(b) (4)

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

090177e196ae2e73\Final\Final On: 01-Apr-2021 03:14 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 2 -
Unscheduled Visit on Oct/17/2020

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: 12312868

Subject Initials: ---

Generated By:

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

(b) (4)

[Back to Form](#)

Vital Signs

1.	Date:	//
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Vital Signs Details

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

Header Text: C4591001

Visit: POT_COVID_ILL 2

Form: VITAL SIGNS - PULSE OX ROOM AIR

Form Version: 21-Aug-2020 02:51

Site No: 1231

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

Subject No: 12312868

Subject Initials: ---

Generated By:

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

(b) (4)

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

090177e196ae2e73\Final\Final On: 01-Apr-2021 03:14 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 2 -
Unscheduled Visit on Oct/17/2020

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: 12312868

Subject Initials: ---

Generated By:

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

(b) (4)

[Back to Form](#)

Vital Signs

1.	Date:	//
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Vital Signs Details

2.	Record Identifier:	
	SPO2 Pulse Oximetry %	[]

090177e196ae2e73\Final\Final On: 01-Apr-2021 03:14 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 2

Form: OXYGENATION PARAMETERS

Form Version: 06-Jul-2020 21:52

Site No: 1231

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

Subject No: 12312868

Subject Initials: ---

Generated By:

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

(b) (4)

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

090177e196ae2e73\Final\Final On: 01-Apr-2021 03:14 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 2 -
Unscheduled Visit on Oct/17/2020

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: 12312868

Subject Initials: ---

Generated By:

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

(b) (4)

[Back to Form](#)

Oxygenation Parameters

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

Header Text: C4591001

Visit: POT_COVID_ILL 2

Form: CONCOMITANT MEDICATIONS -
VASOPRESSORS

Form Version: 06-Jul-2020 21:55

Site No: 1231

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

Subject No: 12312868

Subject Initials: ---

Generated By:

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

(b) (4)

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

090177e196ae2e73\Final\Final On: 01-Apr-2021 03:14 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 2 -
Unscheduled Visit on Oct/17/2020

Form Version: 06-Jul-2020 21:55

Site No: 1231

Subject No: 12312868

Generated By:

(b) (4)

Form: CONCOMITANT MEDICATIONS -
VASOPRESSORS

Form Status: Not Started

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

Subject Initials: ---

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

[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?	

090177e196ae2e73\Final\Final On: 01-Apr-2021 03:14 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 2

Form: IMAGING

Form Version: 06-Jul-2020 21:53

Site No: 1231

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

Subject No: 12312868

Subject Initials: ---

Generated By:

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

(b) (4)

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

090177e196ae2e73\Final\Final On: 01-Apr-2021 03:14 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 2 -
Unscheduled Visit on Oct/17/2020

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: 12312868

Subject Initials: ---

Generated By:

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

(b) (4)

[Back to Form](#)

Imaging

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

Header Text: C4591001

Visit: POT_COVID_ILL 3 -
Unscheduled Visit on Jan/22/2021

Form Version: 22-Apr-2020 21:03

Site No: 1231

Subject No: 12312868

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 20:20

[eCRF Audit Trail History](#)

Date of Visit

1.	Date of Visit	Jan/22/2021
2.	Erroneous Visit	

COVID-19 Illness Visit

3.	COVID-19 Illness Visit:	COVID_C
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090177e196ae2e73\Final\Final On: 01-Apr-2021 03:14 (GMT)

Header Text: C4591001**Visit:** POT_COVID_ILL 3 -
Unscheduled Visit on Jan/22/2021**Form Version:** 14-Jan-2021 02:23**Site No:** 1231**Subject No:** 12312868**Generated By:**

(b) (4)

Form: SIGNS AND SYMPTOMS OF POTENTIAL
COVID-19**Form Status:** Data Complete**Site Name:** (1231) Hospital Militar Central Cirujano
Mayor Dr. Cosme Argerich**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 20:20[eCRF Audit Trail History](#)**Signs and Symptoms**

1.	Date of Assessment:	Jan/22/2021
2.	Date of First Symptom Started:	Jan/19/2021
3.	Symptoms Ongoing?	NO Date of Last Symptom Resolved: Jan/26/2021

Symptoms

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

Header Text: C4591001

Visit: POT_COVID_ILL 3 -
Unscheduled Visit on Jan/22/2021

Form Version: 14-Jan-2021 02:23

Site No: 1231

Subject No: 12312868

Generated By:

(b) (4)

Form: SIGNS AND SYMPTOMS OF POTENTIAL
COVID-19

Form Status: Data Complete

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

Subject Initials: ---

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

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.	Symptoms - Other Text:	[]

090177e196ae2e73\Final\Final On: 01-Apr-2021 03:14 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 3

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: 12312868

Subject Initials: ---

Generated By:

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

(b) (4)

#	Date of Collection	Specimen Type	Specimen Collection Location	Assay Code and Description	Device Type	Form Instance
1.	Jan/22/2021	SWABBED MATERIAL	NASOPHARYNX	SEVERE ACUTE RESPIRATORY SYNDROME CORONAVIRUS 2	SARS-COV-2 DIAGNOSTIC TEST	Repeating Pages

090177e196ae2e73\Final\Final On: 01-Apr-2021 03:14 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 3 -
Unscheduled Visit on Jan/22/2021

Form Version: 06-Jul-2020 21:54

Site No: 1231

Subject No: 12312868

Generated By:

(b) (4)

Form: MICROBIOLOGY SPECIMEN

Form Status: Data Complete

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

Subject Initials: ---

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

[Back to Form](#)

[eCRF Audit Trail History](#)

[Form Audit Trail](#)

Microbiology Specimen

1.	Actual Date of Collection:	Jan/22/2021
2.	Specimen Type:	SWABBED MATERIAL
3.	Specimen Collection Location:	NASOPHARYNX
4.	Assay Code and Description:	SEVERE ACUTE RESP SYNDROME CORONAVIRUS 2
5.	Device Type:	SARS-COV-2 DIAGNOSTIC TEST
6.	Trade Name:	ATILA BIOSYSTEMS IAMP COVID-19 DETECTION KIT
7.	Test Result:	NEGATIVE
8.	Comments/Findings /Details:	[]
9.	Trade Name Other, Specify:	[]

090177e196ae2e73\Final\Final On: 01-Apr-2021 03:14 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 3 -
Unscheduled Visit on Jan/22/2021

Form Version: 22-Apr-2020 21:03

Site No: 1231

Subject No: 12312868

Generated By:

(b) (4)

Form: ELECTRONIC SAMPLE TRACKING - NASAL
SWAB SELF

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 20:20

[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	[]
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Header Text: C4591001**Visit:** POT_COVID_ILL 3 -
Unscheduled Visit on Jan/22/2021**Form Version:** 22-Apr-2020 21:03**Site No:** 1231**Subject No:** 12312868**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 20:20[eCRF Audit Trail History](#)**Electronic Sample Tracking**

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB
3.	Sample Collected?	YES Date of Collection: Jan/22/2021
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	[BPWFBO]
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Header Text: C4591001

Visit: POT_COVID_ILL 3 -
Unscheduled Visit on Jan/22/2021

Form: HEALTH CARE UTILIZATION

Form Version: 14-Jan-2021 02:24

Form Status: Data Complete

Site No: 1231

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

Subject No: 12312868

Subject Initials: ---

Generated By:

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

(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

090177e196ae2e73\Final\Final On: 01-Apr-2021 03:14 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 3 -
Unscheduled Visit on Jan/22/2021

Form: HEALTH CARE UTILIZATION

Form Version: 14-Jan-2021 02:24

Form Status: Data Complete

Site No: 1231

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

Subject No: 12312868

Subject Initials: ---

Generated By:

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

(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

090177e196ae2e73\Final\Final On: 01-Apr-2021 03:14 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 3

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: 12312868

Subject Initials: ---

Generated By:

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

(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 3 -
Unscheduled Visit on Jan/22/2021

Form Version: 06-Jul-2020 21:53

Site No: 1231

Subject No: 12312868

Generated By:

(b) (4)

Form: RESPIRATORY TREATMENT

Form Status: Not Started

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

Subject Initials: ---

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

[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?	

090177e196ae2e73\Final\Final On: 01-Apr-2021 03:14 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 3 -
Unscheduled Visit on Jan/22/2021

Form: ILLNESS DETAILS

Form Version: 06-Jul-2020 21:52

Form Status: Data Complete

Site No: 1231

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

Subject No: 12312868

Subject Initials: ---

Generated By:

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

(b) (4)

[eCRF Audit Trail History](#)

Illness Details

1.	Category of Clinical Event:	POTENTIAL COVID-19 ILLNESS
2.	Was a diagnosis obtained for Potential COVID-19 Illness?	YES Respiratory Illness Diagnosis: [Pharyngitis] Date of Diagnosis: Jan/22/2021
3.	Toxicity Grade:	1

Header Text: C4591001

Visit: POT_COVID_ILL 3

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: 12312868

Subject Initials: ---

Generated By:

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

(b) (4)

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

090177e196ae2e73\Final\Final On: 01-Apr-2021 03:14 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 3 -
Unscheduled Visit on Jan/22/2021

Form Version: 17-Jul-2020 21:55

Site No: 1231

Subject No: 12312868

Generated By:

(b) (4)

Form: ILLNESS DETAILS - SEVERE

Form Status: Not Started

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

Subject Initials: ---

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

[Back to Form](#)

Illness Details

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

090177e196ae2e73\Final\Final On: 01-Apr-2021 03:14 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 3

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: 12312868

Subject Initials: ---

Generated By:

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

(b) (4)

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

090177e196ae2e73\Final\Final On: 01-Apr-2021 03:14 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 3 -
Unscheduled Visit on Jan/22/2021

Form: LOCAL LABORATORY DATA - REPEATING
CHEMISTRY

Form Version: 21-Aug-2020 02:49

Form Status: Not Started

Site No: 1231

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

Subject No: 12312868

Subject Initials: ---

Generated By:

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

(b) (4)

[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

090177e196ae2e73\Final\Final On: 01-Apr-2021 03:14 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 3

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: 12312868

Subject Initials: ---

Generated By:

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

(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

090177e196ae2e73\Final\Final On: 01-Apr-2021 03:14 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 3 -
Unscheduled Visit on Jan/22/2021

Form Version: 21-Aug-2020 02:51

Site No: 1231

Subject No: 12312868

Generated By:

(b) (4)

Form: LOCAL LABORATORY DATA - REPEATING
Hematology

Form Status: Not Started

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

Subject Initials: ---

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

[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

090177e196ae2e73\Final\Final On: 01-Apr-2021 03:14 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 3

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: 12312868

Subject Initials: ---

Generated By:

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

(b) (4)

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

090177e196ae2e73\Final\Final On: 01-Apr-2021 03:14 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 3 -
Unscheduled Visit on Jan/22/2021

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: 12312868

Subject Initials: ---

Generated By:

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

(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:	[]

090177e196ae2e73\Final\Final On: 01-Apr-2021 03:14 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 3

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: 12312868

Subject Initials: ---

Generated By:

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

(b) (4)

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

090177e196ae2e73\Final\Final On: 01-Apr-2021 03:14 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 3 -
Unscheduled Visit on Jan/22/2021

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: 12312868

Subject Initials: ---

Generated By:

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

(b) (4)

[Back to Form](#)

Vital Signs

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

Vital Signs Details

2.	Record Identifier:	
	SPO2 Pulse Oximetry %	[]

Header Text: C4591001

Visit: POT_COVID_ILL 3

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: 12312868

Subject Initials: ---

Generated By:

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

(b) (4)

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

090177e196ae2e73\Final\Final On: 01-Apr-2021 03:14 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 3 -
Unscheduled Visit on Jan/22/2021

Form Version: 06-Jul-2020 21:52

Site No: 1231

Subject No: 12312868

Generated By:

(b) (4)

Form: OXYGENATION PARAMETERS

Form Status: Not Started

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

Subject Initials: ---

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

[Back to Form](#)

Oxygenation Parameters

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

Header Text: C4591001

Visit: POT_COVID_ILL 3

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: 12312868

Subject Initials: ---

Generated By:

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

(b) (4)

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

090177e196ae2e73\Final\Final On: 01-Apr-2021 03:14 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 3 -
Unscheduled Visit on Jan/22/2021

Form Version: 06-Jul-2020 21:55

Site No: 1231

Subject No: 12312868

Generated By:

(b) (4)

Form: CONCOMITANT MEDICATIONS -
VASOPRESSORS

Form Status: Not Started

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

Subject Initials: ---

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

[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?	

090177e196ae2e73\Final\Final On: 01-Apr-2021 03:14 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 3

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: 12312868

Subject Initials: ---

Generated By:

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

(b) (4)

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

Header Text: C4591001

Visit: POT_COVID_ILL 3 -
Unscheduled Visit on Jan/22/2021

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: 12312868

Subject Initials: ---

Generated By:

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

(b) (4)

[Back to Form](#)

Imaging

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

Header Text: C4591001

Visit: POT_COVID_CONVA 1 -
Unscheduled Visit on Nov/11/2020

Form: DATE OF VISIT - ILLNESS CONVALESCENT

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: 12312868

Subject Initials: ---

Generated By:

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

(b) (4)

[Form Comments](#)

[eCRF Audit Trail History](#)

Date of Visit

1.	Date of Visit	Nov/11/2020	Comments
2.	Erroneous Visit	ERRONEOUS VISIT	

COVID-19 Illness Visit

3.	COVID-19 Illness Visit:	Not Applicable	Comments
----	-------------------------	----------------	--------------------------

090177e196ae2e73\Final\Final On: 01-Apr-2021 03:14 (GMT)

Header Text: C4591001

Visit: POT_COVID_CONVA 1 -
Unscheduled Visit on Nov/11/2020

Form Version: 22-Apr-2020 21:03

Site No: 1231

Subject No: 12312868

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 20:20

[Form Comments](#)

[eCRF Audit Trail History](#)

Electronic Sample Tracking

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

Aliquot

Please enter barcode for each aliquot.

5.	Sample ID	Not Applicable _____ []
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090177e196ae2e73\Final\Final On: 01-Apr-2021 03:14 (GMT)

Header Text: C4591001

Visit: POT_COVID_CONVA 2 -
Unscheduled Visit on Nov/30/2020

Form Version: 22-Apr-2020 21:04

Site No: 1231

Subject No: 12312868

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 20:20

[eCRF Audit Trail History](#)

Date of Visit

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

COVID-19 Illness Visit

3.	COVID-19 Illness Visit:	COVID_B1
----	-------------------------	----------

090177e196ae2e73\Final\Final On: 01-Apr-2021 03:14 (GMT)

Header Text: C4591001**Visit:** POT_COVID_CONVA 2 -
Unscheduled Visit on Nov/30/2020**Form Version:** 22-Apr-2020 21:03**Site No:** 1231**Subject No:** 12312868**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 20:20[eCRF Audit Trail History](#)**Electronic Sample Tracking**

1.	Data Origin	SITE
2.	Sample Type	SERUM
3.	Sample Collected?	YES Date of Collection: Nov/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	[BRVP42]
5.b	Sample ID	[BRVP3Y]
5.c	Sample ID	[BPWSV4]

Header Text: C4591001

Visit: POT_COVID_CONVA 3 -
Unscheduled Visit on Mar/13/2021

Form: DATE OF VISIT - ILLNESS CONVALESCENT

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: 12312868

Subject Initials: ---

Generated By:

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

(b) (4)

[eCRF Audit Trail History](#)

Date of Visit

1.	Date of Visit	Mar/13/2021
2.	Erroneous Visit	

COVID-19 Illness Visit

3.	COVID-19 Illness Visit:	COVID_C1
----	-------------------------	----------

090177e196ae2e73\Final\Final On: 01-Apr-2021 03:14 (GMT)

Header Text: C4591001

Visit: POT_COVID_CONVA 3 -
Unscheduled Visit on Mar/13/2021

Form Version: 22-Apr-2020 21:03

Site No: 1231

Subject No: 12312868

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 20:20

[eCRF Audit Trail History](#)

Electronic Sample Tracking

1.	Data Origin	SITE
2.	Sample Type	SERUM
3.	Sample Collected?	YES Date of Collection: Mar/13/2021
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	[BRYH7X]
5.b	Sample ID	[BPT670]
5.c	Sample ID	[BRYH74]

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: 12312868 **Subject Initials:** ---

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

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: 12312868 **Subject Initials:** ---

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

Unplanned Assessments

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

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: 12312868

Subject Initials: ---

Generated By:

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

(b) (4)

[eCRF Audit Trail History](#)

Disposition - Treatment

1.	Date of Completion/Discontinuation/Death :	Nov/11/2020
2.	Phase of Disposition:	VACCINATION
3.	Status:	COMPLETED
4.	Specify Status:	[]

090177e196ae2e73\Final\Final On: 01-Apr-2021 03:14 (GMT)

Header Text: C4591001

Visit: Follow-Up - Unscheduled

Form Version: 15-Sep-2020 21:53

Site No: 1231

Subject No: 12312868

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 20:20

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: 12312868

Subject Initials: ---

Generated By:

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

(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:** 12312868**Subject Initials:** ---**Generated By:****Generated Time (GMT):** 29-Mar-2021 20:20

(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	[]
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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: 12312868

Subject Initials: ---

Generated By:

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

(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: 12312868

Subject Initials: ---

Generated By:

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

(b) (4)

Vital Signs

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

Vital Signs Details

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

090177e196ae2e73\Final\Final On: 01-Apr-2021 03:14 (GMT)

Header Text: C4591001

Visit: Unplanned Vaccination -
Unscheduled

Form Version: 20-Feb-2021 02:14

Site No: 1231

Subject No: 12312868

Generated By:

(b) (4)

Form: LAB URINALYSIS - PREGNANCY TEST

Form Status: Not Started

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

Subject Initials: ---

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

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:	

090177e196ae2e73\Final\Final On: 01-Apr-2021 03:14 (GMT)

Header Text: C4591001

Visit: Unplanned Vaccination -
Unscheduled

Form: VACCINATION

Form Version: 10-Dec-2020 02:26

Form Status: Not Started

Site No: 1231

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

Subject No: 12312868

Subject Initials: ---

Generated By:

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

(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?	

090177e196ae2e73\Final\Final On: 01-Apr-2021 03:14 (GMT)

Header Text: C4591001

Visit: Unplanned Vaccination -
Unscheduled

Form Version: 10-Oct-2020 15:57

Site No: 1231

Subject No: 12312868

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 20:20

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: 12312868

Subject Initials: ---

Generated By:

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

(b) (4)

Contact Outcome

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

Header Text: C4591001

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

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: 12312868

Subject Initials: ---

Generated By:

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

(b) (4)

[eCRF Audit Trail History](#)

Date of Visit

1.	Date of Visit	Mar/10/2021
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, Locked, Frozen

Site No: 1231

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

Subject No: 12312868

Subject Initials: ---

Generated By:

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

(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 per other protocol allowance(s) and confirmed to have received only placebo at Vaccination 1/2
----	---	---

Header Text: C4591001

Visit: V101_VAX3

Form Version: 22-Apr-2020 21:02

Site No: 1231

Subject No: 12312868

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 20:20

[eCRF Audit Trail History](#)

Date of Visit

1.	Date of Visit	Mar/13/2021
2.	Erroneous Visit	

Header Text: C4591001

Visit: V101_VAX3

Form: INFORMED CONSENT - FURTHER VACCINATION

Form Version: 10-Dec-2020 02:31

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1231

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

Subject No: 12312868

Subject Initials: ---

Generated By:

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

(b) (4)

[eCRF Audit Trail History](#)

Informed Consent - Further Vaccination

1.	Consent Was:	OBTAINED Date Written Consent Obtained Mar/13/2021
----	--------------	--

Header Text: C4591001

Visit: V101_VAX3

Form: INCLUSION/EXCLUSION CRITERIA - FURTHER VACCINATION

Form Version: 10-Dec-2020 02:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1231

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

Subject No: 12312868

Subject Initials: ---

Generated By:

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

(b) (4)

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

090177e196ae2e73\Final\Final On: 01-Apr-2021 03:14 (GMT)

Header Text: C4591001

Visit: V101_VAX3

Form: DISPOSITION - SCREENING FOR FURTHER VACCINATION

Form Version: 10-Dec-2020 02:31

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1231

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

Subject No: 12312868

Subject Initials: ---

Generated By:

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

(b) (4)

[eCRF Audit Trail History](#)

Disposition - Screening for Further Vaccination

1.	Date of Completion/Discontinuation/Death :	Mar/13/2021
2.	Phase of Disposition:	REPEAT SCREENING 1
3.	Status:	COMPLETED
4.	Specify Status:	[]

Header Text: C4591001

Visit: V101_VAX3

Form Version: 20-Feb-2021 02:14

Site No: 1231

Subject No: 12312868

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 20:20

[eCRF Audit Trail History](#)

Lab Urinalysis

1.	Lab Panel:	URINALYSIS
2.	Lab Sub-Panel:	PREGNANCY
3.	Collection Date:	Mar/13/2021
4.	Laboratory Name and Address (Derived)	[STUDY SITE]
5.	Specimen Type:	URINE

Lab Result

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

090177e196ae2e73\Final\Final On: 01-Apr-2021 03:14 (GMT)

Header Text: C4591001

Visit: V101_VAX3

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: 12312868

Subject Initials: ---

Generated By:

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

(b) (4)

[eCRF Audit Trail History](#)

Electronic Sample Tracking

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

Aliquot

Please enter barcode for each aliquot.

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

090177e196ae2e73\Final\Final On: 01-Apr-2021 03:14 (GMT)

Header Text: C4591001

Visit: V101_VAX3

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: 12312868

Subject Initials: ---

Generated By:

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

(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: Mar/13/2021
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	[BR1LMS]
-----	-----------	----------

090177e196ae2e73\Final\Final On: 01-Apr-2021 03:14 (GMT)

Header Text: C4591001

Visit: V101_VAX3

Form Version: 10-Dec-2020 02:26

Site No: 1231

Subject No: 12312868

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 20:20

[eCRF Audit Trail History](#)

Vaccination

1.	Was there a temporary delay of vaccination?	NO
2.	Treatment Name	[BNT162b2]
3.	Formulation:	INJECTION
4.	Dose Date Time:	Mar/13/2021 18:35
5.	Anatomical Location:	DELTOID MUSCLE
6.	Body Side:	LEFT
7.	Route:	INTRAMUSCULAR
8.	Actual Dose:	[30.0]
9.	Unit:	ug
10.	Timeframe Subject Was Observed	30 MINUTES
11.	Was the subject observed for at least the protocol specified observation period after investigational product administration?	YES

090177e196ae2e73\Final\Final On: 01-Apr-2021 03:14 (GMT)

Header Text: C4591001

Visit: V102_VAX4

Form Version: 22-Apr-2020 21:02

Site No: 1231

Subject No: 12312868

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 20:20

Date of Visit

1.	Date of Visit	//
2.	Erroneous Visit	

Header Text: C4591001**Visit:** V102_VAX4**Form Version:** 20-Feb-2021 02:14**Site No:** 1231**Subject No:** 12312868**Generated By:**

(b) (4)

Form: LAB URINALYSIS - PREGNANCY TEST**Form Status:** Not Started**Site Name:** (1231) Hospital Militar Central Cirujano
Mayor Dr. Cosme Argerich**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 20:20**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: V102_VAX4

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1231

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

Subject No: 12312868

Subject Initials: ---

Generated By:

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

(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	[]
----	-----------	-----

090177e196ae2e73\Final\Final On: 01-Apr-2021 03:14 (GMT)

Header Text: C4591001

Visit: V102_VAX4

Form Version: 10-Dec-2020 02:26

Site No: 1231

Subject No: 12312868

Generated By:

(b) (4)

Form: VACCINATION

Form Status: Not Started

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

Subject Initials: ---

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

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?	

090177e196ae2e73\Final\Final On: 01-Apr-2021 03:14 (GMT)

Header Text: C4591001

Visit: V103_MONTH1

Form Version: 22-Apr-2020 21:02

Site No: 1231

Subject No: 12312868

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 20:20

Date of Visit

1.	Date of Visit	//
2.	Erroneous Visit	

Header Text: C4591001

Visit: V103_MONTH1

Form Version: 22-Apr-2020 21:04

Site No: 1231

Subject No: 12312868

Generated By:

(b) (4)

Form: CONTACT OUTCOME

Form Status: Not Started

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

Subject Initials: ---

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

Contact Outcome

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

Header Text: C4591001

Visit: V104_MONTH6

Form Version: 22-Apr-2020 21:02

Site No: 1231

Subject No: 12312868

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 20:20

Date of Visit

1.	Date of Visit	//
2.	Erroneous Visit	

Header Text: C4591001

Visit: V104_MONTH6

Form Version: 22-Apr-2020 21:04

Site No: 1231

Subject No: 12312868

Generated By:

(b) (4)

Form: CONTACT OUTCOME

Form Status: Not Started

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

Subject Initials: ---

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

Contact Outcome

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

Header Text: C4591001

Visit: V105_MONTH18

Form Version: 22-Apr-2020 21:02

Site No: 1231

Subject No: 12312868

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 20:20

Date of Visit

1.	Date of Visit	//
2.	Erroneous Visit	

Header Text: C4591001

Visit: V105_MONTH18

Form Version: 22-Apr-2020 21:04

Site No: 1231

Subject No: 12312868

Generated By:

(b) (4)

Form: CONTACT OUTCOME

Form Status: Not Started

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

Subject Initials: ---

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

Contact Outcome

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

Header Text: C4591001

Visit:
FURTHER_VACCINATION_EOT -
Unscheduled

Form: DISPOSITION - TREATMENT

Form Version: 20-Feb-2021 02:26

Form Status: Not Started

Site No: 1231

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

Subject No: 12312868

Subject Initials: ---

Generated By:

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

(b) (4)

Disposition - Treatment

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

090177e196ae2e73\Final\Final On: 01-Apr-2021 03:14 (GMT)

Header Text: C4591001

Visit: Logs

Form: ADVERSE EVENT REPORT

Form Version: 22-Apr-2020 21:02

Site No: 1231

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

Subject No: 12312868

Subject Initials: ---

Generated By:

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

(b) (4)

#	Category	AE Identifier	Adverse Event	Start Date	Is the Adverse Event Still Ongoing	Form Instance
1.	ADVERSE EVENT	1	syncope	Oct/8/2020 12:18	NO End Date Time: Oct/8/2020 14:06	Repeating Pages
2.	ADVERSE EVENT	2	minor cranioencephalic trauma	Oct/8/2020 12:18	NO End Date Time: Oct/8/2020 12:18	Repeating Pages

090177e196ae2e73\Final\Final On: 01-Apr-2021 03:14 (GMT)

Header Text: C4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT

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: 12312868

Subject Initials: ---

Generated By:

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

(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)	[syncope]
4.	Start Date Time:	Oct/8/2020 12:18
5.	Is the adverse event still ongoing?	NO End Date Time: Oct/8/2020 14:06
6.	Toxicity Grade:	3

090177e196ae2e73\Final\Final On: 01-Apr-2021 03:14 (GMT)

Header Text: C4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1231

Subject No: 12312868

Generated By:

(b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

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

090177e196ae2e73\Final\Final On: 01-Apr-2021 03:14 (GMT)

Header Text: C4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT

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: 12312868

Subject Initials: ---

Generated By:

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

(b) (4)

10.	Latest Action Taken with Study Treatment:	NOT APPLICABLE
11.	Was a Concomitant Medication given?	NO
12.	Was a Non-Drug Treatment given?	YES
13.	What was the outcome of this adverse event?:	RECOVERED/RESOLVED
14.	Did the adverse event cause the subject to be discontinued from the study?	NO
15.	Serious Adverse Event Number: For Pfizer Use Only	[2020392233]

090177e196ae2e73\Final\Final On: 01-Apr-2021 03:14 (GMT)

Header Text: C4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1231

Subject No: 12312868

Generated By:

(b) (4)

Form: ADVERSE EVENT REPORT

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

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

Subject Initials: ---

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

[Back to Form](#)

[eCRF Audit Trail History](#)

[Form Audit Trail](#)

Adverse Event Report

1.	Category:	ADVERSE EVENT
2.	AE ID:	[2]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[minor cranioencephalic trauma]
4.	Start Date Time:	Oct/8/2020 12:18
5.	Is the adverse event still ongoing?	NO End Date Time: Oct/8/2020 12:18
6.	Toxicity Grade:	1

090177e196ae2e73\Final\Final On: 01-Apr-2021 03:14 (GMT)

Header Text: C4591001**Visit:** Logs - Unscheduled**Form Version:** 22-Apr-2020 21:02**Site No:** 1231**Subject No:** 12312868**Generated By:**

(b) (4)

Form: ADVERSE EVENT REPORT**Form Status:** Data Complete, Locked, Frozen, Not Complete**Site Name:** (1231) Hospital Militar Central Cirujano Mayor Dr. Cosme Argerich**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 20:20

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

Header Text: C4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT

Form Version: 22-Apr-2020 21:02

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

Site No: 1231

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

Subject No: 12312868

Subject Initials: ---

Generated By:

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

(b) (4)

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

090177e196ae2e73\Final\Final On: 01-Apr-2021 03:14 (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: 12312868

Subject Initials: ---

Generated By:

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

(b) (4)

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

090177e196ae2e73\Final\Final On: 01-Apr-2021 03:14 (GMT)

Header Text: C4591001

Visit: Logs - Unscheduled

Form Version: 17-Jul-2020 21:54

Site No: 1231

Subject No: 12312868

Generated By:

(b) (4)

Form: MEDICATION ERROR

Form Status: Not Started

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

Subject Initials: ---

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

[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	[]

090177e196ae2e73\Final\Final On: 01-Apr-2021 03:14 (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: 12312868

Subject Initials: ---

Generated By:

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

(b) (4)

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

090177e196ae2e73\Final\Final On: 01-Apr-2021 03:14 (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: 12312868

Subject Initials: ---

Generated By:

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

(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:	//

090177e196ae2e73\Final\Final On: 01-Apr-2021 03:14 (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: 12312868

Subject Initials: ---

Generated By:

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

(b) (4)

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

090177e196ae2e73\Final\Final On: 01-Apr-2021 03:14 (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: 12312868

Subject Initials: ---

Generated By:

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

(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?	

090177e196ae2e73\Final\Final On: 01-Apr-2021 03:14 (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: 12312868

Subject Initials: ---

Generated By:

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

(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: 12312868

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 20:20

[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?	

090177e196ae2e73\Final\Final On: 01-Apr-2021 03:14 (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: 12312868

Subject Initials: ---

Generated By:

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

(b) (4)

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

090177e196ae2e73\Final\Final On: 01-Apr-2021 03:14 (GMT)

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: 12312868

Subject Initials: ---

Generated By:

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

(b) (4)

[Back to Form](#)

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

Header Text: C4591001

Visit: Disposition - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1231

Subject No: 12312868

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 20:20

[eCRF Audit Trail History](#)

Treatment Unblinded

1.	Date Treatment Unblinded :	Mar/10/2021
2.	Primary Reason for Unblinding:	ASSESS ELIGIBILITY FOR ADDITIONAL VACCINATION

090177e196ae2e73\Final\Final On: 01-Apr-2021 03:14 (GMT)

Header Text: C4591001

Visit: Disposition - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1231

Subject No: 12312868

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 20:20

Withdrawal Of Consent

1.	Withdrawal of Consent Date :	//
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Header Text: C4591001

Visit: Disposition - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1231

Subject No: 12312868

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 20:20

Death Details

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

Cause of Death

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

090177e196ae2e73\Final\Final On: 01-Apr-2021 03:14 (GMT)

Header Text: C4591001

Visit: Subject Status - Unscheduled

Form: SUBJECT STATUS

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Verified

Site No: 1231

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

Subject No: 12312868

Subject Initials: ---

Generated By:

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

(b) (4)

[eCRF Audit Trail History](#)

Subject Status

1.	Subject Status	FOLLOW-UP
2.	Subject Status Date	Nov/11/2020

Header Text: C4591001

Visit: Investigator Signature -
Unscheduled

Form: CASEBOOK SIGNATURE FORM

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Signed, Verified

Site No: 1231

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

Subject No: 12312868

Subject Initials: ---

Generated By:

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

(b) (4)

[eCRF Audit Trail History](#)

Casebook Signature Form

1.	Casebook Signature	Click Here to Enable
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Header Text: C4591001

Visit: Investigator Signature -
Unscheduled

Form: CASEBOOK SIGNATURE FORM

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Signed, Verified

Site No: 1231

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

Subject No: 12312868

Subject Initials: ---

Generated By:

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

(b) (4)

[Audit Trail](#)

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

- CRF_Sign

Name	Signature Meaning	Date	Type	Action
(b) (6)	Approved	Mar-19-2021 16:19:36 (UTC-03:00) City of Buenos Aires	BOOK	Signed

Affidavit:

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

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

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

090177e196ae2e73\Final\Final On: 01-Apr-2021 03:14 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form: GENERAL MEDICAL HISTORY - Comments

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: 12312868

Subject Initials: ---

Generated By:

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

(b) (4)

[Back to Form](#)

Item	Date	User	Comment
Form	Mar-17-2021 10:31:24 (UTC-03:00) City of Buenos Aires	(b) (4), (b) (6)	
Form	Aug-21-2020 16:51:04 (UTC-03:00) City of Buenos Aires	(b) (4), (b) (6)	Not Applicable

090177e196ae2e73\Final\Final On: 01-Apr-2021 03:14 (GMT)

Header Text: C4591001

Visit: POT_COVID_CONVA 1 -
Unscheduled Visit on Nov/11/2020

Form Version: 22-Apr-2020 21:04

Site No: 1231

Subject No: 12312868

Generated By:

(b) (4)

Form: DATE OF VISIT - ILLNESS CONVALESCENT -
Comments

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 20:20

[Back to Form](#)

Item	Date	User	Comment
Form	Dec-03-2020 10:09:09 (UTC-03:00) City of Buenos Aires	(b) (4), (b) (6)	Not applicable.
Form	Dec-01-2020 13:43:56 (UTC-03:00) City of Buenos Aires	(b) (4), (b) (6)	The volunteer was cited on different occasions that for personal reasons and / or unrelated to the protocol, she has not been able to attend the convalescence visits for covid A. Thanks

090177e196ae2e73\Final\Final On: 01-Apr-2021 03:14 (GMT)

Header Text: C4591001

Visit: POT_COVID_CONVA 1

Form: DATE OF VISIT - ILLNESS CONVALESCENT -
Comments

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: 12312868

Subject Initials: ---

Generated By:

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

(b) (4)

[Back to Form](#)

Item	Date	User	Comment
1	Dec-02-2020 12:42:37 (UTC-03:00) City of Buenos Aires	(b) (4), (b) (6) [Redacted] [Redacted]	Not applicable.

Header Text: C4591001

Visit: POT_COVID_CONVA 1

Form: DATE OF VISIT - ILLNESS CONVALESCENT - Comments

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: 12312868

Subject Initials: ---

Generated By:

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

(b) (4)

[Back to Form](#)

Item	Date	User	Comment
3	Dec-01-2020 13:39:06 (UTC-03:00) City of Buenos Aires	(b) (4), (b) (6)	Not Applicable

Header Text: C4591001

Visit: POT_COVID_CONVA 1 -
Unscheduled Visit on Nov/11/2020

Form Version: 22-Apr-2020 21:03

Site No: 1231

Subject No: 12312868

Generated By:

(b) (4)

Form: ELECTRONIC SAMPLE TRACKING -
IMMUNOGENICITY - Comments

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 20:20

[Back to Form](#)

Item	Date	User	Comment
Form	Dec-01-2020 13:39:28 (UTC-03:00) City of Buenos Aires	(b) (4), (b) (6)	Not Applicable

Header Text: C4591001

Visit: POT_COVID_CONVA 1

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - Comments

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: 12312868

Subject Initials: ---

Generated By:

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

(b) (4)

[Back to Form](#)

Item	Date	User	Comment
1	Dec-01-2020 13:39:28 (UTC-03:00) City of Buenos Aires	(b) (4), (b) (6)	Not Applicable

Header Text: C4591001

Visit: POT_COVID_CONVA 1

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - Comments

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: 12312868

Subject Initials: ---

Generated By:

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

(b) (4)

[Back to Form](#)

Item	Date	User	Comment
2	Dec-01-2020 13:39:28 (UTC-03:00) City of Buenos Aires	(b) (4), (b) (6)	Not Applicable

Header Text: C4591001

Visit: POT_COVID_CONVA 1

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - Comments

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: 12312868

Subject Initials: ---

Generated By:

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

(b) (4)

[Back to Form](#)

Item	Date	User	Comment
3	Dec-01-2020 13:39:28 (UTC-03:00) City of Buenos Aires	(b) (4), (b) (6)	Not Applicable

Header Text: C4591001

Visit: POT_COVID_CONVA 1

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - Comments

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: 12312868

Subject Initials: ---

Generated By:

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

(b) (4)

[Back to Form](#)

Item	Date	User	Comment
4	Dec-01-2020 13:39:28 (UTC-03:00) City of Buenos Aires	(b) (4), (b) (6)	Not Applicable

Header Text: C4591001

Visit: V101_VAX3

Form: INCLUSION/EXCLUSION CRITERIA - FURTHER VACCINATION - Comments

Form Version: 10-Dec-2020 02:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1231

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

Subject No: 12312868

Subject Initials: ---

Generated By:

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

(b) (4)

[Back to Form](#)

Item	Date	User	Comment
Form	Mar-14-2021 10:56:41 (UTC-03:00) City of Buenos Aires	(b) (4), (b) (6)	Not Applicable

Header Text: C4591001

Visit: Investigator Signature -
Unscheduled

Form: CASEBOOK SIGNATURE FORM - Signature
History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Signed, Verified

Site No: 1231

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

Subject No: 12312868

Subject Initials: ---

Generated By:

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

(b) (4)

[Back to Form](#)

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

- CRF_Sign

Name	Signature Meaning	Date	Type	Action
(b) (6)	Approved	Mar-19-2021 16:19:36 (UTC-03:00) City of Buenos Aires	BOOK	Signed

Affidavit:

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

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

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

(b) (6)	N/A	Mar-17-2021 10:31:24 (UTC-03:00) City of Buenos Aires		Edit - All signatures invalidated
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Affidavit:

N/A

(b) (6)	Approved	Mar-16-2021 20:41:15 (UTC-03:00) City of Buenos Aires	BOOK	Signed
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090177e196ae2e73\Final\Final On: 01-Apr-2021 03:14 (GMT)

Header Text: C4591001

Visit: Investigator Signature -
Unscheduled

Form: CASEBOOK SIGNATURE FORM - Signature
History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Signed, Verified

Site No: 1231

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

Subject No: 12312868

Subject Initials: ---

Generated By:

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

(b) (4)

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	Mar-13-2021 17:33:39 (UTC-03:00) City of Buenos Aires		Edit - All signatures invalidated
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Affidavit:

N/A

(b) (6)	Approved	Mar-11-2021 17:14:19 (UTC-03:00) City of Buenos Aires	BOOK	Signed
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090177e196ae2e73\Final\Final On: 01-Apr-2021 03:14 (GMT)

Header Text: C4591001

Visit: Investigator Signature -
Unscheduled

Form: CASEBOOK SIGNATURE FORM - Signature
History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Signed, Verified

Site No: 1231

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

Subject No: 12312868

Subject Initials: ---

Generated By:

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

(b) (4)

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	Mar-10-2021 17:03:17 (UTC-03:00) City of Buenos Aires		Edit - All signatures invalidated
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Affidavit:

N/A

(b) (6)	Approved	Jan-29-2021 20:24:57 (UTC-03:00) City of Buenos Aires	BOOK	Signed
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090177e196ae2e73\Final\Final On: 01-Apr-2021 03:14 (GMT)

Header Text: C4591001

Visit: Investigator Signature -
Unscheduled

Form: CASEBOOK SIGNATURE FORM - Signature
History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Signed, Verified

Site No: 1231

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

Subject No: 12312868

Subject Initials: ---

Generated By:

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

(b) (4)

Affidavit:

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

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

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

(b) (6)	N/A	Jan-23-2021 11:35:22 (UTC-03:00) City of Buenos Aires		Edit - All signatures invalidated
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Affidavit:

N/A

(b) (6)	Approved	Jan-21-2021 00:38:16 (UTC-03:00) City of Buenos Aires	BOOK	Signed
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090177e196ae2e73\Final\Final On: 01-Apr-2021 03:14 (GMT)

Header Text: C4591001

Visit: Investigator Signature -
Unscheduled

Form: CASEBOOK SIGNATURE FORM - Signature
History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Signed, Verified

Site No: 1231

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

Subject No: 12312868

Subject Initials: ---

Generated By:

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

(b) (4)

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-30-2020 19:32:17 (UTC-03:00) City of Buenos Aires		Edit - All signatures invalidated
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Affidavit:

N/A

(b) (6)	Approved	Nov-13-2020 18:35:15 (UTC-03:00) City of Buenos Aires	BOOK	Signed
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090177e196ae2e73\Final\Final On: 01-Apr-2021 03:14 (GMT)

Header Text: C4591001

Visit: Investigator Signature -
Unscheduled

Form: CASEBOOK SIGNATURE FORM - Signature
History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Signed, Verified

Site No: 1231

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

Subject No: 12312868

Subject Initials: ---

Generated By:

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

(b) (4)

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.

Martina Davalli	N/A	Nov-11-2020 19:45:41 (UTC-03:00) City of Buenos Aires		Edit - All signatures invalidated
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Affidavit:

N/A

(b) (6)	Approved	Nov-06-2020 13:59:28 (UTC-03:00) City of Buenos Aires	BOOK	Signed
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090177e196ae2e73\Final\Final On: 01-Apr-2021 03:14 (GMT)

Header Text: C4591001

Visit: Investigator Signature -
Unscheduled

Form Version: 22-Apr-2020 21:04

Site No: 1231

Subject No: 12312868

Generated By:

(b) (4)

Form: CASEBOOK SIGNATURE FORM - Signature
History

Form Status: Data Complete, Signed, Verified

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

Subject Initials: ---

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

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.

090177e196ae2e73\Final\Final On: 01-Apr-2021 03:14 (GMT)

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: 12312868

Subject Initials: ---

Generated By:

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

(b) (4)

[Back to Form](#)

1. Select appropriate response - Protocol version

Date	Location	User	Value	Reason
Aug-21-2020 16:49:41 (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-21-2020 16:49:41 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: STAGE 3 COHORTS	Initial Entry

090177e196ae2e73\Final\Final On: 01-Apr-2021 03:14 (GMT)

Header Text: C4591001

Visit: COHORT_SELECTION

Form Version: 22-Apr-2020 21:02

Site No: 1231

Subject No: 12312868

Generated By:

(b) (4)

Form: MAIN INFORMED CONSENT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

[Back to Form](#)

1. Consent Was:

Date	Location	User	Value	Reason
Aug-21-2020 16:49:48 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: OBTAINED Date Written Consen t Obtained Aug/21/2020	Initial Entry

090177e196ae2e73\Final\Final On: 01-Apr-2021 03:14 (GMT)

Header Text: C4591001

Visit: COHORT_SELECTION

Form Version: 06-Jul-2020 21:55

Site No: 1231

Subject No: 12312868

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 20:20

[Back to Form](#)

1. Subject ID

Date	Location	User	Value	Reason
Oct-13-2020 21:46:15 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	event entered in AE CRF
Oct-11-2020 10:39:53 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	SAE RECON:AER#2020392233 SYNCOPE(onset date:08Oct2020)was reported as serious in Safety database but missing in AE CRF. Please confirm and update CRF. If safety update is required, submit a follow-up SAE Form.
Aug-21-2020 12:59:47 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry : 12312868	Item copied from previous form

2. Birth Date:

Date	Location	User	Value	Reason
Aug-21-2020	ACV0PFEINFP6000	auto calc	Data Entry:	Enrollment

090177e196ae2e73\Final\Final On: 01-Apr-2021 03:14 (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: 12312868

Subject Initials: ---

Generated By:

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

(b) (4)

12:59:44 (UTC-03:00) City of Buenos Aires		(autocalc)	(b) (6)/1977	Entry
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3. Sex:

Date	Location	User	Value	Reason
Aug-21-2020 16:50:04 (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-21-2020 16:50:04 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: HISPANIC OR LATI NO(A) OR OF SPANI SH ORIGIN	Initial Entry

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

Date	Location	User	Value	Reason
Aug-21-2020 16:50:04 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: WHITE	Initial Entry

090177e196ae2e73\Final\Final On: 01-Apr-2021 03:14 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:02

Site No: 1231

Subject No: 12312868

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 20:20

[Back to Form](#)

1. Date of Visit

Date	Location	User	Value	Reason
Aug-21-2020 16:50:16 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Aug/21/2020	Initial Entry

090177e196ae2e73\Final\Final On: 01-Apr-2021 03:14 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form: INCLUSION/EXCLUSION CRITERIA - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:50

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1231

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

Subject No: 12312868

Subject Initials: ---

Generated By:

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

(b) (4)

[Back to Form](#)

1.a

Date	Location	User	Value	Reason
Aug-21-2020 16:50:38 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<p>Data Entry:</p> <p>Incl 1 usio n N umb er:</p> <p>Crit Male or female erio participants bet n D ween the ages o escr f 18 and 55 year iptio s, inclusive, 65 n: and 85 years, in clusive, or 18 a nd 85 years, inc lusive, at rando mization (depen dent upon study stage)</p> <p>Crit YES erio n m et?:</p>	Initial Entry

090177e196ae2e73\Final\Final On: 01-Apr-2021 03:14 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form: INCLUSION/EXCLUSION CRITERIA - eCRF
Audit Trail History

Form Version: 21-Aug-2020 02:50

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1231

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

Subject No: 12312868

Subject Initials: ---

Generated By:

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

(b) (4)

			Crit IN01A00 erion ID : (F or P fizer use only):	
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1.a Inclusion Number:

Date	Location	User	Value	Reason
Aug-21-2020 16:50:38 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 1	Initial Entry

1.a Criterion Description:

Date	Location	User	Value	Reason
Aug-21-2020 16:50:38 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Male or female partici pants between the age s of 18 and 55 years, i nclusive, 65 and 85 ye ars, inclusive, or 18 an d 85 years, inclusive, at randomization (dep endent upon study sta ge)	Initial Entry

090177e196ae2e73\Final\Final On: 01-Apr-2021 03:14 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form: INCLUSION/EXCLUSION CRITERIA - eCRF
Audit Trail History

Form Version: 21-Aug-2020 02:50

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1231

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

Subject No: 12312868

Subject Initials: ---

Generated By:

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

(b) (4)

1.a Criterion met?

Date	Location	User	Value	Reason
Aug-21-2020 16:50:38 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

1.a Criterion ID: (For Pfizer use only)

Date	Location	User	Value	Reason
Aug-21-2020 16:50:38 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: IN01A00	Initial Entry

1.b

Date	Location	User	Value	Reason
Aug-21-2020 16:50:38 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Incl 2 usio n Nu mbe r:	Initial Entry

090177e196ae2e73\Final\Final On: 01-Apr-2021 03:14 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form: INCLUSION/EXCLUSION CRITERIA - eCRF
Audit Trail History

Form Version: 21-Aug-2020 02:50

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1231

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

Subject No: 12312868

Subject Initials: ---

Generated By:

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

(b) (4)

			<p>Crit Participants wh erio o are willing an n De d able to compl scri y with all sched ptio uled visits, vac n: cination plan, l aboratory tests, lifestyle consid erations, and ot her study proce dures</p> <p>Crit YES erio n me t?:</p> <p>Crit IN02A00 erio n ID : (Fo r Pfi zer use only):</p>	
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090177e196ae2e73\Final\Final On: 01-Apr-2021 03:14 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form: INCLUSION/EXCLUSION CRITERIA - eCRF
Audit Trail History

Form Version: 21-Aug-2020 02:50

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1231

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

Subject No: 12312868

Subject Initials: ---

Generated By:

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

(b) (4)

1.b Inclusion Number:

Date	Location	User	Value	Reason
Aug-21-2020 16:50:38 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 2	Initial Entry

1.b Criterion Description:

Date	Location	User	Value	Reason
Aug-21-2020 16:50:38 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Participants who are w illing and able to com ply with all scheduled visits, vaccination pla n, laboratory tests, life style considerations, a nd other study proced ures	Initial Entry

1.b Criterion met?

Date	Location	User	Value	Reason
Aug-21-2020 16:50:38 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

1.b Criterion ID: (For Pfizer use only)

090177e196ae2e73\Final\Final On: 01-Apr-2021 03:14 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form: INCLUSION/EXCLUSION CRITERIA - eCRF
Audit Trail History

Form Version: 21-Aug-2020 02:50

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1231

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

Subject No: 12312868

Subject Initials: ---

Generated By:

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

(b) (4)

Date	Location	User	Value	Reason
Aug-21-2020 16:50:38 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: IN02A00	Initial Entry

l.c

Date	Location	User	Value	Reason
Aug-21-2020 16:50:38 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Incl 3 usio n N umb er: Crit Healthy partici erio pants who are d n De etermined by m scri edical history, p ptio hysical examin n: ation, and clinic al judgment of t he investigator to be eligible fo r inclusion in th e study Crit YES erio n m et?:	Initial Entry

090177e196ae2e73\Final\Final On: 01-Apr-2021 03:14 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 21-Aug-2020 02:50

Site No: 1231

Subject No: 12312868

Generated By:

(b) (4)

Form: INCLUSION/EXCLUSION CRITERIA - 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 20:20

			Crit IN03A00 erio n ID : (Fo r Pfi zer use only):	
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090177e196ae2e73\Final\Final On: 01-Apr-2021 03:14 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form: INCLUSION/EXCLUSION CRITERIA - eCRF
Audit Trail History

Form Version: 21-Aug-2020 02:50

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1231

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

Subject No: 12312868

Subject Initials: ---

Generated By:

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

(b) (4)

I.c Inclusion Number:

Date	Location	User	Value	Reason
Aug-21-2020 16:50:38 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 3	Initial Entry

I.c Criterion Description:

Date	Location	User	Value	Reason
Aug-21-2020 16:50:38 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Healthy participants w ho are determined by medical history, physi cal examination, and c linical judgment of the investigator to be eligi ble for inclusion in the study	Initial Entry

I.c Criterion met?

Date	Location	User	Value	Reason
Aug-21-2020 16:50:38 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

I.c Criterion ID: (For Pfizer use only)

090177e196ae2e73\Final\Final On: 01-Apr-2021 03:14 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form: INCLUSION/EXCLUSION CRITERIA - eCRF
Audit Trail History

Form Version: 21-Aug-2020 02:50

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1231

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

Subject No: 12312868

Subject Initials: ---

Generated By:

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

(b) (4)

Date	Location	User	Value	Reason
Aug-21-2020 16:50:38 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: IN03A00	Initial Entry

1.d

Date	Location	User	Value	Reason
Aug-21-2020 16:50:38 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Incl 4 usio n Nu mbe r: Crit Capable of givi erio ng personal sig n De ned informed c scrip onsent, which i tion: ncludes compli ance with the re quirements and restrictions liste d in the ICD an d in this protoc ol Crit YES erio n me t?:	Initial Entry

090177e196ae2e73\Final\Final On: 01-Apr-2021 03:14 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 21-Aug-2020 02:50

Site No: 1231

Subject No: 12312868

Generated By:

(b) (4)

Form: INCLUSION/EXCLUSION CRITERIA - 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 20:20

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			r Pfi	
			zer	
			use	
			only	
):	

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form: INCLUSION/EXCLUSION CRITERIA - eCRF
Audit Trail History

Form Version: 21-Aug-2020 02:50

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1231

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

Subject No: 12312868

Subject Initials: ---

Generated By:

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

(b) (4)

1.d Inclusion Number:

Date	Location	User	Value	Reason
Aug-21-2020 16:50:38 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 4	Initial Entry

1.d Criterion Description:

Date	Location	User	Value	Reason
Aug-21-2020 16:50:38 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Capable of giving pers onal signed informed consent, which includ es compliance with th e requirements and res trictions listed in the I CD and in this protoco l	Initial Entry

1.d Criterion met?

Date	Location	User	Value	Reason
Aug-21-2020 16:50:38 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

1.d Criterion ID: (For Pfizer use only)

090177e196ae2e73\Final\Final On: 01-Apr-2021 03:14 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form: INCLUSION/EXCLUSION CRITERIA - eCRF
Audit Trail History

Form Version: 21-Aug-2020 02:50

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1231

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

Subject No: 12312868

Subject Initials: ---

Generated By:

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

(b) (4)

Date	Location	User	Value	Reason
Aug-21-2020 16:50:38 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: IN04A00	Initial Entry

2.a

Date	Location	User	Value	Reason
Aug-21-2020 16:50:38 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Excl 1 usio n N umb er: Crit Other medical o erio r psychiatric co n De ndition incl. rec scri ent (within past ptio year) or active s n: uicidal ideation/ behavior/lab ab normality that may increase th e risk of study p articipation Crit NO erio n m et?:	Initial Entry

090177e196ae2e73\Final\Final On: 01-Apr-2021 03:14 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form: INCLUSION/EXCLUSION CRITERIA - eCRF
Audit Trail History

Form Version: 21-Aug-2020 02:50

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1231

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

Subject No: 12312868

Subject Initials: ---

Generated By:

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

(b) (4)

			Crit EX01A00 erio n ID : (Fo r Pfi zer use only):	
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2.a Exclusion Number:

Date	Location	User	Value	Reason
Aug-21-2020 16:50:38 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 1	Initial Entry

2.a Criterion Description:

Date	Location	User	Value	Reason
Aug-21-2020 16:50:38 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Other medical or psyc hiatric condition incl. recent (within past yea r) or active suicidal id eation/behavior/lab ab normality that may inc rease the risk of study participation	Initial Entry

090177e196ae2e73\Final\Final On: 01-Apr-2021 03:14 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form: INCLUSION/EXCLUSION CRITERIA - eCRF
Audit Trail History

Form Version: 21-Aug-2020 02:50

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1231

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

Subject No: 12312868

Subject Initials: ---

Generated By:

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

(b) (4)

2.a Criterion met?

Date	Location	User	Value	Reason
Aug-21-2020 16:50:38 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2.a Criterion ID: (For Pfizer use only)

Date	Location	User	Value	Reason
Aug-21-2020 16:50:38 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: EX01A00	Initial Entry

2.b

Date	Location	User	Value	Reason
Aug-21-2020 16:50:38 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Exclu 2 sion Num ber:	Initial Entry

090177e196ae2e73\Final\Final On: 01-Apr-2021 03:14 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form: INCLUSION/EXCLUSION CRITERIA - eCRF
Audit Trail History

Form Version: 21-Aug-2020 02:50

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1231

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

Subject No: 12312868

Subject Initials: ---

Generated By:

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

(b) (4)

			<p>Crite rion Known infecti on with human Descr immunodefici iptio ency virus (HI n: V), hepatitis C virus (HCV), or hepatitis B virus (HBV)</p> <p>Crite rion NO met?:</p> <p>Crite rion I EX02A00 D: (F or Pfi zer u se onl y):</p>	
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090177e196ae2e73\Final\Final On: 01-Apr-2021 03:14 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form: INCLUSION/EXCLUSION CRITERIA - eCRF
Audit Trail History

Form Version: 21-Aug-2020 02:50

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1231

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

Subject No: 12312868

Subject Initials: ---

Generated By:

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

(b) (4)

2.b Exclusion Number:

Date	Location	User	Value	Reason
Aug-21-2020 16:50:38 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 2	Initial Entry

2.b Criterion Description:

Date	Location	User	Value	Reason
Aug-21-2020 16:50:38 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Known infection with human immunodeficie ncy virus (HIV), hepat itis C virus (HCV), or hepatitis B virus (HB V)	Initial Entry

2.b Criterion met?

Date	Location	User	Value	Reason
Aug-21-2020 16:50:38 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2.b Criterion ID: (For Pfizer use only)

Date	Location	User	Value	Reason
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090177e196ae2e73\Final\Final On: 01-Apr-2021 03:14 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form: INCLUSION/EXCLUSION CRITERIA - eCRF
Audit Trail History

Form Version: 21-Aug-2020 02:50

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1231

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

Subject No: 12312868

Subject Initials: ---

Generated By:

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

(b) (4)

Aug-21-2020 16:50:38 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: EX02A00	Initial Entry
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2.c

Date	Location	User	Value	Reason
Aug-21-2020 16:50:38 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Excl 3 usio n Nu mbe r: Crit History of severe erio re adverse react n De ion associated scrip with a vaccine tion: and/or severe al lergic reaction (eg, anaphylaxis) to any compo nent of the stud y intervention(s) Crit NO erio n me t?:	Initial Entry

090177e196ae2e73\Final\Final On: 01-Apr-2021 03:14 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form: INCLUSION/EXCLUSION CRITERIA - eCRF
Audit Trail History

Form Version: 21-Aug-2020 02:50

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1231

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

Subject No: 12312868

Subject Initials: ---

Generated By:

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

(b) (4)

			Crit EX03A00 erio n ID : (Fo r Pfi zer use only):	
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090177e196ae2e73\Final\Final On: 01-Apr-2021 03:14 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form: INCLUSION/EXCLUSION CRITERIA - eCRF
Audit Trail History

Form Version: 21-Aug-2020 02:50

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1231

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

Subject No: 12312868

Subject Initials: ---

Generated By:

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

(b) (4)

2.c Exclusion Number:

Date	Location	User	Value	Reason
Aug-21-2020 16:50:38 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 3	Initial Entry

2.c Criterion Description:

Date	Location	User	Value	Reason
Aug-21-2020 16:50:38 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: History of severe adverse reaction associated with a vaccine and/or severe allergic reaction (eg, anaphylaxis) to any component of the study intervention(s)	Initial Entry

2.c Criterion met?

Date	Location	User	Value	Reason
Aug-21-2020 16:50:38 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2.c Criterion ID: (For Pfizer use only)

Date	Location	User	Value	Reason
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090177e196ae2e73\Final\Final On: 01-Apr-2021 03:14 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form: INCLUSION/EXCLUSION CRITERIA - eCRF
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Form Version: 21-Aug-2020 02:50

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1231

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

Subject No: 12312868

Subject Initials: ---

Generated By:

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

(b) (4)

Aug-21-2020 16:50:38 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: EX03A00	Initial Entry
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2.d

Date	Location	User	Value	Reason
Aug-21-2020 16:50:38 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Exclusion Number: 4 Criterion Description: Receipt of medications intended to prevent COVID-19 Criterion met?: NO Criterion ID: (For Pfizer only): EX04A00	Initial Entry

090177e196ae2e73\Final\Final On: 01-Apr-2021 03:14 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form: INCLUSION/EXCLUSION CRITERIA - eCRF
Audit Trail History

Form Version: 21-Aug-2020 02:50

Form Status: Data Complete, Locked, Frozen, Verified

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Mayor Dr. Cosme Argerich

Subject No: 12312868

Subject Initials: ---

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

(b) (4)

2.d Exclusion Number:

Date	Location	User	Value	Reason
Aug-21-2020 16:50:38 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 4	Initial Entry

2.d Criterion Description:

Date	Location	User	Value	Reason
Aug-21-2020 16:50:38 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Receipt of medication s intended to prevent COVID-19	Initial Entry

2.d Criterion met?

Date	Location	User	Value	Reason
Aug-21-2020 16:50:38 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2.d Criterion ID: (For Pfizer use only)

Date	Location	User	Value	Reason
Aug-21-2020 16:50:38 (UTC-03:00) City	ACV0PFEINFP6000	(b) (6)	Data Entry: EX04A00	Initial Entry

090177e196ae2e73\Final\Final On: 01-Apr-2021 03:14 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form: INCLUSION/EXCLUSION CRITERIA - eCRF
Audit Trail History

Form Version: 21-Aug-2020 02:50

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject No: 12312868

Subject Initials: ---

Generated By:

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

(b) (4)

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(b) (4)

2.e

Date	Location	User	Value	Reason
Aug-21-2020 16:50:38 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<p>Data Entry:</p> <p>Excl 8</p> <p>usio</p> <p>n Nu</p> <p>mbe</p> <p>r:</p> <p>Crit Immunocompr</p> <p>erio omised individ</p> <p>n De uals with know</p> <p>scrip n or suspected i</p> <p>tion: mmunodeficien</p> <p>cy, as determin</p> <p>ed by history a</p> <p>nd/or laborator</p> <p>y/physical exa</p> <p>mination</p> <p>Crit NO</p> <p>erio</p> <p>n me</p> <p>t?:</p>	Initial Entry

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Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 21-Aug-2020 02:50

Site No: 1231

Subject No: 12312868

Generated By:

(b) (4)

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Subject Initials: ---

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

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			se on	
			ly):	

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Header Text: C4591001

Visit: V1_DAY1_VAX1_L

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Audit Trail History

Form Version: 21-Aug-2020 02:50

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Subject Initials: ---

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(b) (4)

2.e Exclusion Number:

Date	Location	User	Value	Reason
Aug-21-2020 16:50:38 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 8	Initial Entry

2.e Criterion Description:

Date	Location	User	Value	Reason
Aug-21-2020 16:50:38 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Immunocompromised individuals with know n or suspected immun odeficiency, as determ ined by history and/or laboratory/physical ex amination	Initial Entry

2.e Criterion met?

Date	Location	User	Value	Reason
Aug-21-2020 16:50:38 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2.e Criterion ID: (For Pfizer use only)

Date	Location	User	Value	Reason
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090177e196ae2e73\Final\Final On: 01-Apr-2021 03:14 (GMT)

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Visit: V1_DAY1_VAX1_L

Form: INCLUSION/EXCLUSION CRITERIA - eCRF
Audit Trail History

Form Version: 21-Aug-2020 02:50

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Subject No: 12312868

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Generated By:

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

(b) (4)

Aug-21-2020 16:50:38 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: EX08A00	Initial Entry
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2.f

Date	Location	User	Value	Reason
Aug-21-2020 16:50:38 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Excl 10 usio n Nu mbe r: Crit Bleeding diathe erio sis or condition n De associated with scrip prolonged blee tion: ding that would , in the opinion of the investiga tor, contraindic ate intramuscul ar injection Crit NO erio n me t?:	Initial Entry

090177e196ae2e73\Final\Final On: 01-Apr-2021 03:14 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 21-Aug-2020 02:50

Site No: 1231

Subject No: 12312868

Generated By:

(b) (4)

Form: INCLUSION/EXCLUSION CRITERIA - eCRF
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Subject Initials: ---

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

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Header Text: C4591001

Visit: V1_DAY1_VAX1_L

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Audit Trail History

Form Version: 21-Aug-2020 02:50

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1231

Site Name: (1231) Hospital Militar Central Cirujano
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Subject No: 12312868

Subject Initials: ---

Generated By:

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

(b) (4)

2.f Exclusion Number:

Date	Location	User	Value	Reason
Aug-21-2020 16:50:38 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 10	Initial Entry

2.f Criterion Description:

Date	Location	User	Value	Reason
Aug-21-2020 16:50:38 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Bleeding diathesis or condition associated with prolonged bleeding that would, in the opinion of the investigator, contraindicate intramuscular injection	Initial Entry

2.f Criterion met?

Date	Location	User	Value	Reason
Aug-21-2020 16:50:38 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2.f Criterion ID: (For Pfizer use only)

Date	Location	User	Value	Reason
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090177e196ae2e73\Final\Final On: 01-Apr-2021 03:14 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form: INCLUSION/EXCLUSION CRITERIA - eCRF
Audit Trail History

Form Version: 21-Aug-2020 02:50

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Site No: 1231

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

Subject No: 12312868

Subject Initials: ---

Generated By:

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

(b) (4)

Aug-21-2020 16:50:38 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: EX10A00	Initial Entry
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2.g

Date	Location	User	Value	Reason
Aug-21-2020 16:50:38 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Exclusion Number: Criterion Description: Women who are pregnant or breastfeeding Criterion met?: NO Criterion ID: (For Pfizer use only): EX11A00	Initial Entry

090177e196ae2e73\Final\Final On: 01-Apr-2021 03:14 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form: INCLUSION/EXCLUSION CRITERIA - eCRF
Audit Trail History

Form Version: 21-Aug-2020 02:50

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Site No: 1231

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Subject No: 12312868

Subject Initials: ---

Generated By:

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

(b) (4)

2.g Exclusion Number:

Date	Location	User	Value	Reason
Aug-21-2020 16:50:38 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 11	Initial Entry

2.g Criterion Description:

Date	Location	User	Value	Reason
Aug-21-2020 16:50:38 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Women who are pregn ant or breastfeeding	Initial Entry

2.g Criterion met?

Date	Location	User	Value	Reason
Aug-21-2020 16:50:38 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2.g Criterion ID: (For Pfizer use only)

Date	Location	User	Value	Reason
Aug-21-2020 16:50:38 (UTC-03:00) City	ACV0PFEINFP6000	(b) (6)	Data Entry: EX11A00	Initial Entry

090177e196ae2e73\Final\Final On: 01-Apr-2021 03:14 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form: INCLUSION/EXCLUSION CRITERIA - eCRF
Audit Trail History

Form Version: 21-Aug-2020 02:50

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Subject No: 12312868

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Generated By:

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

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2.h

Date	Location	User	Value	Reason
Aug-21-2020 16:50:38 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<p>Data Entry:</p> <p>Exclusion Number: 12</p> <p>Criterion Description: Previous vaccination with any coronavirus vaccine</p> <p>Criterion met?: NO</p> <p>Criterion ID: (For Pfizer use only): EX12A00</p>	Initial Entry

090177e196ae2e73\Final\Final On: 01-Apr-2021 03:14 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form: INCLUSION/EXCLUSION CRITERIA - eCRF
Audit Trail History

Form Version: 21-Aug-2020 02:50

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1231

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Subject No: 12312868

Subject Initials: ---

Generated By:

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

(b) (4)

2.h Exclusion Number:

Date	Location	User	Value	Reason
Aug-21-2020 16:50:38 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 12	Initial Entry

2.h Criterion Description:

Date	Location	User	Value	Reason
Aug-21-2020 16:50:38 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Previous vaccination with any coronavirus vaccine	Initial Entry

2.h Criterion met?

Date	Location	User	Value	Reason
Aug-21-2020 16:50:38 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2.h Criterion ID: (For Pfizer use only)

Date	Location	User	Value	Reason
Aug-21-2020 16:50:38 (UTC-03:00) City	ACV0PFEINFP6000	(b) (6)	Data Entry: EX12A00	Initial Entry

090177e196ae2e73\Final\Final On: 01-Apr-2021 03:14 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form: INCLUSION/EXCLUSION CRITERIA - eCRF
Audit Trail History

Form Version: 21-Aug-2020 02:50

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1231

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

Subject No: 12312868

Subject Initials: ---

Generated By:

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

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of Buenos Aires

(b) (4)

2.i

Date	Location	User	Value	Reason
Aug-21-2020 16:50:38 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<p>Data Entry:</p> <p>Exclusion Number:</p> <p>Criterion Description: Subjects who receive immunosuppressive therapy, such as cytotoxic agents or systemic corticosteroids</p> <p>Criterion met?: NO</p> <p>Criterion ID: EX13A01</p> <p>D: (F or Pfizer use only):</p>	Initial Entry

090177e196ae2e73\Final\Final On: 01-Apr-2021 03:14 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form: INCLUSION/EXCLUSION CRITERIA - eCRF
Audit Trail History

Form Version: 21-Aug-2020 02:50

Form Status: Data Complete, Locked, Frozen, Verified

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Subject No: 12312868

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

(b) (4)

2.i Exclusion Number:

Date	Location	User	Value	Reason
Aug-21-2020 16:50:38 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 13	Initial Entry

2.i Criterion Description:

Date	Location	User	Value	Reason
Aug-21-2020 16:50:38 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Subjects who receive i mmunosuppressive th erapy, such as cytotoxi c agents or systemic c orticosteroids	Initial Entry

2.i Criterion met?

Date	Location	User	Value	Reason
Aug-21-2020 16:50:38 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2.i Criterion ID: (For Pfizer use only)

Date	Location	User	Value	Reason
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090177e196ae2e73\Final\Final On: 01-Apr-2021 03:14 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form: INCLUSION/EXCLUSION CRITERIA - eCRF
Audit Trail History

Form Version: 21-Aug-2020 02:50

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1231

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

Subject No: 12312868

Subject Initials: ---

Generated By:

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

(b) (4)

Aug-21-2020 16:50:38 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: EX13A01	Initial Entry
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2.j

Date	Location	User	Value	Reason
Aug-21-2020 16:50:38 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Excl 15 usio n Nu mbe r: Crit Receipt of bloo erio d/plasma produ n De cts or immunog scrip lobulin, from 6 tion: 0 days before st udy interventio n administratio n or planned re ceipt throughou t the study Crit NO erio n me t?:	Initial Entry

090177e196ae2e73\Final\Final On: 01-Apr-2021 03:14 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 21-Aug-2020 02:50

Site No: 1231

Subject No: 12312868

Generated By:

(b) (4)

Form: INCLUSION/EXCLUSION CRITERIA - eCRF
Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1231) Hospital Militar Central Cirujano
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Subject Initials: ---

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

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090177e196ae2e73\Final\Final On: 01-Apr-2021 03:14 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form: INCLUSION/EXCLUSION CRITERIA - eCRF
Audit Trail History

Form Version: 21-Aug-2020 02:50

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1231

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Subject No: 12312868

Subject Initials: ---

Generated By:

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

(b) (4)

2.j Exclusion Number:

Date	Location	User	Value	Reason
Aug-21-2020 16:50:38 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 15	Initial Entry

2.j Criterion Description:

Date	Location	User	Value	Reason
Aug-21-2020 16:50:38 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Receipt of blood/plasma products or immunoglobulin, from 60 days before study intervention administration or planned receipt throughout the study	Initial Entry

2.j Criterion met?

Date	Location	User	Value	Reason
Aug-21-2020 16:50:38 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2.j Criterion ID: (For Pfizer use only)

Date	Location	User	Value	Reason
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090177e196ae2e73\Final\Final On: 01-Apr-2021 03:14 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form: INCLUSION/EXCLUSION CRITERIA - eCRF
Audit Trail History

Form Version: 21-Aug-2020 02:50

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1231

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

Subject No: 12312868

Subject Initials: ---

Generated By:

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

(b) (4)

Aug-21-2020 16:50:38 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: EX14A01	Initial Entry
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Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form: INCLUSION/EXCLUSION CRITERIA - eCRF
Audit Trail History

Form Version: 21-Aug-2020 02:50

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1231

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

Subject No: 12312868

Subject Initials: ---

Generated By:

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

(b) (4)

[Back to Form](#)

2.k

Date	Location	User	Value	Reason
Aug-21-2020 16:50:38 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<p>Data Entry:</p> <p>Excl 16</p> <p>usion</p> <p>Num</p> <p>ber:</p> <p>Crite Participation i</p> <p>tion n other studies</p> <p>Desc involving stud</p> <p>ripti y intervention</p> <p>on: within 28 days</p> <p>prior to study</p> <p>entry and/or d</p> <p>uring study pa</p> <p>rticipation</p> <p>Crite NO</p> <p>tion</p> <p>met?</p> <p>:</p> <p>Crite EX15A01</p> <p>tion</p> <p>ID: (</p> <p>For</p> <p>Pfize</p> <p>r use</p> <p>only)</p> <p>:</p>	Initial Entry

090177e196ae2e73\Final\Final On: 01-Apr-2021 03:14 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form: INCLUSION/EXCLUSION CRITERIA - eCRF
Audit Trail History

Form Version: 21-Aug-2020 02:50

Form Status: Data Complete, Locked, Frozen, Verified

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Subject No: 12312868

Subject Initials: ---

Generated By:

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

(b) (4)

2.k Exclusion Number:

Date	Location	User	Value	Reason
Aug-21-2020 16:50:38 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 16	Initial Entry

2.k Criterion Description:

Date	Location	User	Value	Reason
Aug-21-2020 16:50:38 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Participation in other studies involving stud y intervention within 28 days prior to study entry and/or during st udy participation	Initial Entry

2.k Criterion met?

Date	Location	User	Value	Reason
Aug-21-2020 16:50:38 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2.k Criterion ID: (For Pfizer use only)

Date	Location	User	Value	Reason
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090177e196ae2e73\Final\Final On: 01-Apr-2021 03:14 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form: INCLUSION/EXCLUSION CRITERIA - eCRF
Audit Trail History

Form Version: 21-Aug-2020 02:50

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1231

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

Subject No: 12312868

Subject Initials: ---

Generated By:

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

(b) (4)

Aug-21-2020 16:50:38 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: EX15A01	Initial Entry
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2.1

Date	Location	User	Value	Reason
Aug-21-2020 16:50:38 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Exclu 17 sion Numb er: Cr iter Previous parti ion D cipation in ot escrip her studies in tion: volving study intervention c ontaining lipi d nanoparticl es Cr iter NO ion m et?:	Initial Entry

090177e196ae2e73\Final\Final On: 01-Apr-2021 03:14 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 21-Aug-2020 02:50

Site No: 1231

Subject No: 12312868

Generated By:

(b) (4)

Form: INCLUSION/EXCLUSION CRITERIA - 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 20:20

			Criterion I D: (Former Pfizer only):	
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Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form: INCLUSION/EXCLUSION CRITERIA - eCRF
Audit Trail History

Form Version: 21-Aug-2020 02:50

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1231

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

Subject No: 12312868

Subject Initials: ---

Generated By:

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

(b) (4)

2.1 Exclusion Number:

Date	Location	User	Value	Reason
Aug-21-2020 16:50:38 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 17	Initial Entry

2.1 Criterion Description:

Date	Location	User	Value	Reason
Aug-21-2020 16:50:38 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Previous participation in other studies involv ing study intervention containing lipid nano particles	Initial Entry

2.1 Criterion met?

Date	Location	User	Value	Reason
Aug-21-2020 16:50:38 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2.1 Criterion ID: (For Pfizer use only)

Date	Location	User	Value	Reason
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090177e196ae2e73\Final\Final On: 01-Apr-2021 03:14 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form: INCLUSION/EXCLUSION CRITERIA - eCRF
Audit Trail History

Form Version: 21-Aug-2020 02:50

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1231

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

Subject No: 12312868

Subject Initials: ---

Generated By:

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

(b) (4)

Aug-21-2020 16:50:38 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: EX16A01	Initial Entry
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2.m

Date	Location	User	Value	Reason
Aug-21-2020 16:50:38 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Excl 22 usio n N umb er: Crit Investigator sit erio e staff or Pfizer n De employees dire scri ctly involved in ptio the conduct of t n: he study, site st aff otherwise s upervised by th e investigator, a nd their respect ive family mem bers Crit NO erio n m et?:	Initial Entry

090177e196ae2e73\Final\Final On: 01-Apr-2021 03:14 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 21-Aug-2020 02:50

Site No: 1231

Subject No: 12312868

Generated By:

(b) (4)

Form: INCLUSION/EXCLUSION CRITERIA - 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 20:20

			Crit EX21A01 erion ID : (F or P fizer use only):	
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090177e196ae2e73\Final\Final On: 01-Apr-2021 03:14 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form: INCLUSION/EXCLUSION CRITERIA - eCRF
Audit Trail History

Form Version: 21-Aug-2020 02:50

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1231

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

Subject No: 12312868

Subject Initials: ---

Generated By:

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

(b) (4)

2.m Exclusion Number:

Date	Location	User	Value	Reason
Aug-21-2020 16:50:38 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 22	Initial Entry

2.m Criterion Description:

Date	Location	User	Value	Reason
Aug-21-2020 16:50:38 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Investigator site staff or Pfizer employees d irectly involved in the conduct of the study, s ite staff otherwise sup ervised by the investi gator, and their respec tive family members	Initial Entry

2.m Criterion met?

Date	Location	User	Value	Reason
Aug-21-2020 16:50:38 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2.m Criterion ID: (For Pfizer use only)

090177e196ae2e73\Final\Final On: 01-Apr-2021 03:14 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form: INCLUSION/EXCLUSION CRITERIA - eCRF
Audit Trail History

Form Version: 21-Aug-2020 02:50

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1231

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

Subject No: 12312868

Subject Initials: ---

Generated By:

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

(b) (4)

Date	Location	User	Value	Reason
Aug-21-2020 16:50:38 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: EX21A01	Initial Entry

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form: DISPOSITION - SCREENING - 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: 12312868

Subject Initials: ---

Generated By:

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

(b) (4)

[Back to Form](#)

1. Date of Completion/Discontinuation/Death

Date	Location	User	Value	Reason
Aug-21-2020 16:50:47 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Aug/21/2020	Initial Entry

2. Phase of Disposition:

Date	Location	User	Value	Reason
Aug-21-2020 16:50:47 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SCREENING	Initial Entry

3. Status:

Date	Location	User	Value	Reason
Aug-21-2020 16:50:47 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: COMPLETED	Initial Entry

090177e196ae2e73\Final\Final On: 01-Apr-2021 03:14 (GMT)

Header Text: C4591001**Visit:** V1_DAY1_VAX1_L**Form Version:** 22-Apr-2020 21:03**Site No:** 1231**Subject No:** 12312868**Generated By:**

(b) (4)

Form: GENERAL MEDICAL HISTORY - 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 20:20[Back to Form](#)*1.a*

Date	Location	User	Value	Reason
Mar-17-2021 10:32:44 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH 1 Number: Medical Hi Depressiv story Term e disorder : Start Date: Mar/15/2 020 Ongoing: YES	Initial Entry

1.a Line/MH Number:

Date	Location	User	Value	Reason
Mar-17-2021 10:32:44 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 1	Initial Entry

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

Date	Location	User	Value	Reason
Mar-17-2021 10:32:44 (UTC-03:00) City	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Depressive disorder	Initial Entry

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Verified

Site No: 1231

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

Subject No: 12312868

Subject Initials: ---

Generated By:

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

(b) (4)

of Buenos Aires				
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1.a Start Date:

Date	Location	User	Value	Reason
Mar-17-2021 10:32:44 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Mar/15/2020	Initial Entry

1.a Ongoing:

Date	Location	User	Value	Reason
Mar-17-2021 10:32:44 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

090177e196ae2e73\Final\Final On: 01-Apr-2021 03:14 (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: 12312868

Subject Initials: ---

Generated By:

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

(b) (4)

[Back to Form](#)

1. Date:

Date	Location	User	Value	Reason
Aug-21-2020 16:51:45 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Aug/21/2020	Initial Entry

2. Weight:

Date	Location	User	Value	Reason
Aug-21-2020 16:51:45 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 70.8	Initial Entry

3. Unit:

Date	Location	User	Value	Reason
Aug-21-2020 16:51:45 (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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090177e196ae2e73\Final\Final On: 01-Apr-2021 03:14 (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: 12312868

Subject Initials: ---

Generated By:

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

(b) (4)

Aug-21-2020 16:51:45 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 162.0	Initial Entry
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5. Unit:

Date	Location	User	Value	Reason
Aug-21-2020 16:51:45 (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-21-2020 16:51:45 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 27.0	Initial Entry

7.a

Date	Location	User	Value	Reason
Aug-21-2020 16:51:45 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Record Identifier: 1 Temperature: 36.3	Initial Entry

090177e196ae2e73\Final\Final On: 01-Apr-2021 03:14 (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: 12312868

Subject Initials: ---

Generated By:

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

(b) (4)

Temperature Unit:
Temperature Location: ORAL
CAVITY

7.a Record Identifier:

Date	Location	User	Value	Reason
Aug-21-2020 16:51:45 (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-21-2020 16:51:45 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 36.3	Initial Entry

7.a Unit:

Date	Location	User	Value	Reason
Aug-21-2020 16:51:45 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: C	Initial Entry

090177e196ae2e73\Final\Final On: 01-Apr-2021 03:14 (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: 12312868

Subject Initials: ---

Generated By:

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

(b) (4)

7.a Temperature Location:

Date	Location	User	Value	Reason
Aug-21-2020 16:51:45 (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: 12312868

Subject Initials: ---

Generated By:

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

(b) (4)

[Back to Form](#)

1. Lab Panel:

Date	Location	User	Value	Reason
Aug-21-2020 16:51:55 (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-21-2020 16:51:55 (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-21-2020 16:51:55 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Aug/21/2020	Initial Entry

4. Laboratory Name and Address (Derived)

Date	Location	User	Value	Reason
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090177e196ae2e73\Final\Final On: 01-Apr-2021 03:14 (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: 12312868

Subject Initials: ---

Generated By:

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

(b) (4)

Aug-21-2020 16:51:55 (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-21-2020 16:51:55 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: URINE	Initial Entry

6.a

Date	Location	User	Value	Reason
Aug-21-2020 16:51:55 (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:

090177e196ae2e73\Final\Final On: 01-Apr-2021 03:14 (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: 12312868

Subject Initials: ---

Generated By:

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

(b) (4)

Date	Location	User	Value	Reason
Aug-21-2020 16:51:55 (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-21-2020 16:51:55 (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
Aug-21-2020 16:51:55 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NEGATIVE	Initial Entry

090177e196ae2e73\Final\Final On: 01-Apr-2021 03:14 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1231

Subject No: 12312868

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 20:20

[Back to Form](#)

1. Randomization Date :

Date	Location	User	Value	Reason
Aug-21-2020 16:52:15 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Aug/21/2020	Initial Entry

2. Randomization Number:

Date	Location	User	Value	Reason
Aug-21-2020 16:52:15 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 60566	Initial Entry

090177e196ae2e73\Final\Final On: 01-Apr-2021 03:14 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1231

Subject No: 12312868

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 20:20

[Back to Form](#)

1. Data Origin

Date	Location	User	Value	Reason
Sep-02-2020 15:03:09 (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-02-2020 15:03:09 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SERUM	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Sep-02-2020 15:03:28 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Sep-02-2020 15:03:09 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes

090177e196ae2e73\Final\Final On: 01-Apr-2021 03:14 (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: 12312868

Subject Initials: ---

Generated By:

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

(b) (4)

				are entered. Please review and correct as appropriate.
Sep-02-2020 15:03:09 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Date of Collection : Aug/21/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Sep-02-2020 15:03:28 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BJ4965	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Sep-02-2020 15:03:28 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BJ4965	Initial Entry

5.b

Date	Location	User	Value	Reason
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090177e196ae2e73\Final\Final On: 01-Apr-2021 03:14 (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: 12312868

Subject Initials: ---

Generated By:

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

(b) (4)

Sep-02-2020 15:03:40 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BJ4966	Initial Entry
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5.b Sample ID

Date	Location	User	Value	Reason
Sep-02-2020 15:03:40 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BJ4966	Initial Entry

5.c

Date	Location	User	Value	Reason
Sep-02-2020 15:03:49 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BJ4967	Initial Entry

5.c Sample ID

Date	Location	User	Value	Reason
Sep-02-2020 15:03:49 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BJ4967	Initial Entry

5.d

090177e196ae2e73\Final\Final On: 01-Apr-2021 03:14 (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: 12312868

Subject Initials: ---

Generated By:

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

(b) (4)

Date	Location	User	Value	Reason
Sep-02-2020 15:03:59 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample I BHY5P D: P	Initial Entry

5.d Sample ID

Date	Location	User	Value	Reason
Sep-02-2020 15:03:59 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BHY5PP	Initial Entry

5.e

Date	Location	User	Value	Reason
Sep-02-2020 15:04:09 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample I BHY5P D: R	Initial Entry

5.e Sample ID

Date	Location	User	Value	Reason
Sep-02-2020 15:04:09 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BHY5PR	Initial Entry

090177e196ae2e73\Final\Final On: 01-Apr-2021 03:14 (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: 12312868

Subject Initials: ---

Generated By:

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

(b) (4)

5.f

Date	Location	User	Value	Reason
Sep-02-2020 15:04:19 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample I BHY5P D: S	Initial Entry

5.f Sample ID

Date	Location	User	Value	Reason
Sep-02-2020 15:04:19 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BHY5PS	Initial Entry

090177e196ae2e73\Final\Final On: 01-Apr-2021 03:14 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1231

Subject No: 12312868

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 20:20

[Back to Form](#)

1. Data Origin

Date	Location	User	Value	Reason
Aug-25-2020 11:12:04 (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 11:12:04 (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-25-2020 11:12:12 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Aug-25-2020 11:12:04 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes

090177e196ae2e73\Final\Final On: 01-Apr-2021 03:14 (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: 12312868

Subject Initials: ---

Generated By:

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

(b) (4)

				are entered. Please review and correct as appropriate.
Aug-25-2020 11:12:04 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Date of Collection: Aug/21/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Aug-25-2020 11:12:12 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample I BHY5V D: N	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Aug-25-2020 11:12:12 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BHY5VN	Initial Entry

090177e196ae2e73\Final\Final On: 01-Apr-2021 03:14 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:04

Site No: 1231

Subject No: 12312868

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 20:20

[Back to Form](#)

1. Was there a temporary delay of vaccination?

Date	Location	User	Value	Reason
Aug-21-2020 16:52:41 (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-21-2020 16:52:41 (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-21-2020 16:52:41 (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-21-2020	ACV0PFEINFP6000	(b) (6)	Data Entry:	Initial Entry

090177e196ae2e73\Final\Final On: 01-Apr-2021 03:14 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:04

Site No: 1231

Subject No: 12312868

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 20:20

16:52:41 (UTC-03:00) City of Buenos Aires	(b) (4), (b) (6)	Aug/21/2020 13:40
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5. Anatomical Location:

Date	Location	User	Value	Reason
Aug-21-2020 16:52:41 (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-21-2020 16:52:41 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: LEFT	Initial Entry

7. Route:

Date	Location	User	Value	Reason
Aug-21-2020 16:52:41 (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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090177e196ae2e73\Final\Final On: 01-Apr-2021 03:14 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:04

Site No: 1231

Subject No: 12312868

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 20:20

Aug-21-2020 16:52:41 (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-21-2020 16:52:41 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

090177e196ae2e73\Final\Final On: 01-Apr-2021 03:14 (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: 12312868

Subject Initials: ---

Generated By:

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

(b) (4)

[Back to Form](#)

1. Select appropriate response - Reactogenicity diary collection

Date	Location	User	Value	Reason
Aug-21-2020 16:52:47 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO - REACTOGENI CITY E-DIARY NOT COLLECTED FOR T HIS SUBJECT	Initial Entry

090177e196ae2e73\Final\Final On: 01-Apr-2021 03:14 (GMT)

Header Text: C4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:02

Site No: 1231

Subject No: 12312868

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 20:20

[Back to Form](#)

1. Date of Visit

Date	Location	User	Value	Reason
Oct-22-2020 10:41:41 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 3: Deleted	Close Auto Query
Oct-22-2020 10:40:42 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Closed	Close Auto Query
Oct-22-2020 10:40:42 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Oct/8/2020	Transcription Error
Oct-22-2020 10:40:24 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 3: Candidate	Erroneous Visit is marked, but date of visit is entered. Please check whether other assessments are performed at this visit.

090177e196ae2e73\Final\Final On: 01-Apr-2021 03:14 (GMT)

Header Text: C4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:02

Site No: 1231

Subject No: 12312868

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 20:20

Oct-22-2020 10:40:24 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Opened	Date of Visit, 08/Nov/2020 is a future date relative to when it was entered on 22/Oct/2020. Please correct.
Oct-22-2020 10:40:24 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Nov/8/2020	Initial Entry
Sep-28-2020 12:31:17 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Sep-28-2020 09:10:42 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	V2 opened due to loading error. No information to load.
Sep-26-2020 10:51:36 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	DM: Kindly review and complete 'Date of Visit, Vaccination, Vital Signs' forms at this

090177e196ae2e73\Final\Final On: 01-Apr-2021 03:14 (GMT)

Header Text: C4591001

Visit: V2_VAX2_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: 12312868

Subject Initials: ---

Generated By:

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

(b) (4)

visit. Thank you.

2. Erroneous Visit

Date	Location	User	Value	Reason
Oct-22-2020 10:41:41 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Transcription Error
Oct-20-2020 17:36:45 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	moved query to date and time line for VAX 2
Oct-12-2020 10:09:23 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	CLINICAL VAX #2 date not entered in CRF; however, SAE report states VAX #2 on 08 Oct 2020. Please confirm if this is correct, and enter VAX #2 date if appropriate.
Sep-28-2020 09:10:34	ACV0PFEINFP6000	(b) (6)	Data Entry: ERRONEOUS VI	Initial Entry

090177e196ae2e73\Final\Final On: 01-Apr-2021 03:14 (GMT)

Header Text: C4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:02

Site No: 1231

Subject No: 12312868

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 20:20

(UTC-03:00)
City of Buenos
Aires

(b) (4)

SIT

Header Text: C4591001

Visit: V2_VAX2_L

Form Version: 10-Oct-2020 16:01

Site No: 1231

Subject No: 12312868

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 20:20

[Back to Form](#)

1. Date:

Date	Location	User	Value	Reason
Oct-22-2020 11:14:59 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Oct/8/2020	Initial Entry

2.a

Date	Location	User	Value	Reason
Oct-27-2020 11:35:01 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Record Id 1 entifier:: Temperat 36.3 ure: Temperat C ure Unit: Temperat ORAL ure Locati CAVIT on:: Y	Transcription Error
Oct-22-2020 11:14:59 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Record Id 1 entifier:: Temperat 36.6 ure:	Initial Entry

090177e196ae2e73\Final\Final On: 01-Apr-2021 03:14 (GMT)

Header Text: C4591001

Visit: V2_VAX2_L

Form: VITAL SIGNS - TEMP - eCRF Audit Trail History

Form Version: 10-Oct-2020 16:01

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1231

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

Subject No: 12312868

Subject Initials: ---

Generated By:

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

(b) (4)

Temperat C
ure Unit:
Temperat ORAL
ure Locati CAVIT
on:: Y

2.a Record Identifier:

Date	Location	User	Value	Reason
Oct-22-2020 11:14:59 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 1	Initial Entry

2.a Temperature:

Date	Location	User	Value	Reason
Oct-27-2020 11:35:01 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 36.3	Transcription Error
Oct-22-2020 11:14:59 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 36.6	Initial Entry

2.a Unit:

Date	Location	User	Value	Reason
Oct-22-2020	ACV0PFEINFP6000	(b) (6)	Data Entry:	Initial Entry

090177e196ae2e73\Final\Final On: 01-Apr-2021 03:14 (GMT)

Header Text: C4591001

Visit: V2_VAX2_L

Form: VITAL SIGNS - TEMP - eCRF Audit Trail History

Form Version: 10-Oct-2020 16:01

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1231

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

Subject No: 12312868

Subject Initials: ---

Generated By:

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

(b) (4)

11:14:59 (UTC-03:00) City of Buenos Aires		(b) (4), (b) (6)	C	
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2.a Temperature Location:

Date	Location	User	Value	Reason
Oct-22-2020 11:14:59 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: ORAL CAVITY	Initial Entry

090177e196ae2e73\Final\Final On: 01-Apr-2021 03:14 (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: 12312868

Subject Initials: ---

Generated By:

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

(b) (4)

[Back to Form](#)

1. Lab Panel:

Date	Location	User	Value	Reason
Oct-22-2020 11:15:06 (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
Oct-22-2020 11:15:06 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: PREGNANCY	Initial Entry

3. Collection Date:

Date	Location	User	Value	Reason
Oct-22-2020 11:15:06 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Oct/8/2020	Initial Entry

4. Laboratory Name and Address (Derived)

Date	Location	User	Value	Reason
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090177e196ae2e73\Final\Final On: 01-Apr-2021 03:14 (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: 12312868

Subject Initials: ---

Generated By:

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

(b) (4)

Oct-22-2020 11:15:06 (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
Oct-22-2020 11:15:06 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: URINE	Initial Entry

6.a

Date	Location	User	Value	Reason
Oct-22-2020 11:15:06 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sponsor- 113 Defined Identifier: Test:: Choriogon adotropin Beta_PX11 3 Result:: NEGATIV E Not Done ::	Initial Entry

6.a Sponsor ID:

090177e196ae2e73\Final\Final On: 01-Apr-2021 03:14 (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: 12312868

Subject Initials: ---

Generated By:

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

(b) (4)

Date	Location	User	Value	Reason
Oct-22-2020 11:15:06 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 113	Initial Entry

6.a Test:

Date	Location	User	Value	Reason
Oct-22-2020 11:15:06 (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
Oct-22-2020 11:15:06 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NEGATIVE	Initial Entry

090177e196ae2e73\Final\Final On: 01-Apr-2021 03:14 (GMT)

Header Text: C4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:03

Site No: 1231

Subject No: 12312868

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 20:20

[Back to Form](#)

1. Data Origin

Date	Location	User	Value	Reason
Sep-21-2020 08:51:09 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry
Sep-13-2020 18:37:54 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry:	Transcription Error
Sep-11-2020 19:01:17 (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-21-2020 08:51:09 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: NASAL_SWAB	Initial Entry
Sep-13-2020 18:37:54 (UTC-03:00) City	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry:	Transcription Error

090177e196ae2e73\Final\Final On: 01-Apr-2021 03:14 (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: 12312868

Subject Initials: ---

Generated By:

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

(b) (4)

of Buenos Aires				
Sep-11-2020 19:01:17 (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
Oct-22-2020 10:56:34 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 6: Closed	Close Auto Query
Oct-22-2020 10:55:55 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 6: Opened	Date of Collection is more than 1 day before Dose Date on the Vaccination form. Please review and update as appropriate, else clarify.
Oct-13-2020 08:31:08 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 5: Deleted	Close Auto Query

090177e196ae2e73\Final\Final On: 01-Apr-2021 03:14 (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: 12312868

Subject Initials: ---

Generated By:

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

(b) (4)

Oct-13-2020 08:30:46 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 5: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Oct-13-2020 08:30:46 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Date of Collection: Oct/8/2020	New Information
Sep-21-2020 12:26:24 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 4: Closed	Response satisfies query
Sep-21-2020 08:51:09 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 4: Answered	Initial Entry
Sep-21-2020 08:51:09 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	Agustin Morato Cabral (b) (4)	Data Entry: NO	Initial Entry

090177e196ae2e73\Final\Final On: 01-Apr-2021 03:14 (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: 12312868

Subject Initials: ---

Generated By:

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

(b) (4)

Sep-20-2020 06:40:25 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 4: Reissued:Opened	DM1: Thank you for the response. However, Kindly mark the form as NA if the visit has not started yet. Please confirm and update appropriately. Else clarify.
Sep-19-2020 10:05:33 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 4: Answered	Not applicable.
Sep-18-2020 17:12:47 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 4: Reissued:Opened	DM: Kindly mark the form as NA if the visit has not started yet. Thank you.
Sep-18-2020 11:29:43 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 4: Answered	Original value is correct
Sep-18-2020	ACV0PFEINFP6000	(b) (6)	Query 4: Reissue	Please update

090177e196ae2e73\Final\Final On: 01-Apr-2021 03:14 (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: 12312868

Subject Initials: ---

Generated By:

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

(b) (4)

09:28:43 (UTC-03:00) City of Buenos Aires		(b) (4), (b) (6) [Redacted]	d:Opened	visit 2 when data is available.
Sep-18-2020 09:05:46 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6) [Redacted]	Query 4: Answered	Visit 2 not yet applied
Sep-15-2020 16:44:10 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6) [Redacted]	Query 4: Reissued: d:Opened	DM: Kindly mark the form as NA if the visit has not started yet. Thank you.
Sep-15-2020 12:46:06 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	Romina Barrera (b) (4)	Query 4: Answered	Changed data per query
Sep-15-2020 11:42:21 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6) [Redacted]	Query 4: Opened	DM: Kindly mark the form as NA if the visit has not started yet. Thank you.
Sep-13-2020 18:37:54 (UTC-03:00)	ACV0PFEINFP6000	auto query (autoquery)	Query 3: Deleted	Close Auto Query

090177e196ae2e73\Final\Final On: 01-Apr-2021 03:14 (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: 12312868

Subject Initials: ---

Generated By:

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

(b) (4)

City of Buenos Aires				
Sep-13-2020 18:37:54 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Transcription Error
Sep-13-2020 18:37:12 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 3: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Sep-13-2020 18:37:12 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Deleted	Close Auto Query
Sep-13-2020 18:36:44 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.

090177e196ae2e73\Final\Final On: 01-Apr-2021 03:14 (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: 12312868

Subject Initials: ---

Generated By:

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

(b) (4)

Sep-11-2020 19:01:26 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Sep-11-2020 19:01:17 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Sep-11-2020 19:01:17 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Date of Collection: Sep/11/2020	Initial Entry

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

Date	Location	User	Value	Reason
Oct-29-2020 18:53:54 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query

090177e196ae2e73\Final\Final On: 01-Apr-2021 03:14 (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: 12312868

Subject Initials: ---

Generated By:

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

(b) (4)

Oct-29-2020 09:19:52 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	New Information
Oct-29-2020 09:19:52 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	New Information
Oct-29-2020 07:25:46 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	CLINQUERY: please clarify if comment, "visit 2 not applicable yet" still applies, as it appears visit 2 has been performed.
Oct-28-2020 12:49:17 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Candidate	CLINQUERY: please clarify if comment, "visit 2 not applicable yet" still applies, as it appears visit 2 has been performed.
Sep-21-2020	ACV0PFEINFP6000	Agustin	Data Entry:	Initial Entry

090177e196ae2e73\Final\Final On: 01-Apr-2021 03:14 (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: 12312868

Subject Initials: ---

Generated By:

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

(b) (4)

08:51:09 (UTC-03:00) City of Buenos Aires		Morato Cabral (b) (4)	visit 2 not applicable yet	
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5.a

Date	Location	User	Value	Reason
Sep-13-2020 18:37:12 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID:	Transcription Error (DELETED)
Sep-13-2020 18:36:44 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID:	Transcription Error
Sep-11-2020 19:01:26 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BP1Y ID: 6D	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Sep-13-2020 18:37:12 (UTC-03:00)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Transcription Error (DELETED)

090177e196ae2e73\Final\Final On: 01-Apr-2021 03:14 (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: 12312868

Subject Initials: ---

Generated By:

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

(b) (4)

City of Buenos Aires				
Sep-13-2020 18:36:44 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Transcription Error
Sep-11-2020 19:01:26 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BP1Y6D	Initial Entry

5.b

Date	Location	User	Value	Reason
Oct-13-2020 08:31:08 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample I BPXWY D: D	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Oct-13-2020 08:31:08 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BPXWYD	Initial Entry

090177e196ae2e73\Final\Final On: 01-Apr-2021 03:14 (GMT)

Header Text: C4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:04

Site No: 1231

Subject No: 12312868

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 20:20

[Back to Form](#)

1. Was there a temporary delay of vaccination?

Date	Location	User	Value	Reason
Oct-29-2020 18:55:18 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Closed	Response satisfies query
Oct-29-2020 15:21:42 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Answered	Yes, the corticosteroid was used due to covid illness related symptoms
Oct-27-2020 11:15:29 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Reissued :Opened	CLINQUERY: Please clarify if corticosteroid use was related to covid illness symptoms reported occurring 06-16Sep2020, or clarify reason for corticosteroid use.

090177e196ae2e73\Final\Final On: 01-Apr-2021 03:14 (GMT)

Header Text: C4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:04

Site No: 1231

Subject No: 12312868

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 20:20

Oct-27-2020 09:35:59 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 3: Closed	Close Auto Query
Oct-27-2020 09:35:59 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	Maria Beretta (b) (4)	Data Entry: YES Date of First Delay: Sep/10/2020 Reason(s) for Temporary Delay of Vaccination RECENT SYSTEMIC CORTICOSTEROID TREATMENT	New Information
Oct-27-2020 09:15:06 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 3: Opened	'Was there a temporary delay of vaccination?' is marked as Yes and 'Date of First Delay' is not entered. Please review and update as appropriate.
Oct-27-2020	ACV0PFEINFP6000	auto query	Query 2: Answered	Transcription

090177e196ae2e73\Final\Final On: 01-Apr-2021 03:14 (GMT)

Header Text: C4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:04

Site No: 1231

Subject No: 12312868

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 20:20

09:15:06 (UTC-03:00) City of Buenos Aires		(autoquery)	d	Error
Oct-27-2020 09:15:06 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Date of First Delay: Reason(s) for Temporary Delay of Vaccination RECENT SYSTEMIC CORTICOSTEROID TREATMENT	Transcription Error
Oct-23-2020 17:20:35 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Reissued :Opened	CLINQUERY: please confirm 'Was there a temporary delay of vaccination?' should be YES. A temporary delay on 10Sep2020 was previously reported.
Oct-23-2020 13:39:44 (UTC-03:00)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Answered d	New Information

090177e196ae2e73\Final\Final On: 01-Apr-2021 03:14 (GMT)

Header Text: C4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:04

Site No: 1231

Subject No: 12312868

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 20:20

City of Buenos Aires				
Oct-23-2020 13:39:44 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	New Information
Oct-23-2020 12:25:38 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Opened	CLINQUERY: Please clarify if corticosteroid use was related to covid illness symptoms reported occurring 06-16Sep2020, or clarify reason for corticosteroid use.
Oct-22-2020 10:57:51 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Oct-22-2020 10:57:51 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Date of First Delay:	Transcription Error

090177e196ae2e73\Final\Final On: 01-Apr-2021 03:14 (GMT)

Header Text: C4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:04

Site No: 1231

Subject No: 12312868

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 20:20

			Sep/10/2020 Reason(s) for Temporary Delay of Vaccination RECENT SYSTEMIC CORTICOSTEROID TREATMENT	
Oct-22-2020 10:55:55 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	'Was there a temporary delay of vaccination?' is marked as Yes and 'Date of First Delay' is not entered. Please review and update as appropriate.
Oct-22-2020 10:55:55 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Reason(s) for Temporary Delay of Vaccination RECENT SYSTEMIC CORTICOSTEROID TREATMENT	Initial Entry

2. Treatment Name

090177e196ae2e73\Final\Final On: 01-Apr-2021 03:14 (GMT)

Header Text: C4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:04

Site No: 1231

Subject No: 12312868

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 20:20

Date	Location	User	Value	Reason
Oct-22-2020 10:55:55 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: BLINDED THERAPY	Initial Entry

3. Formulation:

Date	Location	User	Value	Reason
Oct-22-2020 10:55:55 (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
Oct-26-2020 13:57:11 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Oct-22-2020 10:56:34 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 3: Closed	Close Auto Query
Oct-22-2020 10:56:34 (UTC-03:00)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Closed	Close Auto Query

090177e196ae2e73\Final\Final On: 01-Apr-2021 03:14 (GMT)

Header Text: C4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:04

Site No: 1231

Subject No: 12312868

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 20:20

City of Buenos Aires				
Oct-22-2020 10:56:34 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Oct/8/2020 11:26	Transcription Error
Oct-22-2020 10:55:55 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 3: Opened	Dose Date is not equal to Date of Visit 08/Oct/2020 of the corresponding Visit. Please review and update as appropriate.
Oct-22-2020 10:55:55 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Opened	Dose Date, 08/Nov/2020 11:26 is a future date relative to when it was entered on 22/Oct/2020 10:55. Please correct.
Oct-22-2020 10:55:55 (UTC-03:00)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Initial Entry

090177e196ae2e73\Final\Final On: 01-Apr-2021 03:14 (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: 12312868

Subject Initials: ---

Generated By:

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

(b) (4)

City of Buenos Aires				
Oct-22-2020 10:55:55 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Nov/8/2020 11:26	Initial Entry
Oct-20-2020 17:36:11 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	CLINICAL SAE report has VAX #2 on 08Oct2020 at 11:26; with syncope AE occurring 52 minutes later. Please record VAX #2 date and time.

5. Anatomical Location:

Date	Location	User	Value	Reason
Oct-22-2020 10:55:55 (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
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090177e196ae2e73\Final\Final On: 01-Apr-2021 03:14 (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: 12312868

Subject Initials: ---

Generated By:

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

(b) (4)

Oct-22-2020 10:55:55 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: LEFT	Initial Entry
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7. Route:

Date	Location	User	Value	Reason
Oct-22-2020 10:55:55 (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
Oct-22-2020 10:55:55 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: THE PROTOCOL SPECIFIED OBSERVATION PERIOD	Initial Entry

11. Was the subject observed for at least the protocol specified observation period after investigational product administration?

Date	Location	User	Value	Reason
Oct-22-2020 10:55:55 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

090177e196ae2e73\Final\Final On: 01-Apr-2021 03:14 (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: 12312868

Subject Initials: ---

Generated By:

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

(b) (4)

[Back to Form](#)

1. Date of Visit

Date	Location	User	Value	Reason
Nov-11-2020 19:45:41 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	Martina Davalli (b) (4)	Data Entry: Nov/11/2020	Initial Entry

090177e196ae2e73\Final\Final On: 01-Apr-2021 03:14 (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: 12312868 **Subject Initials:** ---

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

[Back to Form](#)

1. Data Origin

Date	Location	User	Value	Reason
Nov-11-2020 19:45:50 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Nov-11-2020 19:45:50 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SERUM	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Nov-12-2020 11:20:14 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Nov-11-2020 22:41:14 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	Sample Collected? is Yes, however no barcodes

090177e196ae2e73\Final\Final On: 01-Apr-2021 03:14 (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:** 12312868**Subject Initials:** ---**Generated By:****Generated Time (GMT):** 29-Mar-2021 20:20

(b) (4)

				are entered. Please review and correct as appropriate.
Nov-11-2020 19:45:50 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Nov-11-2020 19:45:50 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	Martina Davalli (b) (4)	Data Entry: YES Date of Collection : Nov/11/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Nov-12-2020 11:20:14 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	Agustin Morato Cabral (b) (4)	Data Entry: Sample ID BJ4F0 : H	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
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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: 12312868 Subject Initials: ---

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

Nov-12-2020 11:20:14 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	Agustin Morato Cabral (b) (4)	Data Entry: BJ4F0H	Initial Entry
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5.b

Date	Location	User	Value	Reason
Nov-12-2020 12:11:55 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID BJ4F1 : T	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Nov-12-2020 12:11:55 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BJ4F1T	Initial Entry

5.c

Date	Location	User	Value	Reason
Nov-12-2020 12:54:16 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID BP1P9 : L	Initial Entry

090177e196ae2e73\Final\Final On: 01-Apr-2021 03:14 (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: 12312868 **Subject Initials:** ---

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

5.c Sample ID

Date	Location	User	Value	Reason
Nov-12-2020 12:54:16 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BP1P9L	Initial Entry

Header Text: C4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Sep/11/2020

Form Version: 22-Apr-2020 21:03

Site No: 1231

Subject No: 12312868

Generated By:

(b) (4)

Form: DATE OF VISIT - ILLNESS ONSET - 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 20:20

[Back to Form](#)

1. Date of Visit

Date	Location	User	Value	Reason
Sep-13-2020 16:18:10 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Sep-13-2020 16:12:53 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Deleted	Close Auto Query
Sep-13-2020 16:11:39 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Candidate	Date of Visit is completed but Date of Assessment in the Signs and Symptoms form is missing. Please review and update as appropriate.
Sep-13-2020 16:11:39 (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

090177e196ae2e73\Final\Final On: 01-Apr-2021 03:14 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Sep/11/2020

Form Version: 22-Apr-2020 21:03

Site No: 1231

Subject No: 12312868

Generated By:

(b) (4)

Form: DATE OF VISIT - ILLNESS ONSET - 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 20:20

				Swab Self and Nasal Swab are missing. Please review and update as appropriate.
Sep-13-2020 16:11:39 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sep/11/2020	Initial Entry

3. COVID-19 Illness Visit:

Date	Location	User	Value	Reason
Sep-13-2020 16:11:39 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: COVID_A	Initial Entry

090177e196ae2e73\Final\Final On: 01-Apr-2021 03:14 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Sep/11/2020

Form Version: 21-Aug-2020 02:52

Site No: 1231

Subject No: 12312868

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 20:20

[Back to Form](#)

1. Date of Assessment:

Date	Location	User	Value	Reason
Sep-13-2020 16:12:53 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sep/11/2020	Initial Entry

2. Date of First Symptom Started:

Date	Location	User	Value	Reason
Sep-13-2020 16:12:53 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sep/6/2020	Initial Entry

3. Symptoms Ongoing?

Date	Location	User	Value	Reason
Dec-02-2020 05:20:25 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Closed	Response satisfies query
Dec-01-2020 10:33:51 (UTC-03:00)	ACV0PFEINFP6000	Santiago Corradetti (b) (4)	Query 3: Answer ed	Convalescent visit data has been uploaded.

090177e196ae2e73\Final\Final On: 01-Apr-2021 03:14 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Sep/11/2020

Form Version: 21-Aug-2020 02:52

Site No: 1231

Subject No: 12312868

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 20:20

City of Buenos Aires				Thank you.
Nov-30-2020 01:58:03 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Reissued:Opened	DM 1: Convalescent Visit is not yet initiated. Thus, kindly respond to this query once data is available, until then please keep this query in open status. Thank you.
Nov-27-2020 11:38:35 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Answered	The volunteer for personal reasons unrelated to the protocol is cited on multiple occasions to make the convalescence visit of COVID, has not been able to attend the corresponding convalescence visits. It will be recited.

090177e196ae2e73\Final\Final On: 01-Apr-2021 03:14 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Sep/11/2020

Form Version: 21-Aug-2020 02:52

Site No: 1231

Subject No: 12312868

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 20:20

Nov-27-2020 09:12:31 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Query 3: Reissue d:Opened	DM: Corresponding Convalescent Visit is not yet initiated, please review and update appropriately.
Nov-23-2020 03:13:25 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Query 3: Reissue d:Candidate	DM: Per site response, Convalescent visit is scheduled for 26-NOV, 14:00 hs (local ARG time). Please review once data available. Thank you.
Nov-20-2020 09:09:55 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	Santiago Corradetti (b) (4) [REDACTED]	Query 3: Answer ed	Convalescent visit is scheduled for 26-NOV, 14:00 hs (local ARG time)
Nov-20-2020 07:36:34 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Query 3: Reissue d:Opened	DM: Please confirm current subject status and if Convalescent

090177e196ae2e73\Final\Final On: 01-Apr-2021 03:14 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Sep/11/2020

Form Version: 21-Aug-2020 02:52

Site No: 1231

Subject No: 12312868

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 20:20

				Visit will be performed. Thanks
Nov-19-2020 10:14:04 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Answered	The subject has schedule V3 but cancel in all opportunities.
Nov-19-2020 08:23:33 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Opened	DM: Subject has completed illness Visit and symptoms are resolved, however corresponding Convalescent Visit not yet initiated. Please review and update as appropriate. Thank you.
Nov-12-2020 08:20:27 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Candidate	will wait till 18 nov, then query
Nov-05-2020 15:50:49	ACV0PFEINFP6000	(b) (6)	Query 2: Closed	Response satisfies query

090177e196ae2e73\Final\Final On: 01-Apr-2021 03:14 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Sep/11/2020

Form Version: 21-Aug-2020 02:52

Site No: 1231

Subject No: 12312868

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 20:20

(UTC-03:00) City of Buenos Aires		(b) (4)		
Nov-05-2020 08:51:42 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Answer ed	The Convalescent visit is schedule on 18 NOV 2020. Thank You.
Nov-05-2020 06:22:41 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Opened	DM2: Subject has completed illness Visit and symptoms are resolved, however corresponding Convalescent Visit not yet initiated. Please review and update as appropriate. Thank you.
Nov-04-2020 03:10:30 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Nov-02-2020	ACV0PFEINFP6000	(b) (6)	Query 1: Answer	Up until today,

090177e196ae2e73\Final\Final On: 01-Apr-2021 03:14 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Sep/11/2020

Form Version: 21-Aug-2020 02:52

Site No: 1231

Subject No: 12312868

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 20:20

10:09:13 (UTC-03:00) City of Buenos Aires		(b) (4), (b) (6) [REDACTED]	ed	the subject is still participating in the study. Thank you
Nov-02-2020 03:02:28 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Query 1: Reissue d:Opened	DM1: Thanks for your response. Please confirm current subject status in the study. Thanks
Oct-30-2020 13:24:08 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Query 1: Answer ed	The convalescence visit has not been carried out for reasons of the volunteer, she has been cited on 2 different occasions, in which she confirmed and did not attend.
Oct-27-2020 11:50:04 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Query 1: Opened	DM: Subject has completed illness Visit and symptoms are resolved,

090177e196ae2e73\Final\Final On: 01-Apr-2021 03:14 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Sep/11/2020

Form Version: 21-Aug-2020 02:52

Site No: 1231

Subject No: 12312868

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 20:20

				however Convalescent Visit not yet initiated. Please review and update as appropriate. Thank you.
Oct-15-2020 11:42:43 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6) [Redacted]	Data Entry: NO Date of Last Sy mptom Resolve d: Sep/16/2020	New Information
Sep-13-2020 16:12:53 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6) [Redacted]	Data Entry: YES	Initial Entry

4.a

Date	Location	User	Value	Reason
Sep-13-2020 16:12:53 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6) [Redacted]	Data Entry: Symptoms: FEV ER Symptom Pr NO esent:	Initial Entry

090177e196ae2e73\Final\Final On: 01-Apr-2021 03:14 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Sep/11/2020

Form Version: 21-Aug-2020 02:52

Site No: 1231

Subject No: 12312868

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 20:20

4.a Symptoms:

Date	Location	User	Value	Reason
Sep-13-2020 16:12:53 (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-13-2020 16:12:53 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

4.b

Date	Location	User	Value	Reason
Sep-13-2020 16:12:53 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sympt NEW OR I oms: NCREASE D COUGH Sympt NO om Pre sent:	Initial Entry

090177e196ae2e73\Final\Final On: 01-Apr-2021 03:14 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Sep/11/2020

Form Version: 21-Aug-2020 02:52

Site No: 1231

Subject No: 12312868

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 20:20

4.b Symptoms:

Date	Location	User	Value	Reason
Sep-13-2020 16:12:53 (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-13-2020 16:12:53 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

4.c

Date	Location	User	Value	Reason
Sep-13-2020 16:12:53 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symp NEW OR IN toms: CREASED S HORTNESS OF BREATH Symp NO tom Prese nt:	Initial Entry

090177e196ae2e73\Final\Final On: 01-Apr-2021 03:14 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Sep/11/2020

Form Version: 21-Aug-2020 02:52

Site No: 1231

Subject No: 12312868

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 20:20

4.c Symptoms:

Date	Location	User	Value	Reason
Sep-13-2020 16:12:53 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NEW OR INCREAS ED SHORTNESS O F BREATH	Initial Entry

4.c Was symptom present?

Date	Location	User	Value	Reason
Sep-13-2020 16:12:53 (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-13-2020 16:12:53 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptoms: CHIL LS Symptom Pr NO esent:	Initial Entry

090177e196ae2e73\Final\Final On: 01-Apr-2021 03:14 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Sep/11/2020

Form Version: 21-Aug-2020 02:52

Site No: 1231

Subject No: 12312868

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 20:20

4.d Symptoms:

Date	Location	User	Value	Reason
Sep-13-2020 16:12:53 (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-13-2020 16:12:53 (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-13-2020 16:12:53 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sympt NEW OR IN oms: CREASED MUSCLE P AIN Sympt YES om Pr esent:	Initial Entry

090177e196ae2e73\Final\Final On: 01-Apr-2021 03:14 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Sep/11/2020

Form Version: 21-Aug-2020 02:52

Site No: 1231

Subject No: 12312868

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 20:20

4.e Symptoms:

Date	Location	User	Value	Reason
Sep-13-2020 16:12:53 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NEW OR INCREAS ED MUSCLE PAIN	Initial Entry

4.e Was symptom present?

Date	Location	User	Value	Reason
Sep-13-2020 16:12:53 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

4.f

Date	Location	User	Value	Reason
Sep-13-2020 16:12:53 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sympt NEW LOSS oms: OF TASTE OR SMELL Sympt NO om Pr esent:	Initial Entry

090177e196ae2e73\Final\Final On: 01-Apr-2021 03:14 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Sep/11/2020

Form Version: 21-Aug-2020 02:52

Site No: 1231

Subject No: 12312868

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 20:20

4.f Symptoms:

Date	Location	User	Value	Reason
Sep-13-2020 16:12:53 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NEW LOSS OF TAS TE OR SMELL	Initial Entry

4.f Was symptom present?

Date	Location	User	Value	Reason
Sep-13-2020 16:12:53 (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-13-2020 16:12:53 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symp NEW OR IN toms: CREASED SORE THR OAT Symp YES tom P resent :	Initial Entry

090177e196ae2e73\Final\Final On: 01-Apr-2021 03:14 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Sep/11/2020

Form Version: 21-Aug-2020 02:52

Site No: 1231

Subject No: 12312868

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 20:20

4.g Symptoms:

Date	Location	User	Value	Reason
Sep-13-2020 16:12:53 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NEW OR INCREAS ED SORE THROAT	Initial Entry

4.g Was symptom present?

Date	Location	User	Value	Reason
Sep-13-2020 16:12:53 (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-13-2020 16:12:53 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptoms DIARR : HEA Symptom NO Present:	Initial Entry

090177e196ae2e73\Final\Final On: 01-Apr-2021 03:14 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Sep/11/2020

Form Version: 21-Aug-2020 02:52

Site No: 1231

Subject No: 12312868

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 20:20

4.h Symptoms:

Date	Location	User	Value	Reason
Sep-13-2020 16:12:53 (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-13-2020 16:12:53 (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-13-2020 16:12:53 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptoms VOMI : TING Symptom NO Present:	Initial Entry

090177e196ae2e73\Final\Final On: 01-Apr-2021 03:14 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Sep/11/2020

Form Version: 21-Aug-2020 02:52

Site No: 1231

Subject No: 12312868

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 20:20

4.i Symptoms:

Date	Location	User	Value	Reason
Sep-13-2020 16:12:53 (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-13-2020 16:12:53 (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-13-2020 16:14:45 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptoms - otalg Other: ia	Initial Entry

5.a Symptoms - Other Text:

Date	Location	User	Value	Reason
Sep-13-2020 16:14:45 (UTC-03:00) City	ACV0PFEINFP6000	(b) (6)	Data Entry: otalgia	Initial Entry

090177e196ae2e73\Final\Final On: 01-Apr-2021 03:14 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Sep/11/2020

Form Version: 21-Aug-2020 02:52

Site No: 1231

Subject No: 12312868

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 20:20

of Buenos Aires

(b) (4)

090177e196ae2e73\Final\Final On: 01-Apr-2021 03:14 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Sep/11/2020

Form Version: 06-Jul-2020 21:54

Site No: 1231

Subject No: 12312868

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 20:20

[Back to Form](#)

Date	Location	User	Value	Reason
Sep-13-2020 16:17:07 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Created	

Header Text: C4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Sep/11/2020

Form: MICROBIOLOGY SPECIMEN - eCRF Audit
Trail History

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen, Verified

Site No: 1231

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

Subject No: 12312868

Subject Initials: ---

Generated By:

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

(b) (4)

[Back to Form](#)

1. Actual Date of Collection:

Date	Location	User	Value	Reason
Sep-13-2020 16:17:07 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sep/11/2020	Initial Entry

2. Specimen Type:

Date	Location	User	Value	Reason
Sep-13-2020 16:17:07 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: SWABBED MATER IAL	Initial Entry

3. Specimen Collection Location:

Date	Location	User	Value	Reason
Sep-13-2020 16:17:07 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NASOPHARYNX	Initial Entry

4. Assay Code and Description:

Date	Location	User	Value	Reason
Sep-13-2020	ACV0PFEINFP6000	auto calc	Data Entry:	Initial Entry

090177e196ae2e73\Final\Final On: 01-Apr-2021 03:14 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Sep/11/2020

Form Version: 06-Jul-2020 21:54

Site No: 1231

Subject No: 12312868

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 20:20

16:17:07
(UTC-03:00) City
of Buenos Aires

(autocalc)

SEVERE ACUTE RES
P SYNDROME CORO
NAVIRUS 2

5. Device Type:

Date	Location	User	Value	Reason
Sep-13-2020 16:17:07 (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-13-2020 16:17:07 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: ATILA BIOSYSTE MS IAMP COVID-1 9 DETECTION KIT	Initial Entry

7. Test Result:

Date	Location	User	Value	Reason
Sep-13-2020 16:17:07 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NEGATIVE	Initial Entry

090177e196ae2e73\Final\Final On: 01-Apr-2021 03:14 (GMT)

Header Text: C4591001**Visit:** POT_COVID_ILL 1 -
Unscheduled Visit on Sep/11/2020**Form Version:** 22-Apr-2020 21:03**Site No:** 1231**Subject No:** 12312868**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 20:20[Back to Form](#)**1. Data Origin**

Date	Location	User	Value	Reason
Sep-13-2020 16:17:51 (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-13-2020 16:17:51 (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-13-2020 16:17:51 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	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/11/2020

Form Version: 22-Apr-2020 21:03

Site No: 1231

Subject No: 12312868

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 20:20

Sep-13-2020 16:17:51 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample collected by a team physician	Initial Entry
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Header Text: C4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Sep/11/2020

Form Version: 22-Apr-2020 21:03

Site No: 1231

Subject No: 12312868

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 20:20

[Back to Form](#)

1. Data Origin

Date	Location	User	Value	Reason
Sep-13-2020 16:18:10 (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-13-2020 16:18:10 (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-13-2020 18:38:39 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Sep-13-2020 16:18:10 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes

090177e196ae2e73\Final\Final On: 01-Apr-2021 03:14 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Sep/11/2020

Form Version: 22-Apr-2020 21:03

Site No: 1231

Subject No: 12312868

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 20:20

				are entered. Please review and correct as appropriate.
Sep-13-2020 16:18:10 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Date of Collection : Sep/11/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Sep-13-2020 18:38:39 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample I BP1Y6 D: D	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Sep-13-2020 18:38:39 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BP1Y6D	Initial Entry

090177e196ae2e73\Final\Final On: 01-Apr-2021 03:14 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Sep/11/2020

Form Version: 21-Aug-2020 02:50

Site No: 1231

Subject No: 12312868

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 20:20

[Back to Form](#)

1.a

Date	Location	User	Value	Reason
Sep-13-2020 16:18:59 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Type of Prac SPEC titioner: IALI ST Occurrence NO of Visits or C ontacts:	Initial Entry

1.a Physician or Healthcare Professional:

Date	Location	User	Value	Reason
Sep-13-2020 16:18:59 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: SPECIALIST	Initial Entry

1.a Occurrence of Visits or Contacts:

Date	Location	User	Value	Reason
Sep-13-2020 16:18:59 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

090177e196ae2e73\Final\Final On: 01-Apr-2021 03:14 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Sep/11/2020

Form: HEALTH CARE UTILIZATION - eCRF Audit
Trail History

Form Version: 21-Aug-2020 02:50

Form Status: Data Complete, Frozen, Verified

Site No: 1231

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

Subject No: 12312868

Subject Initials: ---

Generated By:

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

(b) (4)

1.b

Date	Location	User	Value	Reason
Sep-13-2020 16:18:59 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Type of Pr EMER actitioner: GENC Y ROO M Occurrence NO e of Visits or Contact s:	Initial Entry

1.b Physician or Healthcare Professional:

Date	Location	User	Value	Reason
Sep-13-2020 16:18:59 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: EMERGENCY ROO M	Initial Entry

1.b Occurrence of Visits or Contacts:

Date	Location	User	Value	Reason
Sep-13-2020 16:18:59 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

1.c

090177e196ae2e73\Final\Final On: 01-Apr-2021 03:14 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Sep/11/2020

Form Version: 21-Aug-2020 02:50

Site No: 1231

Subject No: 12312868

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 20:20

Date	Location	User	Value	Reason
Sep-13-2020 16:18:59 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Type of P PRIMAR ractitione Y CARE r: PHYSICI AN Occurren NO ce of Visi ts or Con tacts:	Initial Entry

1.c Physician or Healthcare Professional:

Date	Location	User	Value	Reason
Sep-13-2020 16:18:59 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: PRIMARY CARE P HYSICIAN	Initial Entry

1.c Occurrence of Visits or Contacts:

Date	Location	User	Value	Reason
Sep-13-2020 16:18:59 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

1.d

Date	Location	User	Value	Reason
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090177e196ae2e73\Final\Final On: 01-Apr-2021 03:14 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Sep/11/2020

Form: HEALTH CARE UTILIZATION - eCRF Audit
Trail History

Form Version: 21-Aug-2020 02:50

Form Status: Data Complete, Frozen, Verified

Site No: 1231

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

Subject No: 12312868

Subject Initials: ---

Generated By:

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

(b) (4)

Sep-13-2020 16:18:59 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Type of Practitioner: URGE NT C ARE Occurrence of Visits or Contacts: NO	Initial Entry
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1.d Physician or Healthcare Professional:

Date	Location	User	Value	Reason
Sep-13-2020 16:18:59 (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-13-2020 16:18:59 (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-13-2020 16:18:59 (UTC-03:00) City	ACV0PFEINFP6000	(b) (6)	Data Entry: Type of Practitioner: TELEPH ONE CO	Initial Entry

090177e196ae2e73\Final\Final On: 01-Apr-2021 03:14 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Sep/11/2020

Form Version: 21-Aug-2020 02:50

Site No: 1231

Subject No: 12312868

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 20:20

of Buenos Aires		(b) (4)	r: NSULTA TION	
			Occurren NO ce of Visi ts or Con tacts:	

1.e Physician or Healthcare Professional:

Date	Location	User	Value	Reason
Sep-13-2020 16:18:59 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: TELEPHONE CON SULTATION	Initial Entry

1.e Occurrence of Visits or Contacts:

Date	Location	User	Value	Reason
Sep-13-2020 16:18:59 (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-13-2020 16:18:59 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Type of Practi OT tioner: HE R	Initial Entry

090177e196ae2e73\Final\Final On: 01-Apr-2021 03:14 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Sep/11/2020

Form: HEALTH CARE UTILIZATION - eCRF Audit
Trail History

Form Version: 21-Aug-2020 02:50

Form Status: Data Complete, Frozen, Verified

Site No: 1231

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

Subject No: 12312868

Subject Initials: ---

Generated By:

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

(b) (4)

			Occurrence of NO Visits or Cont acts:	
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1.f Physician or Healthcare Professional:

Date	Location	User	Value	Reason
Sep-13-2020 16:18:59 (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-13-2020 16:18:59 (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
Sep-14-2020 09:28:53 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Sep-13-2020	ACV0PFEINFP6000	(b) (6)	Query 1: Answered	The

090177e196ae2e73\Final\Final On: 01-Apr-2021 03:14 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Sep/11/2020

Form Version: 21-Aug-2020 02:50

Site No: 1231

Subject No: 12312868

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 20:20

16:19:30 (UTC-03:00) City of Buenos Aires		(b) (4), (b) (6)	d	information is correct. The subject has not been hospitalized. The subject did not need visits or medical attention. Thank you
Sep-13-2020 16:18:59 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	There are no visits or contacts reported and subject has not been hospitalized, please confirm whether the participant sought medical attention for this respiratory illness episode. If not, please correct data.
Sep-13-2020 16:18:59 (UTC-03:00) City of Buenos	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

090177e196ae2e73\Final\Final On: 01-Apr-2021 03:14 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Sep/11/2020

Form Version: 21-Aug-2020 02:50

Site No: 1231

Subject No: 12312868

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 20:20

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Header Text: C4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Sep/11/2020

Form Version: 06-Jul-2020 21:52

Site No: 1231

Subject No: 12312868

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 20:20

[Back to Form](#)

1. Category of Clinical Event:

Date	Location	User	Value	Reason
Sep-13-2020 16:19:11 (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-13-2020 16:19:11 (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-13-2020 16:19:11 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 2	Initial Entry

090177e196ae2e73\Final\Final On: 01-Apr-2021 03:14 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 2 -
Unscheduled Visit on Oct/17/2020

Form Version: 22-Apr-2020 21:03

Site No: 1231

Subject No: 12312868

Generated By:

(b) (4)

Form: DATE OF VISIT - ILLNESS ONSET - 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 20:20

[Back to Form](#)

1. Date of Visit

Date	Location	User	Value	Reason
Oct-19-2020 12:42:10 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Oct-19-2020 12:41:06 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Deleted	Close Auto Query
Oct-19-2020 12:40:03 (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.
Oct-19-2020 12:40:03 (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

090177e196ae2e73\Final\Final On: 01-Apr-2021 03:14 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 2 -
Unscheduled Visit on Oct/17/2020

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: 12312868

Subject Initials: ---

Generated By:

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

(b) (4)

				Swab Self and Nasal Swab are missing. Please review and update as appropriate.
Oct-19-2020 12:40:03 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Oct/17/2020	Initial Entry

3. COVID-19 Illness Visit:

Date	Location	User	Value	Reason
Oct-19-2020 12:40:03 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: COVID_B	Initial Entry

090177e196ae2e73\Final\Final On: 01-Apr-2021 03:14 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 2 -
Unscheduled Visit on Oct/17/2020

Form Version: 10-Oct-2020 16:02

Site No: 1231

Subject No: 12312868

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 20:20

[Back to Form](#)

1. Date of Assessment:

Date	Location	User	Value	Reason
Oct-19-2020 12:41:06 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Oct/17/2020	Initial Entry

2. Date of First Symptom Started:

Date	Location	User	Value	Reason
Oct-19-2020 12:41:06 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Oct/14/2020	Initial Entry

3. Symptoms Ongoing?

Date	Location	User	Value	Reason
Oct-30-2020 08:34:54 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO Date of Last Symptom Resolved: Oct/20/2020	New Information
Oct-19-2020 12:41:06	ACV0PFEINFP6000	(b) (6)	Data Entry: YES	Initial Entry

090177e196ae2e73\Final\Final On: 01-Apr-2021 03:14 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 2 -
Unscheduled Visit on Oct/17/2020

Form Version: 10-Oct-2020 16:02

Site No: 1231

Subject No: 12312868

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 20:20

(UTC-03:00) City
of Buenos Aires

(b) (4)

4.a

Date	Location	User	Value	Reason
Oct-19-2020 12:41:06 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptoms: FEVE R Symptom Pre sent: YES	Initial Entry

4.a Symptoms:

Date	Location	User	Value	Reason
Oct-19-2020 12:41:06 (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
Oct-19-2020 12:41:06 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

4.b

090177e196ae2e73\Final\Final On: 01-Apr-2021 03:14 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 2 -
Unscheduled Visit on Oct/17/2020

Form Version: 10-Oct-2020 16:02

Site No: 1231

Subject No: 12312868

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 20:20

Date	Location	User	Value	Reason
Oct-19-2020 12:41:06 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sympt NEW OR IN oms: CREASED COUGH Sympt NO om Pre sent:	Initial Entry

4.b Symptoms:

Date	Location	User	Value	Reason
Oct-19-2020 12:41:06 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NEW OR INCREASE D COUGH	Initial Entry

4.b Was symptom present?

Date	Location	User	Value	Reason
Oct-19-2020 12:41:06 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

4.c

Date	Location	User	Value	Reason
Oct-19-2020	ACV0PFEINFP6000	(b) (6)	Data Entry:	Initial Entry

090177e196ae2e73\Final\Final On: 01-Apr-2021 03:14 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 2 -
Unscheduled Visit on Oct/17/2020

Form Version: 10-Oct-2020 16:02

Site No: 1231

Subject No: 12312868

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 20:20

12:41:06 (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: NO	
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4.c Symptoms:

Date	Location	User	Value	Reason
Oct-19-2020 12:41:06 (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
Oct-19-2020 12:41:06 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

4.d

Date	Location	User	Value	Reason
Oct-19-2020 12:41:06	ACV0PFEINFP6000	(b) (6)	Data Entry: Symptoms: CHIL	Initial Entry

090177e196ae2e73\Final\Final On: 01-Apr-2021 03:14 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 2 -
Unscheduled Visit on Oct/17/2020

Form Version: 10-Oct-2020 16:02

Site No: 1231

Subject No: 12312868

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 20:20

(UTC-03:00) City of Buenos Aires		(b) (4)	LS Symptom Present: YES
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4.d Symptoms:

Date	Location	User	Value	Reason
Oct-19-2020 12:41:06 (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
Oct-19-2020 12:41:06 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

4.e

Date	Location	User	Value	Reason
Oct-19-2020 12:41:06 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptoms: NEW OR INCREASED MUSCLE PAIN	Initial Entry

090177e196ae2e73\Final\Final On: 01-Apr-2021 03:14 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 2 -
Unscheduled Visit on Oct/17/2020

Form Version: 10-Oct-2020 16:02

Site No: 1231

Subject No: 12312868

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 20:20

			Symptom Present:	
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4.e Symptoms:

Date	Location	User	Value	Reason
Oct-19-2020 12:41:06 (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
Oct-19-2020 12:41:06 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

4.f

Date	Location	User	Value	Reason
Oct-19-2020 12:41:06 (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

090177e196ae2e73\Final\Final On: 01-Apr-2021 03:14 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 2 -
Unscheduled Visit on Oct/17/2020

Form Version: 10-Oct-2020 16:02

Site No: 1231

Subject No: 12312868

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 20:20

4.f Symptoms:

Date	Location	User	Value	Reason
Oct-19-2020 12:41:06 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NEW LOSS OF TAS TE OR SMELL	Initial Entry

4.f Was symptom present?

Date	Location	User	Value	Reason
Oct-19-2020 12:41:06 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

4.g

Date	Location	User	Value	Reason
Oct-19-2020 12:41:06 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sympt NEW OR IN oms: CREASED S ORE THROA T Sympt YES om Pr esent:	Initial Entry

090177e196ae2e73\Final\Final On: 01-Apr-2021 03:14 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 2 -
Unscheduled Visit on Oct/17/2020

Form Version: 10-Oct-2020 16:02

Site No: 1231

Subject No: 12312868

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 20:20

4.g Symptoms:

Date	Location	User	Value	Reason
Oct-19-2020 12:41:06 (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
Oct-19-2020 12:41:06 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

4.h

Date	Location	User	Value	Reason
Oct-19-2020 12:41:06 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptoms: DIARR HEA Symptom P NO resent:	Initial Entry

090177e196ae2e73\Final\Final On: 01-Apr-2021 03:14 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 2 -
Unscheduled Visit on Oct/17/2020

Form Version: 10-Oct-2020 16:02

Site No: 1231

Subject No: 12312868

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 20:20

4.h Symptoms:

Date	Location	User	Value	Reason
Oct-19-2020 12:41:06 (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
Oct-19-2020 12:41:06 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

4.i

Date	Location	User	Value	Reason
Oct-19-2020 12:41:06 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptoms: VOMIT ING Symptom P NO resent:	Initial Entry

090177e196ae2e73\Final\Final On: 01-Apr-2021 03:14 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 2 -
Unscheduled Visit on Oct/17/2020

Form Version: 10-Oct-2020 16:02

Site No: 1231

Subject No: 12312868

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 20:20

4.i Symptoms:

Date	Location	User	Value	Reason
Oct-19-2020 12:41:06 (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
Oct-19-2020 12:41:06 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

090177e196ae2e73\Final\Final On: 01-Apr-2021 03:14 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 2 -
Unscheduled Visit on Oct/17/2020

Form Version: 06-Jul-2020 21:54

Site No: 1231

Subject No: 12312868

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 20:20

[Back to Form](#)

Date	Location	User	Value	Reason
Oct-19-2020 12:41:40 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Created	

Header Text: C4591001

Visit: POT_COVID_ILL 2 -
Unscheduled Visit on Oct/17/2020

Form Version: 06-Jul-2020 21:54

Site No: 1231

Subject No: 12312868

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 20:20

[Back to Form](#)

1. Actual Date of Collection:

Date	Location	User	Value	Reason
Oct-19-2020 12:41:40 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Oct/17/2020	Initial Entry

2. Specimen Type:

Date	Location	User	Value	Reason
Oct-19-2020 12:41:40 (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
Oct-19-2020 15:59:14 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NASOPHARYNX	Initial Entry

4. Assay Code and Description:

Date	Location	User	Value	Reason
Oct-19-2020	ACV0PFEINFP6000	auto calc	Data Entry:	Initial Entry

090177e196ae2e73\Final\Final On: 01-Apr-2021 03:14 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 2 -
Unscheduled Visit on Oct/17/2020

Form Version: 06-Jul-2020 21:54

Site No: 1231

Subject No: 12312868

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 20:20

12:41:40
(UTC-03:00) City
of Buenos Aires

(autocalc)

SEVERE ACUTE RES
P SYNDROME CORO
NAVIRUS 2

5. Device Type:

Date	Location	User	Value	Reason
Oct-19-2020 12:41:40 (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
Oct-19-2020 12:41:40 (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
Oct-19-2020 12:41:40 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NEGATIVE	Initial Entry

090177e196ae2e73\Final\Final On: 01-Apr-2021 03:14 (GMT)

Header Text: C4591001**Visit:** POT_COVID_ILL 2 -
Unscheduled Visit on Oct/17/2020**Form Version:** 22-Apr-2020 21:03**Site No:** 1231**Subject No:** 12312868**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 20:20[Back to Form](#)**1. Data Origin**

Date	Location	User	Value	Reason
Oct-19-2020 12:41:57 (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-19-2020 12:41:57 (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
Oct-19-2020 12:41:57 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	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 2 -
Unscheduled Visit on Oct/17/2020

Form Version: 22-Apr-2020 21:03

Site No: 1231

Subject No: 12312868

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 20:20

Oct-19-2020 12:41:57 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample collected by a team physician	Initial Entry
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Header Text: C4591001

Visit: POT_COVID_ILL 2 -
Unscheduled Visit on Oct/17/2020

Form Version: 22-Apr-2020 21:03

Site No: 1231

Subject No: 12312868

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 20:20

[Back to Form](#)

1. Data Origin

Date	Location	User	Value	Reason
Oct-19-2020 12:42:10 (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-19-2020 12:42:10 (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
Oct-19-2020 13:20:46 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Oct-19-2020 12:42:10 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes

090177e196ae2e73\Final\Final On: 01-Apr-2021 03:14 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 2 -
Unscheduled Visit on Oct/17/2020

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: 12312868

Subject Initials: ---

Generated By:

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

(b) (4)

				are entered. Please review and correct as appropriate.
Oct-19-2020 12:42:10 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Date of Collection: Oct/17/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Oct-19-2020 13:20:46 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	Romina Barrera (b) (4)	Data Entry: Sample ID BPT7V : K	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Oct-19-2020 13:20:46 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	Romina Barrera (b) (4)	Data Entry: BPT7VK	Initial Entry

090177e196ae2e73\Final\Final On: 01-Apr-2021 03:14 (GMT)

Header Text: C4591001**Visit:** POT_COVID_ILL 2 -
Unscheduled Visit on Oct/17/2020**Form Version:** 10-Oct-2020 15:59**Site No:** 1231**Subject No:** 12312868**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 20:20[Back to Form](#)*I.a*

Date	Location	User	Value	Reason
Oct-19-2020 12:42:23 (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
Oct-19-2020 12:42:23 (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-19-2020 12:42:23 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

Header Text: C4591001

Visit: POT_COVID_ILL 2 -
Unscheduled Visit on Oct/17/2020

Form: HEALTH CARE UTILIZATION - eCRF Audit
Trail History

Form Version: 10-Oct-2020 15:59

Form Status: Data Complete, Frozen, Verified

Site No: 1231

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

Subject No: 12312868

Subject Initials: ---

Generated By:

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

(b) (4)

1.b

Date	Location	User	Value	Reason
Oct-19-2020 12:42:23 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Type of Pr EMERG actioner: ENCY ROOM Occurenc NO e of Visits o r Contacts:	Initial Entry

1.b Physician or Healthcare Professional:

Date	Location	User	Value	Reason
Oct-19-2020 12:42:23 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: EMERGENCY ROO M	Initial Entry

1.b Occurrence of Visits or Contacts:

Date	Location	User	Value	Reason
Oct-19-2020 12:42:23 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

1.c

Date	Location	User	Value	Reason
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090177e196ae2e73\Final\Final On: 01-Apr-2021 03:14 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 2 -
Unscheduled Visit on Oct/17/2020

Form: HEALTH CARE UTILIZATION - eCRF Audit
Trail History

Form Version: 10-Oct-2020 15:59

Form Status: Data Complete, Frozen, Verified

Site No: 1231

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

Subject No: 12312868

Subject Initials: ---

Generated By:

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

(b) (4)

Oct-19-2020 12:42:23 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Type of P PRIMAR ractitione Y CARE r: PHYSICI AN Occurren NO ce of Visit s or Cont acts:	Initial Entry
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1.c Physician or Healthcare Professional:

Date	Location	User	Value	Reason
Oct-19-2020 12:42:23 (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
Oct-19-2020 12:42:23 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

1.d

Date	Location	User	Value	Reason
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090177e196ae2e73\Final\Final On: 01-Apr-2021 03:14 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 2 -
Unscheduled Visit on Oct/17/2020

Form: HEALTH CARE UTILIZATION - eCRF Audit
Trail History

Form Version: 10-Oct-2020 15:59

Form Status: Data Complete, Frozen, Verified

Site No: 1231

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

Subject No: 12312868

Subject Initials: ---

Generated By:

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

(b) (4)

Oct-19-2020 12:42:23 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Type of Practitioner: URGE NT C ARE Occurrence of Visits or Contacts: NO	Initial Entry
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1.d Physician or Healthcare Professional:

Date	Location	User	Value	Reason
Oct-19-2020 12:42:23 (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
Oct-19-2020 12:42:23 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

1.e

Date	Location	User	Value	Reason
Oct-19-2020 12:42:23 (UTC-03:00) City	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Type of Practitioner: TELEPH ONE CO	Initial Entry

090177e196ae2e73\Final\Final On: 01-Apr-2021 03:14 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 2 -
Unscheduled Visit on Oct/17/2020

Form Version: 10-Oct-2020 15:59

Site No: 1231

Subject No: 12312868

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 20:20

of Buenos Aires			r: NSULTA TION	
			Occurren NO ce of Visit s or Cont acts:	

1.e Physician or Healthcare Professional:

Date	Location	User	Value	Reason
Oct-19-2020 12:42:23 (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
Oct-19-2020 12:42:23 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

1.f

Date	Location	User	Value	Reason
Oct-19-2020 12:42:23 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Type of Practiti OT oner: HE R	Initial Entry

090177e196ae2e73\Final\Final On: 01-Apr-2021 03:14 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 2 -
Unscheduled Visit on Oct/17/2020

Form: HEALTH CARE UTILIZATION - eCRF Audit
Trail History

Form Version: 10-Oct-2020 15:59

Form Status: Data Complete, Frozen, Verified

Site No: 1231

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

Subject No: 12312868

Subject Initials: ---

Generated By:

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

(b) (4)

			Occurrence of NO Visits or Conta cts:	
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1.f Physician or Healthcare Professional:

Date	Location	User	Value	Reason
Oct-19-2020 12:42:23 (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
Oct-19-2020 12:42:23 (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-19-2020 12:42:23 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

090177e196ae2e73\Final\Final On: 01-Apr-2021 03:14 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 2 -
Unscheduled Visit on Oct/17/2020

Form Version: 06-Jul-2020 21:52

Site No: 1231

Subject No: 12312868

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 20:20

[Back to Form](#)

1. Category of Clinical Event:

Date	Location	User	Value	Reason
Oct-19-2020 12:42:40 (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
Oct-19-2020 12:42:40 (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
Oct-19-2020 12:42:40 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 1	Initial Entry

090177e196ae2e73\Final\Final On: 01-Apr-2021 03:14 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 3 -
Unscheduled Visit on Jan/22/2021

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1231

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

Subject No: 12312868

Subject Initials: ---

Generated By:

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

(b) (4)

[Back to Form](#)

1. Date of Visit

Date	Location	User	Value	Reason
Mar-03-2021 06:27:27 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Closed	Response satisfies query
Mar-01-2021 09:38:39 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	Santiago Corradetti (b) (4)	Query 3: Answered	Convalescent visit will be performed on 03-MAR at 17:00hs local ARG time. Thank you.
Mar-01-2021 06:26:55 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Opened	PDQ: Convalescent visit is missing and 35 days (38) have passed since COVID Illness Visit. If visit occurred record data as a matching CONVA visit; if visit did not

090177e196ae2e73\Final\Final On: 01-Apr-2021 03:14 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 3 -
Unscheduled Visit on Jan/22/2021

Form Version: 22-Apr-2020 21:03

Site No: 1231

Subject No: 12312868

Generated By:

(b) (4)

Form: DATE OF VISIT - ILLNESS ONSET - 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 20:20

				occur attempt to schedule visit even if OOW and obtain the CONVA sample else clarify.
Jan-23-2021 11:37:12 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Jan-23-2021 11:36:00 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Deleted	Close Auto Query
Jan-23-2021 11:35:20 (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.

090177e196ae2e73\Final\Final On: 01-Apr-2021 03:14 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 3 -
Unscheduled Visit on Jan/22/2021

Form Version: 22-Apr-2020 21:03

Site No: 1231

Subject No: 12312868

Generated By:

(b) (4)

Form: DATE OF VISIT - ILLNESS ONSET - 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 20:20

Jan-23-2021 11:35:20 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidat e	Date of Visit is completed but Date of Collection in both Nasal Swab Self and Nasal Swab are missing. Please review and update as appropriate.
Jan-23-2021 11:35:20 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Jan/22/2021	Initial Entry

3. COVID-19 Illness Visit:

Date	Location	User	Value	Reason
Jan-23-2021 11:35:20 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: COVID_C	Initial Entry

090177e196ae2e73\Final\Final On: 01-Apr-2021 03:14 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 3 -
Unscheduled Visit on Jan/22/2021

Form Version: 14-Jan-2021 02:23

Site No: 1231

Subject No: 12312868

Generated By:

(b) (4)

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

Form Status: Data Complete

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

Subject Initials: ---

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

[Back to Form](#)

1. Date of Assessment:

Date	Location	User	Value	Reason
Jan-23-2021 11:36:00 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Jan/22/2021	Initial Entry

2. Date of First Symptom Started:

Date	Location	User	Value	Reason
Jan-23-2021 11:36:00 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Jan/19/2021	Initial Entry

3. Symptoms Ongoing?

Date	Location	User	Value	Reason
Jan-28-2021 12:20:23 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO Date of Last Symptom Resolved: Jan/26/2021	New Information
Jan-23-2021 11:36:00	ACV0PFEINFP6000	(b) (6)	Data Entry: YES	Initial Entry

090177e196ae2e73\Final\Final On: 01-Apr-2021 03:14 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 3 -
Unscheduled Visit on Jan/22/2021

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

Form Version: 14-Jan-2021 02:23

Form Status: Data Complete

Site No: 1231

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

Subject No: 12312868

Subject Initials: ---

Generated By:

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

(b) (4)

(UTC-03:00) City
of Buenos Aires

(b) (4)

4.a

Date	Location	User	Value	Reason
Jan-23-2021 11:36:00 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptoms: FEV ER Symptom Present: YES	Initial Entry

4.a Symptoms:

Date	Location	User	Value	Reason
Jan-23-2021 11:36:00 (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
Jan-23-2021 11:36:00 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

4.b

090177e196ae2e73\Final\Final On: 01-Apr-2021 03:14 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 3 -
Unscheduled Visit on Jan/22/2021

Form Version: 14-Jan-2021 02:23

Site No: 1231

Subject No: 12312868

Generated By:

(b) (4)

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

Form Status: Data Complete

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

Subject Initials: ---

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

Date	Location	User	Value	Reason
Jan-24-2021 19:35:09 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sympt NEW OR I oms: NCREASE D COUGH Sympt NO om Pr esent:	Transcription Error
Jan-23-2021 11:36:00 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sympt NEW OR I oms: NCREASE D COUGH Sympt YES om Pr esent:	Initial Entry

090177e196ae2e73\Final\Final On: 01-Apr-2021 03:14 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 3 -
Unscheduled Visit on Jan/22/2021

Form Version: 14-Jan-2021 02:23

Site No: 1231

Subject No: 12312868

Generated By:

(b) (4)

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

Form Status: Data Complete

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

Subject Initials: ---

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

4.b Symptoms:

Date	Location	User	Value	Reason
Jan-23-2021 11:36:00 (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
Jan-24-2021 19:35:09 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Transcription Error
Jan-23-2021 11:36:00 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

4.c

Date	Location	User	Value	Reason
Jan-23-2021 11:36:00 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptoms: NEW OR INCREASED SHORTNESS OF BREATH	Initial Entry

090177e196ae2e73\Final\Final On: 01-Apr-2021 03:14 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 3 -
Unscheduled Visit on Jan/22/2021

Form Version: 14-Jan-2021 02:23

Site No: 1231

Subject No: 12312868

Generated By:

(b) (4)

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

Form Status: Data Complete

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

Subject Initials: ---

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

			Symp NO tom Prese nt:	
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4.c Symptoms:

Date	Location	User	Value	Reason
Jan-23-2021 11:36:00 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NEW OR INCREAS ED SHORTNESS O F BREATH	Initial Entry

4.c Was symptom present?

Date	Location	User	Value	Reason
Jan-23-2021 11:36:00 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

4.d

Date	Location	User	Value	Reason
Jan-23-2021 11:36:00 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptoms: CHIL LS Symptom Pr NO esent:	Initial Entry

090177e196ae2e73\Final\Final On: 01-Apr-2021 03:14 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 3 -
Unscheduled Visit on Jan/22/2021

Form Version: 14-Jan-2021 02:23

Site No: 1231

Subject No: 12312868

Generated By:

(b) (4)

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

Form Status: Data Complete

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

Subject Initials: ---

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

4.d Symptoms:

Date	Location	User	Value	Reason
Jan-23-2021 11:36:00 (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
Jan-23-2021 11:36:00 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

4.e

Date	Location	User	Value	Reason
Jan-23-2021 11:36:00 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sympt NEW OR IN oms: CREASED MUSCLE P AIN Sympt NO om Pr esent:	Initial Entry

090177e196ae2e73\Final\Final On: 01-Apr-2021 03:14 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 3 -
Unscheduled Visit on Jan/22/2021

Form Version: 14-Jan-2021 02:23

Site No: 1231

Subject No: 12312868

Generated By:

(b) (4)

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

Form Status: Data Complete

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

Subject Initials: ---

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

4.e Symptoms:

Date	Location	User	Value	Reason
Jan-23-2021 11:36:00 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NEW OR INCREASED MUSCLE PAIN	Initial Entry

4.e Was symptom present?

Date	Location	User	Value	Reason
Jan-23-2021 11:36:00 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

4.f

Date	Location	User	Value	Reason
Jan-23-2021 11:36:00 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom: NEW LOSS OF TASTE OR SMELL Symptom Present: NO	Initial Entry

090177e196ae2e73\Final\Final On: 01-Apr-2021 03:14 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 3 -
Unscheduled Visit on Jan/22/2021

Form Version: 14-Jan-2021 02:23

Site No: 1231

Subject No: 12312868

Generated By:

(b) (4)

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

Form Status: Data Complete

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

Subject Initials: ---

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

4.f Symptoms:

Date	Location	User	Value	Reason
Jan-23-2021 11:36:00 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NEW LOSS OF TAS TE OR SMELL	Initial Entry

4.f Was symptom present?

Date	Location	User	Value	Reason
Jan-23-2021 11:36:00 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

4.g

Date	Location	User	Value	Reason
Jan-24-2021 19:34:18 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symp NEW OR I toms: NCREASE D SORE T HROAT Symp YES tom P resent :	Transcription Error
Jan-23-2021	ACV0PFEINFP6000	(b) (6)	Data Entry:	Initial Entry

090177e196ae2e73\Final\Final On: 01-Apr-2021 03:14 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 3 -
Unscheduled Visit on Jan/22/2021

Form Version: 14-Jan-2021 02:23

Site No: 1231

Subject No: 12312868

Generated By:

(b) (4)

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

Form Status: Data Complete

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

Subject Initials: ---

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

11:36:00 (UTC-03:00) City of Buenos Aires	(b) (4), (b) (6)	Symp NEW OR I toms: NCREASE D SORE T HROAT Symp NO tom P resent :
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4.g Symptoms:

Date	Location	User	Value	Reason
Jan-23-2021 11:36:00 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NEW OR INCREAS ED SORE THROAT	Initial Entry

4.g Was symptom present?

Date	Location	User	Value	Reason
Jan-24-2021 19:34:18 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Transcription Error
Jan-23-2021 11:36:00 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

4.h

090177e196ae2e73\Final\Final On: 01-Apr-2021 03:14 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 3 -
Unscheduled Visit on Jan/22/2021

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

Form Version: 14-Jan-2021 02:23

Form Status: Data Complete

Site No: 1231

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

Subject No: 12312868

Subject Initials: ---

Generated By:

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

(b) (4)

Date	Location	User	Value	Reason
Jan-23-2021 11:36:00 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptoms: DIARR HEA Symptom NO Present:	Initial Entry

4.h Symptoms:

Date	Location	User	Value	Reason
Jan-23-2021 11:36:00 (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
Jan-23-2021 11:36:00 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

4.i

Date	Location	User	Value	Reason
Jan-23-2021 11:36:00 (UTC-03:00) City	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptoms: VOMI TING	Initial Entry

090177e196ae2e73\Final\Final On: 01-Apr-2021 03:14 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 3 -
Unscheduled Visit on Jan/22/2021

Form Version: 14-Jan-2021 02:23

Site No: 1231

Subject No: 12312868

Generated By:

(b) (4)

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

Form Status: Data Complete

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

Subject Initials: ---

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

of Buenos Aires

**Symptom NO
Present:**

4.i Symptoms:

Date	Location	User	Value	Reason
Jan-23-2021 11:36:00 (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
Jan-23-2021 11:36:00 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

090177e196ae2e73\Final\Final On: 01-Apr-2021 03:14 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 3 -
Unscheduled Visit on Jan/22/2021

Form Version: 06-Jul-2020 21:54

Site No: 1231

Subject No: 12312868

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 20:20

[Back to Form](#)

Date	Location	User	Value	Reason
Jan-23-2021 11:36:24 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Created	

Header Text: C4591001

Visit: POT_COVID_ILL 3 -
Unscheduled Visit on Jan/22/2021

Form Version: 06-Jul-2020 21:54

Site No: 1231

Subject No: 12312868

Generated By:

(b) (4)

Form: MICROBIOLOGY SPECIMEN - eCRF Audit
Trail History

Form Status: Data Complete

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

Subject Initials: ---

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

[Back to Form](#)

1. Actual Date of Collection:

Date	Location	User	Value	Reason
Jan-23-2021 11:36:24 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Jan/22/2021	Initial Entry

2. Specimen Type:

Date	Location	User	Value	Reason
Jan-23-2021 11:36:24 (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
Jan-23-2021 11:36:24 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NASOPHARYNX	Initial Entry

4. Assay Code and Description:

Date	Location	User	Value	Reason
Jan-23-2021	ACV0PFEINFP6000	auto calc	Data Entry:	Initial Entry

090177e196ae2e73\Final\Final On: 01-Apr-2021 03:14 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 3 -
Unscheduled Visit on Jan/22/2021

Form: MICROBIOLOGY SPECIMEN - eCRF Audit
Trail History

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete

Site No: 1231

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

Subject No: 12312868

Subject Initials: ---

Generated By:

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

(b) (4)

11:36:24 (UTC-03:00) City of Buenos Aires		(autocalc)	SEVERE ACUTE RES P SYNDROME CORO NAVIRUS 2	
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5. Device Type:

Date	Location	User	Value	Reason
Jan-23-2021 11:36:24 (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
Jan-23-2021 11:36:24 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: ATILA BIOSYSTE MS IAMP COVID-1 9 DETECTION KIT	Initial Entry

7. Test Result:

Date	Location	User	Value	Reason
Jan-23-2021 11:36:24 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NEGATIVE	Initial Entry

090177e196ae2e73\Final\Final On: 01-Apr-2021 03:14 (GMT)

Header Text: C4591001**Visit:** POT_COVID_ILL 3 -
Unscheduled Visit on Jan/22/2021**Form Version:** 22-Apr-2020 21:03**Site No:** 1231**Subject No:** 12312868**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 20:20[Back to Form](#)**1. Data Origin**

Date	Location	User	Value	Reason
Jan-23-2021 11:36:42 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Jan-23-2021 11:36:42 (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
Jan-23-2021 11:36:42 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	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 3 -
Unscheduled Visit on Jan/22/2021

Form Version: 22-Apr-2020 21:03

Site No: 1231

Subject No: 12312868

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 20:20

Jan-23-2021 11:36:42 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample collected by t eam physician.	Initial Entry
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Header Text: C4591001

Visit: POT_COVID_ILL 3 -
Unscheduled Visit on Jan/22/2021

Form Version: 22-Apr-2020 21:03

Site No: 1231

Subject No: 12312868

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 20:20

[Back to Form](#)

1. Data Origin

Date	Location	User	Value	Reason
Jan-23-2021 11:37:12 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Jan-23-2021 11:37:12 (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
Jan-26-2021 12:51:59 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Jan-25-2021 09:39:20 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	'Sample Collected?' is Yes, however no barcodes

090177e196ae2e73\Final\Final On: 01-Apr-2021 03:14 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 3 -
Unscheduled Visit on Jan/22/2021

Form Version: 22-Apr-2020 21:03

Site No: 1231

Subject No: 12312868

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 20:20

				are entered. Please review and correct as appropriate.
Jan-23-2021 11:37:12 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Jan-23-2021 11:37:12 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Date of Collection: Jan/22/2021	Initial Entry

5.a

Date	Location	User	Value	Reason
Jan-26-2021 12:51:59 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample I BPWFB D: 0	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
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090177e196ae2e73\Final\Final On: 01-Apr-2021 03:14 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 3 -
Unscheduled Visit on Jan/22/2021

Form Version: 22-Apr-2020 21:03

Site No: 1231

Subject No: 12312868

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 20:20

Jan-26-2021 12:51:59 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	<u>Data Entry:</u> BPWFBO	Initial Entry
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090177e196ae2e73\Final\Final On: 01-Apr-2021 03:14 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 3 -
Unscheduled Visit on Jan/22/2021

Form Version: 14-Jan-2021 02:24

Site No: 1231

Subject No: 12312868

Generated By:

(b) (4)

Form: HEALTH CARE UTILIZATION - eCRF Audit
Trail History

Form Status: Data Complete

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

Subject Initials: ---

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

[Back to Form](#)

1.a

Date	Location	User	Value	Reason
Jan-23-2021 11:38:22 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Type of Prac SPEC titioner: IALI ST Occurrence NO of Visits or C ontacts:	Initial Entry

1.a Physician or Healthcare Professional:

Date	Location	User	Value	Reason
Jan-23-2021 11:38:22 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: SPECIALIST	Initial Entry

1.a Occurrence of Visits or Contacts:

Date	Location	User	Value	Reason
Jan-23-2021 11:38:22 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

090177e196ae2e73\Final\Final On: 01-Apr-2021 03:14 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 3 -
Unscheduled Visit on Jan/22/2021

Form: HEALTH CARE UTILIZATION - eCRF Audit
Trail History

Form Version: 14-Jan-2021 02:24

Form Status: Data Complete

Site No: 1231

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

Subject No: 12312868

Subject Initials: ---

Generated By:

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

(b) (4)

1.b

Date	Location	User	Value	Reason
Jan-23-2021 11:38:22 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Type of Pr EMER actitioner: GENC Y ROO M Occurrence NO of Visits or Contact s:	Initial Entry

1.b Physician or Healthcare Professional:

Date	Location	User	Value	Reason
Jan-23-2021 11:38:22 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: EMERGENCY ROO M	Initial Entry

1.b Occurrence of Visits or Contacts:

Date	Location	User	Value	Reason
Jan-23-2021 11:38:22 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

1.c

090177e196ae2e73\Final\Final On: 01-Apr-2021 03:14 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 3 -
Unscheduled Visit on Jan/22/2021

Form: HEALTH CARE UTILIZATION - eCRF Audit
Trail History

Form Version: 14-Jan-2021 02:24

Form Status: Data Complete

Site No: 1231

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

Subject No: 12312868

Subject Initials: ---

Generated By:

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

(b) (4)

Date	Location	User	Value	Reason
Jan-23-2021 11:38:22 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Type of P PRIMAR ractitione Y CARE r: PHYSICI AN Occurren NO ce of Visi ts or Con tacts:	Initial Entry

1.c Physician or Healthcare Professional:

Date	Location	User	Value	Reason
Jan-23-2021 11:38:22 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: PRIMARY CARE P HYSICIAN	Initial Entry

1.c Occurrence of Visits or Contacts:

Date	Location	User	Value	Reason
Jan-23-2021 11:38:22 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

1.d

Date	Location	User	Value	Reason
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090177e196ae2e73\Final\Final On: 01-Apr-2021 03:14 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 3 -
Unscheduled Visit on Jan/22/2021

Form: HEALTH CARE UTILIZATION - eCRF Audit
Trail History

Form Version: 14-Jan-2021 02:24

Form Status: Data Complete

Site No: 1231

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

Subject No: 12312868

Subject Initials: ---

Generated By:

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

(b) (4)

Jan-23-2021 11:38:22 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Type of Pra URGE ctitioner: NT C ARE Occurrence NO of Visits or Contacts:	Initial Entry
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1.d Physician or Healthcare Professional:

Date	Location	User	Value	Reason
Jan-23-2021 11:38:22 (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
Jan-23-2021 11:38:22 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

1.e

Date	Location	User	Value	Reason
Jan-23-2021 11:38:22 (UTC-03:00) City	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Type of P TELEPH ractitione ONE CO	Initial Entry

090177e196ae2e73\Final\Final On: 01-Apr-2021 03:14 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 3 -
Unscheduled Visit on Jan/22/2021

Form Version: 14-Jan-2021 02:24

Site No: 1231

Subject No: 12312868

Generated By:

(b) (4)

Form: HEALTH CARE UTILIZATION - eCRF Audit
Trail History

Form Status: Data Complete

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

Subject Initials: ---

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

of Buenos Aires			r: NSULTA TION	
			Occurren NO ce of Visi ts or Con tacts:	

1.e Physician or Healthcare Professional:

Date	Location	User	Value	Reason
Jan-23-2021 11:38:22 (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
Jan-23-2021 11:38:22 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

1.f

Date	Location	User	Value	Reason
Jan-23-2021 11:38:22 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Type of Practi OT tioner: HE R	Initial Entry

090177e196ae2e73\Final\Final On: 01-Apr-2021 03:14 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 3 -
Unscheduled Visit on Jan/22/2021

Form: HEALTH CARE UTILIZATION - eCRF Audit
Trail History

Form Version: 14-Jan-2021 02:24

Form Status: Data Complete

Site No: 1231

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

Subject No: 12312868

Subject Initials: ---

Generated By:

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

(b) (4)

			Occurrence of NO Visits or Cont acts:	
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1.f Physician or Healthcare Professional:

Date	Location	User	Value	Reason
Jan-23-2021 11:38:22 (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
Jan-23-2021 11:38:22 (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
Jan-23-2021 11:38:22 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

090177e196ae2e73\Final\Final On: 01-Apr-2021 03:14 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 3 -
Unscheduled Visit on Jan/22/2021

Form Version: 06-Jul-2020 21:52

Site No: 1231

Subject No: 12312868

Generated By:

(b) (4)

Form: ILLNESS DETAILS - eCRF Audit Trail History

Form Status: Data Complete

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

Subject Initials: ---

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

[Back to Form](#)

1. Category of Clinical Event:

Date	Location	User	Value	Reason
Jan-23-2021 11:38:03 (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
Jan-23-2021 11:38:03 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES <i>Respiratory Illness</i> <i>Diagnosis:</i> Pharyngitis Date of Diagnosis: Jan/22/2021	Initial Entry

3. Toxicity Grade:

Date	Location	User	Value	Reason
Jan-23-2021 11:38:03 (UTC-03:00) City	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 1	Initial Entry

090177e196ae2e73\Final\Final On: 01-Apr-2021 03:14 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 3 -
Unscheduled Visit on Jan/22/2021

Form Version: 06-Jul-2020 21:52

Site No: 1231

Subject No: 12312868

Generated By:

(b) (4)

Form: ILLNESS DETAILS - eCRF Audit Trail History

Form Status: Data Complete

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

Subject Initials: ---

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

of Buenos Aires

090177e196ae2e73\Final\Final On: 01-Apr-2021 03:14 (GMT)

Header Text: C4591001

Visit: POT_COVID_CONVA 1 -
Unscheduled Visit on Nov/11/2020

Form Version: 22-Apr-2020 21:04

Site No: 1231

Subject No: 12312868

Generated By:

(b) (4)

Form: DATE OF VISIT - ILLNESS CONVALESCENT -
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 20:20

[Back to Form](#)

1. Date of Visit

Date	Location	User	Value	Reason
Dec-04-2020 08:58:11 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Dec-03-2020 10:09:30 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Changed data per query
Dec-03-2020 02:12:05 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reissued: Opened	Please adding form level comment "Not applicable" in all forms. Thank you.
Dec-02-2020 12:43:54 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	The visit was not made due to being out of the window. Thank you.
Dec-02-2020 07:48:37	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	DM: As visit is initiated in

090177e196ae2e73\Final\Final On: 01-Apr-2021 03:14 (GMT)

Header Text: C4591001

Visit: POT_COVID_CONVA 1 -
Unscheduled Visit on Nov/11/2020

Form Version: 22-Apr-2020 21:04

Site No: 1231

Subject No: 12312868

Generated By:

(b) (4)

Form: DATE OF VISIT - ILLNESS CONVALESCENT -
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 20:20

(UTC-03:00) City of Buenos Aires				error, please consider adding form level comment "Not applicable" in all forms. Thank you.
Dec-01-2020 13:42:41 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Nov/11/2020	Transcription Error
Dec-01-2020 13:38:57 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidat e	Erroneous Visit is marked, but date of visit is entered. Please check whether other assessments are performed at this visit.
Dec-01-2020 13:38:50 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Oct/11/2020	Transcription Error
Nov-30-2020 19:32:17	ACV0PFEINFP6000	(b) (6)	Data Entry: Nov/30/2020	Initial Entry

090177e196ae2e73\Final\Final On: 01-Apr-2021 03:14 (GMT)

Header Text: C4591001

Visit: POT_COVID_CONVA 1 -
Unscheduled Visit on Nov/11/2020

Form Version: 22-Apr-2020 21:04

Site No: 1231

Subject No: 12312868

Generated By:

(b) (4)

Form: DATE OF VISIT - ILLNESS CONVALESCENT -
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 20:20

(UTC-03:00)
City of Buenos
Aires

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

2. Erroneous Visit

Date	Location	User	Value	Reason
Dec-01-2020 13:38:57 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: ERRONEOUS VISI T	Initial Entry

3. COVID-19 Illness Visit:

Date	Location	User	Value	Reason
Dec-01-2020 13:39:06 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry
Dec-01-2020 13:38:35 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Transcription Error
Nov-30-2020 19:32:17 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: COVID_B1	Initial Entry

090177e196ae2e73\Final\Final On: 01-Apr-2021 03:14 (GMT)

Header Text: C4591001

Visit: POT_COVID_CONVA 1 -
Unscheduled Visit on Nov/11/2020

Form Version: 22-Apr-2020 21:03

Site No: 1231

Subject No: 12312868

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 20:20

[Back to Form](#)

1. Data Origin

Date	Location	User	Value	Reason
Dec-01-2020 13:39:28 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Not Applicable	Initial Entry
Dec-01-2020 13:38:22 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry:	Transcription Error
Nov-30-2020 19:32:27 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Dec-01-2020 13:39:28 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Not Applicable	Initial Entry
Dec-01-2020 13:38:22 (UTC-03:00) City	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry:	Transcription Error

090177e196ae2e73\Final\Final On: 01-Apr-2021 03:14 (GMT)

Header Text: C4591001

Visit: POT_COVID_CONVA 1 -
Unscheduled Visit on Nov/11/2020

Form Version: 22-Apr-2020 21:03

Site No: 1231

Subject No: 12312868

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 20:20

of Buenos Aires				
Nov-30-2020 19:32:27 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SERUM	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Dec-01-2020 13:39:28 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry
Dec-01-2020 13:38:22 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Dec-01-2020 13:38:22 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Transcription Error
Dec-01-2020 13:38:04 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Date of Collection : Oct/11/2020	Transcription Error
Dec-01-2020	ACV0PFEINFP6000	(b) (6)	Query 1: Opened	'Sample

090177e196ae2e73\Final\Final On: 01-Apr-2021 03:14 (GMT)

Header Text: C4591001
Visit: POT_COVID_CONVA 1 -
 Unscheduled Visit on Nov/11/2020
Form Version: 22-Apr-2020 21:03
Site No: 1231
Subject No: 12312868
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 20:20

05:41:48 (UTC-03:00) City of Buenos Aires		(b) (4)		Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Nov-30-2020 19:32:27 (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.
Nov-30-2020 19:32:27 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Date of Collection : Nov/30/2020	Initial Entry

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

Date	Location	User	Value	Reason
Dec-01-2020 13:39:28 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

Header Text: C4591001

Visit: POT_COVID_CONVA 2 -
Unscheduled Visit on Nov/30/2020

Form Version: 22-Apr-2020 21:04

Site No: 1231

Subject No: 12312868

Generated By:

(b) (4)

Form: DATE OF VISIT - ILLNESS CONVALESCENT -
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 20:20

[Back to Form](#)

1. Date of Visit

Date	Location	User	Value	Reason
Dec-01-2020 13:40:00 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Nov/30/2020	Initial Entry

3. COVID-19 Illness Visit:

Date	Location	User	Value	Reason
Dec-01-2020 13:40:00 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: COVID_B1	Initial Entry

090177e196ae2e73\Final\Final On: 01-Apr-2021 03:14 (GMT)

Header Text: C4591001

Visit: POT_COVID_CONVA 2 -
Unscheduled Visit on Nov/30/2020

Form Version: 22-Apr-2020 21:03

Site No: 1231

Subject No: 12312868

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 20:20

[Back to Form](#)

1. Data Origin

Date	Location	User	Value	Reason
Dec-01-2020 13:40:11 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Dec-01-2020 13:40:11 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SERUM	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Dec-01-2020 14:12:41 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Dec-01-2020 13:40:11 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes

090177e196ae2e73\Final\Final On: 01-Apr-2021 03:14 (GMT)

Header Text: C4591001

Visit: POT_COVID_CONVA 2 -
Unscheduled Visit on Nov/30/2020

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1231

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

Subject No: 12312868

Subject Initials: ---

Generated By:

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

(b) (4)

				are entered. Please review and correct as appropriate.
Dec-01-2020 13:40:11 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Date of Collection: Nov/30/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Dec-01-2020 14:12:41 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample I BRVP4 D: 2	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Dec-01-2020 14:12:41 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BRVP42	Initial Entry

5.b

Date	Location	User	Value	Reason
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090177e196ae2e73\Final\Final On: 01-Apr-2021 03:14 (GMT)

Header Text: C4591001

Visit: POT_COVID_CONVA 2 -
Unscheduled Visit on Nov/30/2020

Form Version: 22-Apr-2020 21:03

Site No: 1231

Subject No: 12312868

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 20:20

Dec-01-2020 14:15:21 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample I BRVP3 D: Y	Initial Entry
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5.b Sample ID

Date	Location	User	Value	Reason
Dec-01-2020 14:15:21 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BRVP3Y	Initial Entry

5.c

Date	Location	User	Value	Reason
Dec-01-2020 14:16:40 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample I BPWSV D: 4	Initial Entry

5.c Sample ID

Date	Location	User	Value	Reason
Dec-01-2020 14:16:40 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BPWSV4	Initial Entry

090177e196ae2e73\Final\Final On: 01-Apr-2021 03:14 (GMT)

Header Text: C4591001

Visit: POT_COVID_CONVA 3 -
Unscheduled Visit on Mar/13/2021

Form Version: 22-Apr-2020 21:04

Site No: 1231

Subject No: 12312868

Generated By:

(b) (4)

Form: DATE OF VISIT - ILLNESS CONVALESCENT -
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 20:20

[Back to Form](#)

1. Date of Visit

Date	Location	User	Value	Reason
Mar-13-2021 17:33:38 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Mar/13/2021	Initial Entry

3. COVID-19 Illness Visit:

Date	Location	User	Value	Reason
Mar-13-2021 17:33:38 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: COVID_C1	Initial Entry

090177e196ae2e73\Final\Final On: 01-Apr-2021 03:14 (GMT)

Header Text: C4591001

Visit: POT_COVID_CONVA 3 -
Unscheduled Visit on Mar/13/2021

Form Version: 22-Apr-2020 21:03

Site No: 1231

Subject No: 12312868

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 20:20

[Back to Form](#)

1. Data Origin

Date	Location	User	Value	Reason
Mar-13-2021 17:34:24 (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-13-2021 17:34:24 (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-15-2021 10:59:21 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Mar-14-2021 08:09:39 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	'Sample Collected?' is Yes, however no barcodes

090177e196ae2e73\Final\Final On: 01-Apr-2021 03:14 (GMT)

Header Text: C4591001

Visit: POT_COVID_CONVA 3 -
Unscheduled Visit on Mar/13/2021

Form Version: 22-Apr-2020 21:03

Site No: 1231

Subject No: 12312868

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 20:20

				are entered. Please review and correct as appropriate.
Mar-13-2021 17:34:24 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Mar-13-2021 17:34:24 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Date of Collection: Mar/13/2021	Initial Entry

5.a

Date	Location	User	Value	Reason
Mar-15-2021 10:59:21 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	Agustin Morato Cabral (b) (4)	Data Entry: Sample I BRYH7 D: X	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
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090177e196ae2e73\Final\Final On: 01-Apr-2021 03:14 (GMT)

Header Text: C4591001

Visit: POT_COVID_CONVA 3 -
Unscheduled Visit on Mar/13/2021

Form Version: 22-Apr-2020 21:03

Site No: 1231

Subject No: 12312868

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 20:20

Mar-15-2021 10:59:21 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	Agustin Morato Cabral (b) (4)	Data Entry: BRYH7X	Initial Entry
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5.b

Date	Location	User	Value	Reason
Mar-15-2021 11:16:57 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	Alan Colombo (b) (4)	Data Entry: Sample ID BPT67 : 0	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Mar-15-2021 11:16:57 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	Alan Colombo (b) (4)	Data Entry: BPT670	Initial Entry

5.c

Date	Location	User	Value	Reason
Mar-15-2021 12:01:03 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample I BRYH7 D: 4	Initial Entry

090177e196ae2e73\Final\Final On: 01-Apr-2021 03:14 (GMT)

Header Text: C4591001

Visit: POT_COVID_CONVA 3 -
Unscheduled Visit on Mar/13/2021

Form Version: 22-Apr-2020 21:03

Site No: 1231

Subject No: 12312868

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 20:20

5.c Sample ID

Date	Location	User	Value	Reason
Mar-15-2021 12:01:03 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BRYH74	Initial Entry

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: 12312868 **Subject Initials:** ---

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

[Back to Form](#)

1. Date of Completion/Discontinuation/Death :

Date	Location	User	Value	Reason
Nov-11-2020 20:41:05 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Nov/11/2020	Initial Entry

2. Phase of Disposition:

Date	Location	User	Value	Reason
Nov-11-2020 20:41:05 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: VACCINATION	Initial Entry

3. Status:

Date	Location	User	Value	Reason
Nov-11-2020 20:41:05 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: COMPLETED	Initial Entry

090177e196ae2e73\Final\Final On: 01-Apr-2021 03:14 (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, Locked, Frozen, Verified

Site No: 1231

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

Subject No: 12312868

Subject Initials: ---

Generated By:

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

(b) (4)

[Back to Form](#)

1. Date of Visit

Date	Location	User	Value	Reason
Mar-10-2021 17:05:03 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Mar/10/2021	Initial Entry

090177e196ae2e73\Final\Final On: 01-Apr-2021 03:14 (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, Locked, Frozen

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

Subject No: 12312868 **Subject Initials:** ---

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

[Back to Form](#)

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

Date	Location	User	Value	Reason
Mar-10-2021 17:06:46 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Participant is willing t o return for Vaccinati on 3 Participant is: eligible per other p rotocol allowance(s) and confirmed t o have received on ly placebo at Vacci nation 1/2	Initial Entry

090177e196ae2e73\Final\Final On: 01-Apr-2021 03:14 (GMT)

Header Text: C4591001

Visit: V101_VAX3

Form Version: 22-Apr-2020 21:02

Site No: 1231

Subject No: 12312868

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 20:20

[Back to Form](#)

1. Date of Visit

Date	Location	User	Value	Reason
Mar-14-2021 10:56:10 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Mar/13/2021	Initial Entry

090177e196ae2e73\Final\Final On: 01-Apr-2021 03:14 (GMT)

Header Text: C4591001

Visit: V101_VAX3

Form: INFORMED CONSENT - FURTHER
VACCINATION - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:31

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1231

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

Subject No: 12312868

Subject Initials: ---

Generated By:

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

(b) (4)

[Back to Form](#)

1. Consent Was:

Date	Location	User	Value	Reason
Mar-14-2021 10:56:22 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: OBTAINED Date Written Con- sent Obtained Mar/13/2021	Initial Entry

090177e196ae2e73\Final\Final On: 01-Apr-2021 03:14 (GMT)

Header Text: C4591001

Visit: V101_VAX3

Form: DISPOSITION - SCREENING FOR FURTHER VACCINATION - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:31

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1231

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

Subject No: 12312868

Subject Initials: ---

Generated By:

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

(b) (4)

[Back to Form](#)

1. Date of Completion/Discontinuation/Death :

Date	Location	User	Value	Reason
Mar-14-2021 10:57:00 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Mar/13/2021	Initial Entry

2. Phase of Disposition:

Date	Location	User	Value	Reason
Mar-14-2021 10:57:00 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: REPEAT SCREENING 1	Initial Entry

3. Status:

Date	Location	User	Value	Reason
Mar-14-2021 10:57:00 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: COMPLETED	Initial Entry

090177e196ae2e73\Final\Final On: 01-Apr-2021 03:14 (GMT)

Header Text: C4591001

Visit: V101_VAX3

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

Form Version: 20-Feb-2021 02:14

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1231

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

Subject No: 12312868

Subject Initials: ---

Generated By:

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

(b) (4)

[Back to Form](#)

1. Lab Panel:

Date	Location	User	Value	Reason
Mar-14-2021 10:57:14 (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
Mar-14-2021 10:57:14 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: PREGNANCY	Initial Entry

3. Collection Date:

Date	Location	User	Value	Reason
Mar-14-2021 10:57:14 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Mar/13/2021	Initial Entry

4. Laboratory Name and Address (Derived)

Date	Location	User	Value	Reason
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090177e196ae2e73\Final\Final On: 01-Apr-2021 03:14 (GMT)

Header Text: C4591001

Visit: V101_VAX3

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

Form Version: 20-Feb-2021 02:14

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1231

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

Subject No: 12312868

Subject Initials: ---

Generated By:

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

(b) (4)

Mar-14-2021 10:57:14 (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
Mar-14-2021 10:57:14 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: URINE	Initial Entry

6.a

Date	Location	User	Value	Reason
Mar-14-2021 10:57:14 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sponsor- 113 Defined Identifier: Test:: Choriogon adotropin Beta_PX11 3 Result:: NEGATIV E Not Done ::	Initial Entry

6.a Sponsor ID:

090177e196ae2e73\Final\Final On: 01-Apr-2021 03:14 (GMT)

Header Text: C4591001

Visit: V101_VAX3

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

Form Version: 20-Feb-2021 02:14

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1231

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

Subject No: 12312868

Subject Initials: ---

Generated By:

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

(b) (4)

Date	Location	User	Value	Reason
Mar-14-2021 10:57:14 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 113	Initial Entry

6.a Test:

Date	Location	User	Value	Reason
Mar-14-2021 10:57:14 (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
Mar-14-2021 10:57:14 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NEGATIVE	Initial Entry

090177e196ae2e73\Final\Final On: 01-Apr-2021 03:14 (GMT)

Header Text: C4591001**Visit:** V101_VAX3**Form Version:** 22-Apr-2020 21:03**Site No:** 1231**Subject No:** 12312868**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 20:20[Back to Form](#)**1. Data Origin**

Date	Location	User	Value	Reason
Mar-14-2021 10:57:35 (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-14-2021 10:57:35 (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-14-2021 10:57:35 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	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: V101_VAX3

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: 12312868

Subject Initials: ---

Generated By:

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

(b) (4)

Mar-14-2021 10:57:35 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample destined to co nvalescense visit.	Initial Entry
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090177e196ae2e73\Final\Final On: 01-Apr-2021 03:14 (GMT)

Header Text: C4591001

Visit: V101_VAX3

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1231

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

Subject No: 12312868

Subject Initials: ---

Generated By:

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

(b) (4)

[Back to Form](#)

1. Data Origin

Date	Location	User	Value	Reason
Mar-14-2021 10:57:48 (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-14-2021 10:57:48 (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
Mar-15-2021 15:54:24 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Mar-15-2021 06:32:46 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	'Sample Collected?' is Yes, however no barcodes

090177e196ae2e73\Final\Final On: 01-Apr-2021 03:14 (GMT)

Header Text: C4591001

Visit: V101_VAX3

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1231

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

Subject No: 12312868

Subject Initials: ---

Generated By:

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

(b) (4)

				are entered. Please review and correct as appropriate.
Mar-14-2021 10:57:48 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Mar-14-2021 10:57:48 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Date of Collection: Mar/13/2021	Initial Entry

5.a

Date	Location	User	Value	Reason
Mar-15-2021 15:54:24 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample I BR1LM D: S	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
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090177e196ae2e73\Final\Final On: 01-Apr-2021 03:14 (GMT)

Header Text: C4591001

Visit: V101_VAX3

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1231

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

Subject No: 12312868

Subject Initials: ---

Generated By:

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

(b) (4)

Mar-15-2021 15:54:24 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BR1LMS	Initial Entry
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Header Text: C4591001

Visit: V101_VAX3

Form Version: 10-Dec-2020 02:26

Site No: 1231

Subject No: 12312868

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 20:20

[Back to Form](#)

1. Was there a temporary delay of vaccination?

Date	Location	User	Value	Reason
Mar-14-2021 10:58:02 (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
Mar-14-2021 10:58:02 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: BNT162b2	Initial Entry

3. Formulation:

Date	Location	User	Value	Reason
Mar-14-2021 10:58:02 (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
Mar-14-2021	ACV0PFEINFP6000	(b) (6)	Data Entry:	Initial Entry

090177e196ae2e73\Final\Final On: 01-Apr-2021 03:14 (GMT)

Header Text: C4591001

Visit: V101_VAX3

Form: VACCINATION - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:26

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1231

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

Subject No: 12312868

Subject Initials: ---

Generated By:

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

(b) (4)

10:58:02 (UTC-03:00) City of Buenos Aires		(b) (4), (b) (6)	Mar/13/2021 18:35	
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5. Anatomical Location:

Date	Location	User	Value	Reason
Mar-14-2021 10:58:02 (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
Mar-14-2021 10:58:02 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: LEFT	Initial Entry

7. Route:

Date	Location	User	Value	Reason
Mar-14-2021 10:58:02 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: INTRAMUSCULAR	Initial Entry

8. Actual Dose:

Date	Location	User	Value	Reason
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090177e196ae2e73\Final\Final On: 01-Apr-2021 03:14 (GMT)

Header Text: C4591001

Visit: V101_VAX3

Form: VACCINATION - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:26

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1231

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

Subject No: 12312868

Subject Initials: ---

Generated By:

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

(b) (4)

Mar-14-2021 10:58:02 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 30.0	Initial Entry
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9. Unit:

Date	Location	User	Value	Reason
Mar-14-2021 10:58:02 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: ug	Initial Entry

10. Timeframe Subject Was Observed

Date	Location	User	Value	Reason
Mar-14-2021 10:58:02 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 30 MINUTES	Initial Entry

11. Was the subject observed for at least the protocol specified observation period after investigational product administration?

Date	Location	User	Value	Reason
Mar-14-2021 10:58:02 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

090177e196ae2e73\Final\Final On: 01-Apr-2021 03:14 (GMT)

Header Text: C4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1231

Subject No: 12312868

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 20:20

[Back to Form](#)

Date	Location	User	Value	Reason
Oct-13-2020 11:43:56 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Created	

Header Text: C4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - Audit Trail

Form Version: 22-Apr-2020 21:02

Form Status:

Site No: 1231

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

Subject No: 12312868

Subject Initials: ---

Generated By:

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

(b) (4)

[Back to Form](#)

Date	Location	User	Value	Reason
Oct-13-2020 11:50:35 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Created	

090177e196ae2e73\Final\Final On: 01-Apr-2021 03:14 (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, Verified

Site No: 1231

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

Subject No: 12312868

Subject Initials: ---

Generated By:

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

(b) (4)

[Back to Form](#)

1. Category:

Date	Location	User	Value	Reason
Oct-13-2020 11:43:56 (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-13-2020 11:43:56 (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-14-2020 17:58:25 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	Samuel Dychter (b) (4)	Query 1: Closed	Response satisfies query
Oct-14-2020 14:04:21 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (6)	Query 1: Answered	The cause of the syncope is vasovagal.

090177e196ae2e73\Final\Final On: 01-Apr-2021 03:14 (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, Verified

Site No: 1231

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

Subject No: 12312868

Subject Initials: ---

Generated By:

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

(b) (4)

		(b) (4)		
Oct-13-2020 17:04:41 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	Samuel Dychter (b) (4)	Query 1: Opened	GPD Clin: Could you please elaborate on the potential cause of the syncope? Has medical follow-up been done?
Oct-13-2020 11:43:56 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: syncope	Initial Entry

4. Start Date Time:

Date	Location	User	Value	Reason
Oct-13-2020 11:43:56 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Oct/8/2020 12:18	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Oct-13-2020 11:43:56 (UTC-03:00) City	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO End Date Time:	Initial Entry

090177e196ae2e73\Final\Final On: 01-Apr-2021 03:14 (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, Verified

Site No: 1231

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

Subject No: 12312868

Subject Initials: ---

Generated By:

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

(b) (4)

of Buenos Aires			Oct/8/2020 14:06	
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6. Toxicity Grade:

Date	Location	User	Value	Reason
Oct-13-2020 11:43:56 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 3	Initial Entry

7. Is the adverse event serious?

If Yes, NOTIFY PFIZER IMMEDIATELY.

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

Date	Location	User	Value	Reason
Oct-30-2020 22:13:00 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Closed	Clinical – Thank you. If NO hospital Covid test was performed is known, please submit this information on a follow-up SAE form, as

090177e196ae2e73\Final\Final On: 01-Apr-2021 03:14 (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, Verified

Site No: 1231

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

Subject No: 12312868

Subject Initials: ---

Generated By:

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

(b) (4)

				pertinent information for this trial.
Oct-30-2020 13:10:29 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Answered	The adverse event is not associated with COVID disease.
Oct-21-2020 15:26:14 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Opened	CLINICAL COVID testing has not been reported in the SAE submitted to safety. Please submit a follow-up SAE form [#2020392233] to provide whether COVID testing was performed (yes/no) and if yes, the results.
Oct-13-2020 21:45:39 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query

090177e196ae2e73\Final\Final On: 01-Apr-2021 03:14 (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, Verified

Site No: 1231

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

Subject No: 12312868

Subject Initials: ---

Generated By:

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

(b) (4)

<p>Oct-13-2020 11:43:56 (UTC-03:00) City of Buenos Aires</p>	<p>ACV0PFEINFP6000</p>	<p>auto query (autoquery)</p>	<p>Query 1: Candidate</p>	<p>For AE syncope: Response to "Is the adverse event serious?" is 'Yes' but "Serious Adverse Event Number" is blank.</p>
<p>Oct-13-2020 11:43:56 (UTC-03:00) City of Buenos Aires</p>	<p>ACV0PFEINFP6000</p>	<p>(b) (4), (b) (6)</p>	<p>Data Entry: YES Is this serious event associated with congenital anomaly or birth defect? NO Did this serious event result in death? NO Did this serious event require or prolong hospitalization? NO</p>	<p>Initial Entry</p>

090177e196ae2e73\Final\Final On: 01-Apr-2021 03:14 (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, Verified

Site No: 1231

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

Subject No: 12312868

Subject Initials: ---

Generated By:

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

(b) (4)

			<p>Did this serious event result in persistent or significant disability/incapacity?</p> <p>NO</p> <p>Is this serious event life threatening?</p> <p>NO</p> <p>Other medically important serious event</p> <p>YES</p>	
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8. Is this adverse event the result of a study Medication Error?

If Yes, record the type of medication error on the Medication Error Log.

Date	Location	User	Value	Reason
Oct-13-2020 11:43:56 (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:

090177e196ae2e73\Final\Final On: 01-Apr-2021 03:14 (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, Verified

Site No: 1231

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

Subject No: 12312868

Subject Initials: ---

Generated By:

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

(b) (4)

Date	Location	User	Value	Reason
Oct-13-2020 11:43:56 (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> syncope of probable vasogenic cause	Initial Entry

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Oct-13-2020 11:43:56 (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-13-2020 11:43:56 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

090177e196ae2e73\Final\Final On: 01-Apr-2021 03:14 (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, Verified

Site No: 1231

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

Subject No: 12312868

Subject Initials: ---

Generated By:

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

(b) (4)

12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Oct-13-2020 11:43:56 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

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

Date	Location	User	Value	Reason
Oct-13-2020 11:43:56 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: RECOVERED/RESOLVED	Initial Entry

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

Date	Location	User	Value	Reason
Oct-13-2020 11:43:56 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

15. Serious Adverse Event Number: For Pfizer Use Only

Date	Location	User	Value	Reason
Oct-13-2020 21:45:39 (UTC-03:00) City	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 2020392233	Initial Entry

090177e196ae2e73\Final\Final On: 01-Apr-2021 03:14 (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, Verified

Site No: 1231

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

Subject No: 12312868

Subject Initials: ---

Generated By:

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

(b) (4)

of Buenos Aires

090177e196ae2e73\Final\Final On: 01-Apr-2021 03:14 (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, Not Complete

Site No: 1231

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

Subject No: 12312868

Subject Initials: ---

Generated By:

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

(b) (4)

[Back to Form](#)

1. Category:

Date	Location	User	Value	Reason
Oct-13-2020 11:50:35 (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-13-2020 11:50:35 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 2	Initial Entry

3. Adverse Event:

(If possible specify diagnosis, not individual symptoms)

Date	Location	User	Value	Reason
Oct-26-2020 13:56:06 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Oct-23-2020	ACV0PFEINFP6000	auto query	Query 1: Answer	Transcription

090177e196ae2e73\Final\Final On: 01-Apr-2021 03:14 (GMT)

13:21:47 (UTC-03:00) City of Buenos Aires		(autoquery)	ed	Error
Oct-23-2020 13:21:47 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Data Entry: minor cranioence phalic trauma	Transcription Error
Oct-21-2020 15:37:20 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Query 1: Opened	CLINICAL SAE report states syncope from standing height caused "minor cranioencephalic trauma". Please submit a SAE safety followup describing any signs and symptoms for traumatic brain injury; also any imaging evaluation
Oct-13-2020 11:50:35 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Data Entry: traumatic brain in jury	Initial Entry

4. Start Date Time:

Date	Location	User	Value	Reason
Oct-13-2020 11:50:35 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Data Entry: Oct/8/2020 12:18	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Oct-13-2020 11:50:35 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO End Date Time: Oct/8/2020 12:18	Initial Entry

6. Toxicity Grade:

Date	Location	User	Value	Reason
Oct-26-2020 14:47:32 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	Juleen Gayed (b) (4)	Query 1: Closed	Response satisfies query
Oct-23-2020 13:25:46 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	The diagnosis of AE is minor cranioencephalic trauma due to a fall from one's own height with ad integrum restitution in 10 seconds
Oct-20-2020 13:24:40 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	Juleen Gayed (b) (4)	Query 1: Reissued :Opened	Clin: Thank you for your confirmation, how was this AE diagnosed, was it via imaging and how was it managed?
Oct-19-2020 11:23:37 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	Maria Beretta (b) (4)	Query 1: Answered	Original value is correct
Oct-16-2020 09:52:35	ACV0PFEINFP6000	Juleen Gayed (b) (4)	Query 1: Opened	Clin: Please confirm this

(UTC-03:00) City of Buenos Aires				grading as event seems more severe than grade 1. Please provide some background information about the event.
Oct-13-2020 11:50:35 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	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).

Date	Location	User	Value	Reason
Oct-13-2020 11:50:35 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	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-13-2020 11:50:35 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Data Entry: NO	Initial Entry

9. Is this event related to study treatment:

Date	Location	User	Value	Reason
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Oct-23-2020 03:48:20 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Query 1: Closed	Response satisfies query
Oct-22-2020 11:37:35 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Query 1: Answered	Original value is correct
Oct-22-2020 10:39:59 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Query 1: Reissued: Opened	DM: Thank you for your response, Please review and confirm data entered is correct as is.
Oct-21-2020 16:36:28 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Query 1: Answered	Fall is a cosecuence of syncope
Oct-14-2020 05:06:49 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Query 1: Opened	DM: As per CRF Completion Guidelines Section 8.46.2.2. Fall as well as the Injury due to the fall need to be recorded as two separate Adverse Event. Please consider updating another AE with the term

				Fall, Thank you.
Oct-13-2020 11:50:35 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Data Entry: NOT RELATED If Not Related to study treatment(s), this event is due to: OTHER <i>If Other, specify:</i> Head trauma due to fall from own height after syncope	Initial Entry

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Oct-13-2020 11:50:35 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Data Entry: NOT APPLICABLE	Initial Entry

11. Was a Concomitant Medication given?

Date	Location	User	Value	Reason
Oct-13-2020 11:50:35 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Data Entry: NO	Initial Entry

12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Oct-13-2020 11:50:35 (UTC-03:00) City	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Data Entry: NO	Initial Entry

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

Date	Location	User	Value	Reason
Oct-13-2020 11:50:35 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: RECOVERED/RESO LVED	Initial Entry

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

Date	Location	User	Value	Reason
Oct-13-2020 11:50:35 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

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: 12312868

Subject Initials: ---

Generated By:

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

(b) (4)

[Back to Form](#)

1. Date Treatment Unblinded :

Date	Location	User	Value	Reason
Mar-10-2021 17:03:17 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Mar/10/2021	Initial Entry

2. Primary Reason for Unblinding:

Date	Location	User	Value	Reason
Mar-10-2021 17:03:17 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: ASSESS ELIGIBILITY FOR ADDITIONAL VACCINATION	Initial Entry

090177e196ae2e73\Final\Final On: 01-Apr-2021 03:14 (GMT)

Header Text: C4591001

Visit: Subject Status - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1231

Subject No: 12312868

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 20:20

[Back to Form](#)

1. Subject Status

Date	Location	User	Value	Reason
Nov-11-2020 20:41:05 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: FOLLOW-UP	Initial Entry
Aug-21-2020 16:52:15 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: ENROLLED/RANDO MIZED	Initial Entry
Aug-21-2020 16:50:47 (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
Nov-11-2020 20:41:05 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Nov/11/2020	Initial Entry
Aug-21-2020 16:52:15 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Aug/21/2020	Initial Entry

090177e196ae2e73\Final\Final On: 01-Apr-2021 03:14 (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: 12312868

Subject Initials: ---

Generated By:

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

(b) (4)

Aug-21-2020 16:50:47 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Aug/21/2020	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: 12312868

Generated By:

(b) (4)

Form: CASEBOOK SIGNATURE FORM - eCRF Audit
Trail History

Form Status: Data Complete, Signed, Verified

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

Subject Initials: ---

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

[Back to Form](#)

1. Casebook Signature

Date	Location	User	Value	Reason
Nov-06-2020 13:59:18 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Click Here to Enable	Initial Entry

090177e196ae2e73\Final\Final On: 01-Apr-2021 03:14 (GMT)