

Header Text: C4591001

Visit: COHORT_SELECTION

Form Version: 30-Jul-2020 21:29

Site No: 1231

Subject No: 12312982

Generated By: (b) (4)

Form: COHORT_SELECTION

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

[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

Header Text: C4591001

Visit: COHORT_SELECTION

Form Version: 22-Apr-2020 21:02

Site No: 1231

Subject No: 12312982

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 Version: 06-Jul-2020 21:55

Site No: 1231

Subject No: 12312982

Generated By: (b) (4)

Form: DEMOGRAPHY

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Demography

1.	Subject ID	[12312982]
2.	Birth Date:	(b) (6) /1984
3.	Sex:	MALE
4.	Ethnicity:	NOT HISPANIC OR LATINO(A) OR OF SPANISH ORIGIN
5.	Race: (Check X all that apply):	WHITE
6.	Racial Designation:	

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:02

Site No: 1231

Subject No: 12312982

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:** 12312982**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
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

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 21-Aug-2020 02:50

Site No: 1231

Subject No: 12312982

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
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

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Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 21-Aug-2020 02:50

Site No: 1231

Subject No: 12312982

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
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

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Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1231

Subject No: 12312982

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:	[]

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1231

Subject No: 12312982

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

[Form Comments](#)

Medical History Details

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

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Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 21-Aug-2020 02:51

Site No: 1231

Subject No: 12312982

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:	[83.5]
3.	Unit:	kg
4.	Height:	[182.0]
5.	Unit:	cm
6.	Body Mass Index:	[25.2]

Vital Signs Details

7.a	Record Identifier:	1
	Temperature:	[36.7]
	Unit:	C
	Temperature Location:	ORAL CAVITY

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Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1231

Subject No: 12312982

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:	[61389]
3.	Randomization Group:	[]

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1231

Subject No: 12312982

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

[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	[BHY61W]
5.b	Sample ID	[BHY61X]
5.c	Sample ID	[BHY61Y]
5.d	Sample ID	[BJ4998]
5.e	Sample ID	[BJ4999]
5.f	Sample ID	[BJ4997]

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Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1231

Subject No: 12312982

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	[BHY64K]
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090177e196ae2e71\Final\Final On: 01-Apr-2021 03:13 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:04

Site No: 1231

Subject No: 12312982

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 18:50
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

090177e196ae2e71\Final\Final On: 01-Apr-2021 03:13 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 06-Jul-2020 21:53

Site No: 1231

Subject No: 12312982

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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090177e196ae2e71\Final\Final On: 01-Apr-2021 03:13 (GMT)

Header Text: C4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:02

Site No: 1231

Subject No: 12312982

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	Sep/9/2020
2.	Erroneous Visit	

Header Text: C4591001

Visit: V2_VAX2_L

Form Version: 21-Aug-2020 02:51

Site No: 1231

Subject No: 12312982

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:	Sep/9/2020
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Vital Signs Details

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

090177e196ae2e71\Final\Final On: 01-Apr-2021 03:13 (GMT)

Header Text: C4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:03

Site No: 1231

Subject No: 12312982

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: Sep/9/2020
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	[BP1YWS]
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090177e196ae2e71\Final\Final On: 01-Apr-2021 03:13 (GMT)

Header Text: C4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:04

Site No: 1231

Subject No: 12312982

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:	Sep/9/2020 14:00
5.	Anatomical Location:	DELTOID MUSCLE
6.	Body Side:	LEFT
7.	Route:	INTRAMUSCULAR
8.	Actual Dose:	[]
9.	Unit:	
10.	Timeframe Subject Was Observed	THE PROTOCOL SPECIFIED OBSERVATION PERIOD
11.	Was the subject observed for at least the protocol specified observation period after investigational product administration?	YES

090177e196ae2e71\Final\Final On: 01-Apr-2021 03:13 (GMT)

Header Text: C4591001

Visit: V3_MONTH1_POSTVAX2_L

Form Version: 22-Apr-2020 21:02

Site No: 1231

Subject No: 12312982

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: V3_MONTH1_POSTVAX2_L

Form Version: 22-Apr-2020 21:03

Site No: 1231

Subject No: 12312982

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Status: Not Started

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

Subject Initials: ---

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

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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090177e196ae2e71\Final\Final On: 01-Apr-2021 03:13 (GMT)

Header Text: C4591001

Visit: V4_MONTH6_L

Form Version: 22-Apr-2020 21:02

Site No: 1231

Subject No: 12312982

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: V4_MONTH6_L

Form Version: 22-Apr-2020 21:03

Site No: 1231

Subject No: 12312982

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Status: Not Started

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

Subject Initials: ---

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

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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090177e196ae2e71\Final\Final On: 01-Apr-2021 03:13 (GMT)

Header Text: C4591001

Visit: V5_MONTH12_L

Form Version: 22-Apr-2020 21:02

Site No: 1231

Subject No: 12312982

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: V5_MONTH12_L

Form Version: 22-Apr-2020 21:03

Site No: 1231

Subject No: 12312982

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Status: Not Started

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

Subject Initials: ---

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

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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090177e196ae2e71\Final\Final On: 01-Apr-2021 03:13 (GMT)

Header Text: C4591001

Visit: V6_MONTH24_L

Form Version: 22-Apr-2020 21:02

Site No: 1231

Subject No: 12312982

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: V6_MONTH24_L

Form Version: 22-Apr-2020 21:03

Site No: 1231

Subject No: 12312982

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Status: Not Started

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

Subject Initials: ---

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

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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090177e196ae2e71\Final\Final On: 01-Apr-2021 03:13 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Sep/12/2020 **Form:** DATE OF VISIT - ILLNESS ONSET

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1231

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

Subject No: 12312982

Subject Initials: ---

Generated By: (b) (4)

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

[eCRF Audit Trail History](#)

Date of Visit

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

COVID-19 Illness Visit

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

Visit: POT_COVID_ILL 1 - Unscheduled Visit on **Form:** SIGNS AND SYMPTOMS OF POTENTIAL COVID-19
Sep/12/2020

Form Version: 10-Oct-2020 16:02

Form Status: Data Complete, Frozen, Verified

Site No: 1231

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

Subject No: 12312982

Subject Initials: ---

Generated By: (b) (4)

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

[eCRF Audit Trail History](#)

Signs and Symptoms

1.	Date of Assessment:	Sep/12/2020
2.	Date of First Symptom Started:	Sep/9/2020
3.	Symptoms Ongoing?	NO Date of Last Symptom Resolved: Sep/12/2020

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?	NO
4.e	Symptoms:	NEW OR INCREASED MUSCLE PAIN
	Was symptom present?	YES
4.f	Symptoms:	NEW LOSS OF TASTE OR SMELL
	Was symptom present?	NO
4.g	Symptoms:	NEW OR INCREASED SORE THROAT
	Was symptom present?	NO
4.h	Symptoms:	DIARRHEA
	Was symptom present?	NO
4.i	Symptoms:	VOMITING
	Was symptom present?	NO

Symptoms - Other

090177e196ae2e71\Final\Final On: 01-Apr-2021 03:13 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on **Form:** SIGNS AND SYMPTOMS OF POTENTIAL COVID-19
Sep/12/2020

Form Version: 10-Oct-2020 16:02

Form Status: Data Complete, Frozen, Verified

Site No: 1231

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

Subject No: 12312982

Subject Initials: ---

Generated By: (b) (4)

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

5.a	Symptoms - Other Text:	[HEADACHE]
5.b	Symptoms - Other Text:	[nausea]
5.c	Symptoms - Other Text:	[dark urine]
5.d	Symptoms - Other Text:	[dizziness]

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: 12312982

Subject Initials: ---

Generated By: (b) (4)

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

#	Date of Collection	Specimen Type	Specimen Collection Location	Assay Code and Description	Device Type	Form Instance
1.	Sep/12/2020	SWABBED MATERIAL	NASOPHARYNX	SEVERE ACUTE RESPIRATORY SYNDROME CORONAVIRUS 2	SARS-COV-2 DIAGNOSTIC TEST	Repeating Pages

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on **Form:** MICROBIOLOGY SPECIMEN
Sep/12/2020

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: 12312982

Subject Initials: ---

Generated By: (b) (4)

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

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[Form Audit Trail](#)

Microbiology Specimen

1.	Actual Date of Collection:	Sep/12/2020
2.	Specimen Type:	SWABBED MATERIAL
3.	Specimen Collection Location:	NASOPHARYNX
4.	Assay Code and Description:	SEVERE ACUTE RESP SYNDROME CORONAVIRUS 2
5.	Device Type:	SARS-COV-2 DIAGNOSTIC TEST
6.	Trade Name:	OTHER
7.	Test Result:	NEGATIVE
8.	Comments/Findings/Details:	[]
9.	Trade Name Other, Specify:	[NALT Unknown]

090177e196ae2e71\Final\Final On: 01-Apr-2021 03:13 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Sep/12/2020 **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: 12312982

Subject Initials: ---

Generated By: (b) (4)

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 1 - Unscheduled Visit on Sep/12/2020 **Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1231

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

Subject No: 12312982

Subject Initials: ---

Generated By: (b) (4)

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?	NO
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[Not applicable]

Aliquot

Please enter barcode for each aliquot.

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

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Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on **Form:** HEALTH CARE UTILIZATION
Sep/12/2020

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: 12312982

Subject Initials: ---

Generated By: (b) (4)

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:	YES Number of Visits or Contacts: [2]
1.d	Physician or Healthcare Professional:	URGENT CARE
	Occurrence of Visits or Contacts:	YES Number of Visits or Contacts: [1]
1.e	Physician or Healthcare Professional:	TELEPHONE CONSULTATION
	Occurrence of Visits or Contacts:	NO
1.f	Physician or Healthcare Professional:	OTHER
	Occurrence of Visits or Contacts:	NO

Health Care Utilization Other

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

Health Care Utilization

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

090177e196ae2e71\Final\Final On: 01-Apr-2021 03:13 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1

Form: HOSPITALIZATION DETAILS

Form Version: 22-Apr-2020 21:02

Site No: 1231

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

Subject No: 12312982

Subject Initials: ---

Generated By: (b) (4)

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

#	Hospitalization Category	Hospitalization Term	Admission Date	Ongoing	Form Instance
1.	HOSPITALIZATION STATUS	HOSPITAL	Sep/12/2020	NO Discharge Date: Sep/13/2020	Repeating Pages

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on **Form:** HOSPITALIZATION DETAILS

Sep/12/2020

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen, Verified

Site No: 1231

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

Subject No: 12312982

Subject Initials: ---

Generated By: (b) (4)

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

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Hospitalization Details

1.	Hospitalization Category:	HOSPITALIZATION STATUS
2.	Hospitalization Term:	HOSPITAL
3.	Admission Date:	Sep/12/2020
4.	Ongoing?	NO Discharge Date: Sep/13/2020

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: 12312982

Subject Initials: ---

Generated By: (b) (4)

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

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

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on **Form:** RESPIRATORY TREATMENT
Sep/12/2020

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: 12312982

Subject Initials: ---

Generated By: (b) (4)

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

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Respiratory Treatment

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

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Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on **Form:** ILLNESS DETAILS
Sep/12/2020

Form Version: 06-Jul-2020 21:52

Form Status: Data Complete, Frozen, Verified

Site No: 1231

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

Subject No: 12312982

Subject Initials: ---

Generated By: (b) (4)

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: 12312982

Subject Initials: ---

Generated By: (b) (4)

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

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

090177e196ae2e71\Final\Final On: 01-Apr-2021 03:13 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on **Form:** ILLNESS DETAILS - SEVERE
Sep/12/2020

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: 12312982

Subject Initials: ---

Generated By: (b) (4)

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

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Illness Details

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

Header Text: C4591001

Visit: POT_COVID_ILL 1

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY

Form Version: 21-Aug-2020 02:49

Site No: 1231

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

Subject No: 12312982

Subject Initials: ---

Generated By: (b) (4)

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

#	Category for Lab Test	Vendor Name	Collection Date	Specimen Type	Lab Result			Form Instance
1.	CLINICAL CHEMISTRY	Hospital Aleman, Av. Pueyrredon 1640, C1118 AAT, Buenos Aires, Argentina	Sep/12/2020	BLOOD	Sponsor-Defined Identifier	Test:	Result:	Repeating Pages
					Unknown	Unknown	Unknown	
					Unknown	Alanine Aminotransferase_PX30	Unknown	
					Unknown	Aspartate Aminotransferase_PX28	Unknown	
					Unknown	Alkaline Phosphatase_PX35	Unknown	
					Unknown	Bilirubin_PX21	Unknown	
					Unknown	Blood Urea Nitrogen_PX47	Unknown	
					48	Creatinine_PX48	1.21	

090177e196ae2e71\Final\Final On: 01-Apr-2021 03:13 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on **Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY
Sep/12/2020

Form Version: 21-Aug-2020 02:49

Form Status: Data Complete, Frozen, Verified

Site No: 1231

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

Subject No: 12312982

Subject Initials: ---

Generated By: (b) (4)

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

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Lab Chemistry Details

1.	Lab Panel:	CLINICAL CHEMISTRY
2.	Laboratory Name and Address	[Hospital Aleman, Av. Pueyrredon 1640, C1118 AAT, Buenos Aires, Argentina]
3.	Collection Date:	Sep/12/2020
4.	Specimen Type:	BLOOD

Lab Result

5.a	Sponsor ID:	Unknown _____ []	Comments
	Test:	C Reactive Protein_PX329	
	Result:	Unknown _____ []	Comments
	Not Done:	Unknown _____ []	Comments
	LNMT	Unknown _____ Low [] High [] Unit	Comments

090177e196ae2e71\Final\Final On: 01-Apr-2021 03:13 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on **Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY
Sep/12/2020

Form Version: 21-Aug-2020 02:49

Form Status: Data Complete, Frozen, Verified

Site No: 1231

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

Subject No: 12312982

Subject Initials: ---

Generated By: (b) (4)

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

5.b	Sponsor ID:	Unknown _____ []	Comments
	Test:	Alanine Aminotransferase_PX30	
	Result:	Unknown _____ []	Comments
	Not Done:	Unknown _____ []	Comments
	LNMT	Unknown _____ Low [] High [] Unit	Comments

5.c	Sponsor ID:	Unknown _____ []	Comments
	Test:	Aspartate Aminotransferase_PX28	
	Result:	Unknown _____ []	Comments
	Not Done:	Unknown _____ []	Comments
	LNMT	Unknown _____ Low [] High [] Unit	Comments

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Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on **Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY
Sep/12/2020

Form Version: 21-Aug-2020 02:49

Form Status: Data Complete, Frozen, Verified

Site No: 1231

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

Subject No: 12312982

Subject Initials: ---

Generated By: (b) (4)

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

5.d	Sponsor ID:	Unknown _____ []	Comments
	Test:	Alkaline Phosphatase_PX35	
	Result:	Unknown _____ []	Comments
	Not Done:	Unknown _____ []	Comments
	LNMT	Unknown _____ Low [] High [] Unit	Comments

5.e	Sponsor ID:	Unknown _____ []	Comments
	Test:	Bilirubin_PX21	
	Result:	Unknown _____ []	Comments
	Not Done:	Unknown _____ []	Comments
	LNMT	Unknown _____ Low [] High [] Unit	Comments

090177e196ae2e71\Final\Final On: 01-Apr-2021 03:13 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on **Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY
Sep/12/2020

Form Version: 21-Aug-2020 02:49

Form Status: Data Complete, Frozen, Verified

Site No: 1231

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

Subject No: 12312982

Subject Initials: ---

Generated By: (b) (4)

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

5 f	Sponsor ID:	Unknown []	Comments
	Test:	Blood Urea Nitrogen_PX47	
	Result:	Unknown []	Comments
	Not Done:	Unknown	Comments
	LNMT	Unknown Low [] High [] Unit	Comments

5.g	Sponsor ID:	[48]	
	Test:	Creatinine_PX48	
	Result:	[1.21]	
	Not Done:		
	LNMT	Low [0.7] High [1.3] Unit mg/dL	

090177e196ae2e71\Final\Final On: 01-Apr-2021 03:13 (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: 12312982

Subject Initials: ---

Generated By: (b) (4)

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

#	Category for Lab Test	Vendor Name (DERIVED)	Collection Date	Specimen Type	Lab Result	Form Instance																																	
1.	HEMATOLOGY	Hospital Aleman, Av. Pueyrredon 1640, C1118 AAT, Buenos Aires, Argentina	Sep/12/2020	BLOOD	<table border="1"> <thead> <tr> <th>Sponsor-Defined Identifier</th> <th>Test:</th> <th>Result:</th> </tr> </thead> <tbody> <tr> <td>Unknown</td> <td>Hemoglobin_PX1</td> <td>Unknown</td> </tr> <tr> <td>Unknown</td> <td>Hematocrit_PX2</td> <td>Unknown</td> </tr> <tr> <td>Unknown</td> <td>Erythrocytes_PX3</td> <td>Unknown</td> </tr> <tr> <td>Unknown</td> <td>Platelets_PX5</td> <td>Unknown</td> </tr> <tr> <td>Unknown</td> <td>Leukocytes_PX7</td> <td>Unknown</td> </tr> <tr> <td>Unknown</td> <td>Neutrophils_PX608</td> <td>Unknown</td> </tr> <tr> <td>Unknown</td> <td>Eosinophils_PX609</td> <td>Unknown</td> </tr> <tr> <td>Unknown</td> <td>Monocytes_PX612</td> <td>Unknown</td> </tr> <tr> <td>Unknown</td> <td>Basophils_PX610</td> <td>Unknown</td> </tr> <tr> <td>Unknown</td> <td>Lymphocytes_PX611</td> <td>Unknown</td> </tr> </tbody> </table>	Sponsor-Defined Identifier	Test:	Result:	Unknown	Hemoglobin_PX1	Unknown	Unknown	Hematocrit_PX2	Unknown	Unknown	Erythrocytes_PX3	Unknown	Unknown	Platelets_PX5	Unknown	Unknown	Leukocytes_PX7	Unknown	Unknown	Neutrophils_PX608	Unknown	Unknown	Eosinophils_PX609	Unknown	Unknown	Monocytes_PX612	Unknown	Unknown	Basophils_PX610	Unknown	Unknown	Lymphocytes_PX611	Unknown	Repeating Pages
Sponsor-Defined Identifier	Test:	Result:																																					
Unknown	Hemoglobin_PX1	Unknown																																					
Unknown	Hematocrit_PX2	Unknown																																					
Unknown	Erythrocytes_PX3	Unknown																																					
Unknown	Platelets_PX5	Unknown																																					
Unknown	Leukocytes_PX7	Unknown																																					
Unknown	Neutrophils_PX608	Unknown																																					
Unknown	Eosinophils_PX609	Unknown																																					
Unknown	Monocytes_PX612	Unknown																																					
Unknown	Basophils_PX610	Unknown																																					
Unknown	Lymphocytes_PX611	Unknown																																					

090177e196ae2e71\Final\Final On: 01-Apr-2021 03:13 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on **Form:** LOCAL LABORATORY DATA - REPEATING Hematology
Sep/12/2020

Form Version: 21-Aug-2020 02:51

Form Status: Data Complete, Frozen, Verified

Site No: 1231

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

Subject No: 12312982

Subject Initials: ---

Generated By: (b) (4)

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

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Laboratory Data Hematology

1.	Lab Panel:	HEMATOLOGY
2.	Laboratory Name and Address	[Hospital Aleman, Av. Pueyrredon 1640, C1118 AAT, Buenos Aires, Argentina]
3.	Collection Date:	Sep/12/2020
4.	Specimen Type:	BLOOD

Lab Result

5.a	Sponsor ID:	Unknown _____ []	Comments
	Test:	Hemoglobin_PX1	
	Result:	Unknown _____ []	Comments
	Not Done:	Unknown _____ []	Comments
	LNMT	Unknown _____ Low [] High [] Unit	Comments

090177e196ae2e71\Final\Final On: 01-Apr-2021 03:13 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on **Form:** LOCAL LABORATORY DATA - REPEATING Hematology
Sep/12/2020

Form Version: 21-Aug-2020 02:51

Form Status: Data Complete, Frozen, Verified

Site No: 1231

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

Subject No: 12312982

Subject Initials: ---

Generated By: (b) (4)

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

5.b	Sponsor ID:	Unknown _____ []	Comments
	Test:	Hematocrit_PX2	
	Result:	Unknown _____ []	Comments
	Not Done:	Unknown _____ []	Comments
	LNMT	Unknown _____ Low [] High [] Unit	Comments
5.c	Sponsor ID:	Unknown _____ []	Comments
	Test:	Erythrocytes_PX3	
	Result:	Unknown _____ []	Comments
	Not Done:	Unknown _____ []	Comments
	LNMT	Unknown _____ Low [] High [] Unit	Comments

090177e196ae2e71\Final\Final On: 01-Apr-2021 03:13 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on **Form:** LOCAL LABORATORY DATA - REPEATING Hematology
Sep/12/2020

Form Version: 21-Aug-2020 02:51

Form Status: Data Complete, Frozen, Verified

Site No: 1231

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

Subject No: 12312982

Subject Initials: ---

Generated By: (b) (4)

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

5.d	Sponsor ID:	Unknown _____ []	Comments
	Test:	Platelets_PX5	
	Result:	Unknown _____ []	Comments
	Not Done:	Unknown _____ []	Comments
	LNMT	Unknown _____ Low [] High [] Unit	Comments
5.e	Sponsor ID:	Unknown _____ []	Comments
	Test:	Leukocytes_PX7	
	Result:	Unknown _____ []	Comments
	Not Done:	Unknown _____ []	Comments
	LNMT	Unknown _____ Low [] High [] Unit	Comments

090177e196ae2e71\Final\Final On: 01-Apr-2021 03:13 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on **Form:** LOCAL LABORATORY DATA - REPEATING Hematology
Sep/12/2020

Form Version: 21-Aug-2020 02:51

Form Status: Data Complete, Frozen, Verified

Site No: 1231

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

Subject No: 12312982

Subject Initials: ---

Generated By: (b) (4)

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

5 f	Sponsor ID:	Unknown _____ []	Comments
	Test:	Neutrophils_PX608	
	Result:	Unknown _____ []	Comments
	Not Done:	Unknown _____ []	Comments
	LNMT	Unknown _____ Low [] High [] Unit	Comments

5.g	Sponsor ID:	Unknown _____ []	Comments
	Test:	Eosinophils_PX609	
	Result:	Unknown _____ []	Comments
	Not Done:	Unknown _____ []	Comments
	LNMT	Unknown _____ Low [] High [] Unit	Comments

090177e196ae2e71\Final\Final On: 01-Apr-2021 03:13 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on **Form:** LOCAL LABORATORY DATA - REPEATING Hematology
Sep/12/2020

Form Version: 21-Aug-2020 02:51

Form Status: Data Complete, Frozen, Verified

Site No: 1231

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

Subject No: 12312982

Subject Initials: ---

Generated By: (b) (4)

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

5.h	Sponsor ID:	Unknown _____ []	Comments
	Test:	Monocytes_PX612	
	Result:	Unknown _____ []	Comments
	Not Done:	Unknown _____ []	Comments
	LNMT	Unknown _____ Low [] High [] Unit	Comments
5.i	Sponsor ID:	Unknown _____ []	Comments
	Test:	Basophils_PX610	
	Result:	Unknown _____ []	Comments
	Not Done:	Unknown _____ []	Comments
	LNMT	Unknown _____ Low [] High [] Unit	Comments

090177e196ae2e71\Final\Final On: 01-Apr-2021 03:13 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on **Form:** LOCAL LABORATORY DATA - REPEATING Hematology
Sep/12/2020

Form Version: 21-Aug-2020 02:51

Form Status: Data Complete, Frozen, Verified

Site No: 1231

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

Subject No: 12312982

Subject Initials: ---

Generated By: (b) (4)

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

5.j	Sponsor ID:	Unknown _____ []	Comments
	Test:	Lymphocytes_PX611	
	Result:	Unknown _____ []	Comments
	Not Done:	Unknown _____ []	Comments
	LNMT	Unknown _____ Low [] High [] Unit	Comments

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Header Text: C4591001

Visit: POT_COVID_ILL 1

Form: VITAL SIGNS - COVID

Form Version: 21-Aug-2020 02:50

Site No: 1231

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

Subject No: 12312982

Subject Initials: ---

Generated By: (b) (4)

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

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

090177e196ae2e71\Final\Final On: 01-Apr-2021 03:13 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on **Form:** VITAL SIGNS - COVID
Sep/12/2020

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: 12312982

Subject Initials: ---

Generated By: (b) (4)

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

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Vital Signs

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

Vital Signs Details

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

Header Text: C4591001

Visit: POT_COVID_ILL 1

Form: VITAL SIGNS - PULSE OX ROOM AIR

Form Version: 21-Aug-2020 02:51

Site No: 1231

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

Subject No: 12312982

Subject Initials: ---

Generated By: (b) (4)

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

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

090177e196ae2e71\Final\Final On: 01-Apr-2021 03:13 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on **Form:** VITAL SIGNS - PULSE OX ROOM AIR
Sep/12/2020

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: 12312982

Subject Initials: ---

Generated By: (b) (4)

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

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Vital Signs

1.	Date:	//
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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: 12312982

Subject Initials: ---

Generated By: (b) (4)

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

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

090177e196ae2e71\Final\Final On: 01-Apr-2021 03:13 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on **Form:** OXYGENATION PARAMETERS
Sep/12/2020

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: 12312982

Subject Initials: ---

Generated By: (b) (4)

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

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Oxygenation Parameters

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

Header Text: C4591001

Visit: POT_COVID_ILL 1

Form: CONCOMITANT MEDICATIONS - VASOPRESSORS

Form Version: 06-Jul-2020 21:55

Site No: 1231

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

Subject No: 12312982

Subject Initials: ---

Generated By: (b) (4)

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

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

090177e196ae2e71\Final\Final On: 01-Apr-2021 03:13 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on **Form:** CONCOMITANT MEDICATIONS - VASOPRESSORS
Sep/12/2020

Form Version: 06-Jul-2020 21:55

Form Status: Not Started

Site No: 1231

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

Subject No: 12312982

Subject Initials: ---

Generated By: (b) (4)

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

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Concomitant Medications

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

090177e196ae2e71\Final\Final On: 01-Apr-2021 03:13 (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: 12312982

Subject Initials: ---

Generated By: (b) (4)

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

#	Date of Assessment	Location of Assessment	Imaging Method	Overall Assessment	Form Instance
1.	Sep/12/2020	CHEST	X-RAY	ABNORMAL <i>If abnormal, specify findings:</i> right lung consolidation	Repeating Pages
2.	Sep/12/2020	CHEST	CT SCAN	NORMAL	Repeating Pages

090177e196ae2e71\Final\Final On: 01-Apr-2021 03:13 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on **Form:** IMAGING
Sep/12/2020

Form Version: 06-Jul-2020 21:53

Form Status: Data Complete, Frozen, Verified

Site No: 1231

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

Subject No: 12312982

Subject Initials: ---

Generated By: (b) (4)

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

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Imaging

1.	Date of Assessment:	Sep/12/2020
2.	Location of Assessment:	CHEST
3.	Type of Imaging Exam:	X-RAY
4.	Assessment:	ABNORMAL If abnormal, specify findings: [right lung consolidation]

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on **Form:** IMAGING
Sep/12/2020

Form Version: 06-Jul-2020 21:53

Form Status: Data Complete, Frozen, Verified

Site No: 1231

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

Subject No: 12312982

Subject Initials: ---

Generated By: (b) (4)

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

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Imaging

1.	Date of Assessment:	Sep/12/2020
2.	Location of Assessment:	CHEST
3.	Type of Imaging Exam:	CT SCAN
4.	Assessment:	NORMAL

090177e196ae2e71\Final\Final On: 01-Apr-2021 03:13 (GMT)

Header Text: C4591001

Visit: POT_COVID_CONVA - New Unscheduled Visit **Form:** DATE OF VISIT - ILLNESS CONVALESCENT

Form Version: 22-Apr-2020 21:04

Form Status: Not Started

Site No: 1231

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

Subject No: 12312982

Subject Initials: ---

Generated By: (b) (4)

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

Date of Visit

1.	Date of Visit	//
2.	Erroneous Visit	

COVID-19 Illness Visit

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

Header Text: C4591001

Visit: POT_COVID_CONVA - New Unscheduled **Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY Visit

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: 12312982

Subject Initials: ---

Generated By: (b) (4)

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

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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090177e196ae2e71\Final\Final On: 01-Apr-2021 03:13 (GMT)

Header Text: C4591001

Visit: Unplanned - New Unscheduled Visit

Form Version: 22-Apr-2020 21:02

Site No: 1231

Subject No: 12312982

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: 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: 12312982

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 Version: 15-Sep-2020 21:55

Site No: 1231

Subject No: 12312982

Generated By: (b) (4)

Form: DISPOSITION - TREATMENT

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

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Disposition - Treatment

1.	Date of Completion/Discontinuation /Death :	Sep/23/2020
2.	Phase of Disposition:	VACCINATION
3.	Status:	WITHDRAWAL BY SUBJECT
4.	Specify Status:	[The subject reports that the decision to stop participating in the study is of a personal nature]

Header Text: C4591001

Visit: Follow-Up - Unscheduled

Form Version: 15-Sep-2020 21:53

Site No: 1231

Subject No: 12312982

Generated By: (b) (4)

Form: DISPOSITION - FOLLOW-UP

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 - Follow-Up

1.	Date of Completion/Discontinuation /Death :	Sep/23/2020
2.	Phase of Disposition:	FOLLOW-UP
3.	Status:	WITHDRAWAL BY SUBJECT
4.	Specify Status:	[Withdrawal of consent for personal reasons]

Header Text: C4591001

Visit: POT_COVID_REPEAT_SWAB - New
Unscheduled Visit

Form: DATE OF VISIT - REPEAT SWAB

Form Version: 10-Oct-2020 15:57

Form Status: Not Started

Site No: 1231

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

Subject No: 12312982

Subject Initials: ---

Generated By: (b) (4)

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

Date of Visit

1.	Date of Visit	//
2.	Erroneous Visit	

COVID-19 Repeat Swab

3.	COVID-19 Repeat Swab:	
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Header Text: C4591001

Visit: POT_COVID_REPEAT_SWAB - New
Unscheduled Visit

Form: ELECTRONIC SAMPLE TRACKING - REPEAT SWAB

Form Version: 10-Oct-2020 15:57

Form Status: Not Started

Site No: 1231

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

Subject No: 12312982

Subject Initials: ---

Generated By: (b) (4)

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

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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090177e196ae2e71\Final\Final On: 01-Apr-2021 03:13 (GMT)

Header Text: C4591001

Visit: Unplanned Vaccination - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1231

Subject No: 12312982

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: 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: 12312982

Subject Initials: ---

Generated By: (b) (4)

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

Vital Signs

1.	Date:	//
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Vital Signs Details

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

090177e196ae2e71\Final\Final On: 01-Apr-2021 03:13 (GMT)

Header Text: C4591001

Visit: Unplanned Vaccination - Unscheduled

Form Version: 10-Dec-2020 02:26

Site No: 1231

Subject No: 12312982

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?	

090177e196ae2e71\Final\Final On: 01-Apr-2021 03:13 (GMT)

Header Text: C4591001

Visit: Unplanned Vaccination - Unscheduled

Form: CONTACT OUTCOME - MONTH 1

Form Version: 10-Oct-2020 15:57

Form Status: Not Started

Site No: 1231

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

Subject No: 12312982

Subject Initials: ---

Generated By: (b) (4)

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: 12312982

Subject Initials: ---

Generated By: (b) (4)

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

Contact Outcome

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

Header Text: C4591001

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

Form Version: 22-Apr-2020 21:02

Form Status: Not Started

Site No: 1231

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

Subject No: 12312982

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: V201_SURVEIL_CONSENT - Unscheduled **Form:** INFORMED CONSENT - ASYMPTOMATIC SURVEILLANCE

Form Version: 14-Jan-2021 02:29

Form Status: Not Started

Site No: 1231

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

Subject No: 12312982

Subject Initials: ---

Generated By: (b) (4)

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

Informed Consent - Asymptomatic Surveillance

1.	Consent Was:	
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Header Text: C4591001

Visit: V201_SURVEIL_CONSENT - Unscheduled **Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1231

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

Subject No: 12312982

Subject Initials: ---

Generated By: (b) (4)

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

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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090177e196ae2e71\Final\Final On: 01-Apr-2021 03:13 (GMT)

Header Text: C4591001

Visit: V201_SURVEIL_CONSENT - Unscheduled **Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1231

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

Subject No: 12312982

Subject Initials: ---

Generated By: (b) (4)

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

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

090177e196ae2e71\Final\Final On: 01-Apr-2021 03:13 (GMT)

Header Text: C4591001

Visit: Potential ReVax Initial Contact -
Unscheduled

Form: DATE OF VISIT

Form Version: 22-Apr-2020 21:02

Form Status: Not Started

Site No: 1231

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

Subject No: 12312982

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: Potential ReVax Initial Contact -
Unscheduled

Form: FURTHER VACCINATION CONFIRMATION

Form Version: 10-Dec-2020 02:25

Form Status: Not Started

Site No: 1231

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

Subject No: 12312982

Subject Initials: ---

Generated By: (b) (4)

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

Further Vaccination Confirmation

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

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: 12312982

Subject Initials: ---

Generated By: (b) (4)

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

#	Category	AE Identifier	Adverse Event	Start Date	Is the Adverse Event Still Ongoing	Form Instance
1.	ADVERSE EVENT	1	Suspected COVID-19 Illness	Sep/9/2020 21:00	NO End Date Time: Sep/14/2020 11:00	Repeating Pages
2.	ADVERSE EVENT	2	mild pain at the injection site	Aug/23/2020 11:17	NO End Date Time: Aug/25/2020 14:47	Repeating Pages
3.	ADVERSE EVENT	3	severe anxiety	Sep/23/2020 23:00	NO End Date Time: Oct/14/2020 15:30	Repeating Pages

090177e196ae2e71\Final\Final On: 01-Apr-2021 03:13 (GMT)

Header Text: C4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1231

Subject No: 12312982

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

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Adverse Event Report

1.	Category:	ADVERSE EVENT
2.	AE ID:	[1]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[Suspected COVID-19 Illness]
4.	Start Date Time:	Sep/9/2020 21:00
5.	Is the adverse event still ongoing?	NO End Date Time: Sep/14/2020 11:00
6.	Toxicity Grade:	3
7.	Is the adverse event serious? If Yes, NOTIFY PFIZER IMMEDIATELY. Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).	YES Is this serious event associated with congenital anomaly or birth defect? NO Did this serious event result in death? NO Did this serious event require or prolong hospitalization? YES Did this serious event result in persistent or significant disability/incapacity? NO Is this serious event life threatening? NO Other medically important serious event NO
8.	Is this adverse event the result of a study Medication Error? If Yes, record the type of medication error on the Medication Error Log.	NO
9.	Is this event related to study treatment:	NOT RELATED If Not Related to study treatment(s), this event is due to: OTHER If Other, specify: [unknown]

090177e196ae2e71\Final\Final On: 01-Apr-2021 03:13 (GMT)

Header Text: C4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1231

Subject No: 12312982

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

10.	Latest Action Taken with Study Treatment:	NOT APPLICABLE
11.	Was a Concomitant Medication given?	YES
12.	Was a Non-Drug Treatment given?	NO
13.	What was the outcome of this adverse event?:	RECOVERED/RESOLVED
14.	Did the adverse event cause the subject to be discontinued from the study?	NO
15.	Serious Adverse Event Number: For Pfizer Use Only	[2020354694]

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Header Text: C4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1231

Subject No: 12312982

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

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Adverse Event Report

1.	Category:	ADVERSE EVENT
2.	AE ID:	[2]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[mild pain at the injection site]
4.	Start Date Time:	Aug/23/2020 11:17
5.	Is the adverse event still ongoing?	NO End Date Time: Aug/25/2020 14:47
6.	Toxicity Grade:	1
7.	Is the adverse event serious? If Yes, NOTIFY PFIZER IMMEDIATELY. Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).	NO
8.	Is this adverse event the result of a study Medication Error? If Yes, record the type of medication error on the Medication Error Log.	NO
9.	Is this event related to study treatment:	RELATED
10.	Latest Action Taken with Study Treatment:	NOT APPLICABLE
11.	Was a Concomitant Medication given?	NO
12.	Was a Non-Drug Treatment given?	NO

090177e196ae2e71\Final\Final On: 01-Apr-2021 03:13 (GMT)

Header Text: C4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1231

Subject No: 12312982

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

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	[]

090177e196ae2e71\Final\Final On: 01-Apr-2021 03:13 (GMT)

Header Text: C4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1231

Subject No: 12312982

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

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Adverse Event Report

1.	Category:	ADVERSE EVENT
2.	AE ID:	[3]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[severe anxiety]
4.	Start Date Time:	Sep/23/2020 23:00
5.	Is the adverse event still ongoing?	NO End Date Time: Oct/14/2020 15:30
6.	Toxicity Grade:	3
7.	Is the adverse event serious? If Yes, NOTIFY PFIZER IMMEDIATELY. Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).	NO
8.	Is this adverse event the result of a study Medication Error? If Yes, record the type of medication error on the Medication Error Log.	NO
9.	Is this event related to study treatment:	NOT RELATED If Not Related to study treatment(s), this event is due to: OTHER If Other, specify: [constitutive features]
10.	Latest Action Taken with Study Treatment:	NOT APPLICABLE

090177e196ae2e71\Final\Final On: 01-Apr-2021 03:13 (GMT)

Header Text: C4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1231

Subject No: 12312982

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

11.	Was a Concomitant Medication given?	NO	Comments
12.	Was a Non-Drug Treatment given?	NO	Comments
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	[]	

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Header Text: C4591001

Visit: Logs

Form: MEDICATION ERROR

Form Version: 17-Jul-2020 21:54

Site No: 1231

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

Subject No: 12312982

Subject Initials: ---

Generated By: (b) (4)

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

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

Header Text: C4591001

Visit: Logs - Unscheduled

Form Version: 17-Jul-2020 21:54

Site No: 1231

Subject No: 12312982

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

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Medication Error

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

090177e196ae2e71\Final\Final On: 01-Apr-2021 03:13 (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: 12312982

Subject Initials: ---

Generated By: (b) (4)

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

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

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: 12312982

Subject Initials: ---

Generated By: (b) (4)

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

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Concomitant Medications

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

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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: 12312982

Subject Initials: ---

Generated By: (b) (4)

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

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

Header Text: C4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1231

Subject No: 12312982

Generated By: (b) (4)

Form: CONCOMITANT MEDICATIONS - PROHIBITED

Form Status: Not Started

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

Subject Initials: ---

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

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Concomitant Medications

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

090177e196ae2e71\Final\Final On: 01-Apr-2021 03:13 (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: 12312982

Subject Initials: ---

Generated By: (b) (4)

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

#	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: 12312982

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

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Radiation Treatment

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

Header Text: C4591001

Visit: Logs

Form: TRANSFUSIONS

Form Version: 22-Apr-2020 21:03

Site No: 1231

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

Subject No: 12312982

Subject Initials: ---

Generated By: (b) (4)

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

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

Header Text: C4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1231

Subject No: 12312982

Generated By: (b) (4)

Form: TRANSFUSIONS

Form Status: Not Started

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

Subject Initials: ---

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

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

Header Text: C4591001

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

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

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

Subject No: 12312982 **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_BOOSTER_CONTACT -
Unscheduled

Form: BOOSTER DOSE TRIGGER FORM

Form Version: 20-Feb-2021 02:20

Form Status: Not Started

Site No: 1231

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

Subject No: 12312982

Subject Initials: ---

Generated By: (b) (4)

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

Booster Dose Trigger Form

1.	Select appropriate response - Will the participant return for consent/eligibility assessment for the booster dose visit?	
----	--	--

Header Text: C4591001

Visit: Disposition - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1231

Subject No: 12312982

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

[Form Comments](#)

[eCRF Audit Trail History](#)

Treatment Unblinded

1.	Date Treatment Unblinded :	Not Applicable _____ //	Comments
2.	Primary Reason for Unblinding:	Not Applicable _____	Comments

Header Text: C4591001

Visit: Disposition - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1231

Subject No: 12312982

Generated By: (b) (4)

Form: WITHDRAWAL OF CONSENT

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](#)

Withdrawal Of Consent

1.	Withdrawal of Consent Date :	Sep/23/2020
----	------------------------------	-------------

Header Text: C4591001

Visit: Disposition - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1231

Subject No: 12312982

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:	[]

Header Text: C4591001

Visit: Subject Status - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1231

Subject No: 12312982

Generated By: (b) (4)

Form: SUBJECT STATUS

Form Status: Data Complete, Verified

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

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Subject Status

1.	Subject Status	DISCONTINUED
2.	Subject Status Date	Sep/23/2020

Header Text: C4591001

Visit: Investigator Signature - Unscheduled

Form Version: 22-Apr-2020 21:04

Site No: 1231

Subject No: 12312982

Generated By: (b) (4)

Form: CASEBOOK SIGNATURE FORM

Form Status: Data Complete, Signed, Verified

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

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Casebook Signature Form

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

Header Text: C4591001

Visit: Investigator Signature - Unscheduled

Form: CASEBOOK SIGNATURE FORM

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Signed, Verified

Site No: 1231

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

Subject No: 12312982

Subject Initials: ---

Generated By: (b) (4)

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

[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-09-2021 00:37:04 (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.

090177e196ae2e71\Final\Final On: 01-Apr-2021 03:13 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1231

Subject No: 12312982

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - Comments

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

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Item	Date	User	Comment
Form	Aug-22-2020 09:27:56 (UTC-03:00) City of Buenos Aires	(b) (4), (b) (6)	Not Applicable

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Sep/12/2020 **Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY - Comments

Form Version: 21-Aug-2020 02:49

Form Status: Data Complete, Frozen, Verified

Site No: 1231

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

Subject No: 12312982

Subject Initials: ---

Generated By: (b) (4)

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

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Item	Date	User	Comment
5.a	Oct-29-2020 15:34:06 (UTC-03:00) City of Buenos Aires	(b) (4), (b) (6)	Unknown

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Sep/12/2020 **Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY - Comments

Form Version: 21-Aug-2020 02:49

Form Status: Data Complete, Frozen, Verified

Site No: 1231

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

Subject No: 12312982

Subject Initials: ---

Generated By: (b) (4)

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

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Item	Date	User	Comment
5.a	Oct-29-2020 15:34:06 (UTC-03:00) City of Buenos Aires	(b) (4), (b) (6)	Unknown

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Sep/12/2020

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY - Comments

Form Version: 21-Aug-2020 02:49

Form Status: Data Complete, Frozen, Verified

Site No: 1231

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

Subject No: 12312982

Subject Initials: ---

Generated By: (b) (4)

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Item	Date	User	Comment
5.a	Oct-29-2020 15:34:06 (UTC-03:00) City of Buenos Aires	(b) (4), (b) (6)	Unknown

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Sep/12/2020

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY - Comments

Form Version: 21-Aug-2020 02:49

Form Status: Data Complete, Frozen, Verified

Site No: 1231

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

Subject No: 12312982

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Generated By: (b) (4)

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Item	Date	User	Comment
5.a	Oct-29-2020 15:34:06 (UTC-03:00) City of Buenos Aires	(b) (4), (b) (6)	Unknown

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Sep/12/2020

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY - Comments

Form Version: 21-Aug-2020 02:49

Form Status: Data Complete, Frozen, Verified

Site No: 1231

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

Subject No: 12312982

Subject Initials: ---

Generated By: (b) (4)

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Item	Date	User	Comment
5.b	Oct-29-2020 15:34:24 (UTC-03:00) City of Buenos Aires	(b) (4), (b) (6)	Unknown

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Sep/12/2020 **Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY - Comments

Form Version: 21-Aug-2020 02:49

Form Status: Data Complete, Frozen, Verified

Site No: 1231

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

Subject No: 12312982

Subject Initials: ---

Generated By: (b) (4)

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

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Item	Date	User	Comment
5.b	Oct-29-2020 15:34:24 (UTC-03:00) City of Buenos Aires	(b) (4), (b) (6)	Unknown

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Sep/12/2020

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY - Comments

Form Version: 21-Aug-2020 02:49

Form Status: Data Complete, Frozen, Verified

Site No: 1231

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

Subject No: 12312982

Subject Initials: ---

Generated By: (b) (4)

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

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Item	Date	User	Comment
5.b	Oct-29-2020 15:34:24 (UTC-03:00) City of Buenos Aires	(b) (4), (b) (6)	Unknown

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Sep/12/2020 **Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY - Comments

Form Version: 21-Aug-2020 02:49

Form Status: Data Complete, Frozen, Verified

Site No: 1231

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

Subject No: 12312982

Subject Initials: ---

Generated By: (b) (4)

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

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Item	Date	User	Comment
5.b	Oct-29-2020 15:34:24 (UTC-03:00) City of Buenos Aires	(b) (4), (b) (6)	Unknown

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Sep/12/2020 **Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY - Comments

Form Version: 21-Aug-2020 02:49

Form Status: Data Complete, Frozen, Verified

Site No: 1231

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

Subject No: 12312982

Subject Initials: ---

Generated By: (b) (4)

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

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Item	Date	User	Comment
5.c	Oct-29-2020 15:34:52 (UTC-03:00) City of Buenos Aires	(b) (4), (b) (6)	Unknown

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Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Sep/12/2020 **Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY - Comments

Form Version: 21-Aug-2020 02:49

Form Status: Data Complete, Frozen, Verified

Site No: 1231

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

Subject No: 12312982

Subject Initials: ---

Generated By: (b) (4)

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

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Item	Date	User	Comment
5.c	Oct-29-2020 15:34:52 (UTC-03:00) City of Buenos Aires	(b) (4), (b) (6)	Unknown

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Sep/12/2020 **Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY - Comments

Form Version: 21-Aug-2020 02:49

Form Status: Data Complete, Frozen, Verified

Site No: 1231

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

Subject No: 12312982

Subject Initials: ---

Generated By: (b) (4)

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

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Item	Date	User	Comment
5.c	Oct-29-2020 15:34:52 (UTC-03:00) City of Buenos Aires	(b) (4), (b) (6)	Unknown

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Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Sep/12/2020 **Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY - Comments

Form Version: 21-Aug-2020 02:49

Form Status: Data Complete, Frozen, Verified

Site No: 1231

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

Subject No: 12312982

Subject Initials: ---

Generated By: (b) (4)

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

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Item	Date	User	Comment
5.c	Oct-29-2020 15:34:52 (UTC-03:00) City of Buenos Aires	(b) (4), (b) (6)	Unknown

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Sep/12/2020

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY - Comments

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Form Status: Data Complete, Frozen, Verified

Site No: 1231

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

Subject No: 12312982

Subject Initials: ---

Generated By: (b) (4)

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

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Item	Date	User	Comment
5.d	Oct-29-2020 15:35:19 (UTC-03:00) City of Buenos Aires	(b) (4), (b) (6)	Unknown

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Sep/12/2020 **Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY - Comments

Form Version: 21-Aug-2020 02:49

Form Status: Data Complete, Frozen, Verified

Site No: 1231

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

Subject No: 12312982

Subject Initials: ---

Generated By: (b) (4)

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Item	Date	User	Comment
5.d	Oct-29-2020 15:35:19 (UTC-03:00) City of Buenos Aires	(b) (4), (b) (6)	Unknown

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Sep/12/2020 **Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY - Comments

Form Version: 21-Aug-2020 02:49

Form Status: Data Complete, Frozen, Verified

Site No: 1231

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

Subject No: 12312982

Subject Initials: ---

Generated By: (b) (4)

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

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Item	Date	User	Comment
5.d	Oct-29-2020 15:35:19 (UTC-03:00) City of Buenos Aires	(b) (4), (b) (6)	Unknown

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Sep/12/2020 **Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY - Comments

Form Version: 21-Aug-2020 02:49

Form Status: Data Complete, Frozen, Verified

Site No: 1231

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

Subject No: 12312982

Subject Initials: ---

Generated By: (b) (4)

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Item	Date	User	Comment
5.d	Oct-29-2020 15:35:19 (UTC-03:00) City of Buenos Aires	(b) (4), (b) (6)	Unknown

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Sep/12/2020 **Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY - Comments

Form Version: 21-Aug-2020 02:49

Form Status: Data Complete, Frozen, Verified

Site No: 1231

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

Subject No: 12312982

Subject Initials: ---

Generated By: (b) (4)

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

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Item	Date	User	Comment
5.e	Oct-29-2020 15:35:34 (UTC-03:00) City of Buenos Aires	(b) (4), (b) (6)	Unknown

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Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Sep/12/2020 **Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY - Comments

Form Version: 21-Aug-2020 02:49

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Subject Initials: ---

Generated By: (b) (4)

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

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Item	Date	User	Comment
5.h	Oct-29-2020 15:57:35 (UTC-03:00) City of Buenos Aires	(b) (4), (b) (6)	Unknown

090177e196ae2e71\Final\Final On: 01-Apr-2021 03:13 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Sep/12/2020 **Form:** LOCAL LABORATORY DATA - REPEATING Hematology - Comments

Form Version: 21-Aug-2020 02:51

Form Status: Data Complete, Frozen, Verified

Site No: 1231

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

Subject No: 12312982

Subject Initials: ---

Generated By: (b) (4)

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

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Item	Date	User	Comment
5.h	Oct-29-2020 15:57:35 (UTC-03:00) City of Buenos Aires	(b) (4), (b) (6)	Unknown

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Sep/12/2020 **Form:** LOCAL LABORATORY DATA - REPEATING Hematology - Comments

Form Version: 21-Aug-2020 02:51

Form Status: Data Complete, Frozen, Verified

Site No: 1231

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

Subject No: 12312982

Subject Initials: ---

Generated By: (b) (4)

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

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Item	Date	User	Comment
5.i	Oct-29-2020 15:57:46 (UTC-03:00) City of Buenos Aires	(b) (4), (b) (6)	Unknown

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Sep/12/2020 **Form:** LOCAL LABORATORY DATA - REPEATING Hematology - Comments

Form Version: 21-Aug-2020 02:51

Form Status: Data Complete, Frozen, Verified

Site No: 1231

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

Subject No: 12312982

Subject Initials: ---

Generated By: (b) (4)

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

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Item	Date	User	Comment
5.i	Oct-29-2020 15:57:46 (UTC-03:00) City of Buenos Aires	(b) (4), (b) (6)	Unknown

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Sep/12/2020 **Form:** LOCAL LABORATORY DATA - REPEATING Hematology - Comments

Form Version: 21-Aug-2020 02:51

Form Status: Data Complete, Frozen, Verified

Site No: 1231

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

Subject No: 12312982

Subject Initials: ---

Generated By: (b) (4)

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

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Item	Date	User	Comment
5.i	Oct-29-2020 15:57:46 (UTC-03:00) City of Buenos Aires	(b) (4), (b) (6)	Unknown

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Sep/12/2020 **Form:** LOCAL LABORATORY DATA - REPEATING Hematology - Comments

Form Version: 21-Aug-2020 02:51

Form Status: Data Complete, Frozen, Verified

Site No: 1231

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

Subject No: 12312982

Subject Initials: ---

Generated By: (b) (4)

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

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Item	Date	User	Comment
5.i	Oct-29-2020 15:57:46 (UTC-03:00) City of Buenos Aires	(b) (4), (b) (6)	Unknown

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Sep/12/2020 **Form:** LOCAL LABORATORY DATA - REPEATING Hematology - Comments

Form Version: 21-Aug-2020 02:51

Form Status: Data Complete, Frozen, Verified

Site No: 1231

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

Subject No: 12312982

Subject Initials: ---

Generated By: (b) (4)

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

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Item	Date	User	Comment
5.j	Oct-29-2020 15:58:03 (UTC-03:00) City of Buenos Aires	(b) (4), (b) (6)	Unknown

090177e196ae2e71\Final\Final On: 01-Apr-2021 03:13 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Sep/12/2020 **Form:** LOCAL LABORATORY DATA - REPEATING Hematology - Comments

Form Version: 21-Aug-2020 02:51

Form Status: Data Complete, Frozen, Verified

Site No: 1231

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

Subject No: 12312982

Subject Initials: ---

Generated By: (b) (4)

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

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Item	Date	User	Comment
5.j	Oct-29-2020 15:58:03 (UTC-03:00) City of Buenos Aires	(b) (4), (b) (6)	Unknown

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Sep/12/2020 **Form:** LOCAL LABORATORY DATA - REPEATING Hematology - Comments

Form Version: 21-Aug-2020 02:51

Form Status: Data Complete, Frozen, Verified

Site No: 1231

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

Subject No: 12312982

Subject Initials: ---

Generated By: (b) (4)

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

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Item	Date	User	Comment
5.j	Oct-29-2020 15:58:03 (UTC-03:00) City of Buenos Aires	(b) (4), (b) (6)	Unknown

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Sep/12/2020 **Form:** LOCAL LABORATORY DATA - REPEATING Hematology - Comments

Form Version: 21-Aug-2020 02:51

Form Status: Data Complete, Frozen, Verified

Site No: 1231

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

Subject No: 12312982

Subject Initials: ---

Generated By: (b) (4)

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

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Item	Date	User	Comment
5.j	Oct-29-2020 15:58:03 (UTC-03:00) City of Buenos Aires	(b) (4), (b) (6)	Unknown

Header Text: C4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1231

Subject No: 12312982

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - Comments

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

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Item	Date	User	Comment
11	Oct-29-2020 16:45:52 (UTC-03:00) City of Buenos Aires	(b) (4), (b) (6)	
11	Oct-08-2020 21:01:10 (UTC-03:00) City of Buenos Aires	(b) (4), (b) (6)	Unknown

090177e196ae2e71\Final\Final On: 01-Apr-2021 03:13 (GMT)

Header Text: C4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1231

Subject No: 12312982

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - Comments

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

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Item	Date	User	Comment
12	Oct-29-2020 15:52:45 (UTC-03:00) City of Buenos Aires	Adolfo Gonzalez (b) (4)	
12	Oct-08-2020 21:07:21 (UTC-03:00) City of Buenos Aires	(b) (4), (b) (6)	Unknown

090177e196ae2e71\Final\Final On: 01-Apr-2021 03:13 (GMT)

Header Text: C4591001

Visit: Disposition - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1231

Subject No: 12312982

Generated By: (b) (4)

Form: TREATMENT UNBLINDED - 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

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Item	Date	User	Comment
Form	Mar-01-2021 14:45:21 (UTC-03:00) City of Buenos Aires	(b) (4), (b) (6)	Not Applicable

090177e196ae2e71\Final\Final On: 01-Apr-2021 03:13 (GMT)

Header Text: C4591001

Visit: Disposition

Form Version: 22-Apr-2020 21:03

Site No: 1231

Subject No: 12312982

Generated By: (b) (4)

Form: TREATMENT UNBLINDED - 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

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Item	Date	User	Comment
1	Mar-01-2021 14:45:21 (UTC-03:00) City of Buenos Aires	(b) (4), (b) (6)	Not Applicable

Header Text: C4591001

Visit: Disposition

Form Version: 22-Apr-2020 21:03

Site No: 1231

Subject No: 12312982

Generated By: (b) (4)

Form: TREATMENT UNBLINDED - 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

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Item	Date	User	Comment
2	Mar-01-2021 14:45:21 (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: 12312982

Subject Initials: ---

Generated By: (b) (4)

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

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

- CRF_Sign

Name	Signature Meaning	Date	Type	Action
(b) (6)	Approved	Mar-09-2021 00:37:04 (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-01-2021 14:44:05 (UTC-03:00) City of Buenos Aires		Edit - All signatures invalidated
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Affidavit:

N/A

(b) (6)	Approved	Nov-25-2020 17:34:51 (UTC-03:00) City of Buenos Aires	BOOK	Signed
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Affidavit:

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

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

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

(b) (6)	N/A	Nov-19-2020 15:35:17 (UTC-03:00) City of Buenos Aires		Edit - All signatures invalidated
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Affidavit:

N/A

Fernando Polack	Approved	Nov-17-2020 08:26:57 (UTC-03:00) City of Buenos Aires	BOOK	Signed
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090177e196ae2e71\Final\Final On: 01-Apr-2021 03:13 (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: 12312982

Subject Initials: ---

Generated By: (b) (4)

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

Affidavit:

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

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

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

(b) (6)	N/A	Nov-16-2020 19:01:55 (UTC-03:00) City of Buenos Aires		Edit - All signatures invalidated
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Affidavit:

N/A

Fernando Polack	Approved	Nov-16-2020 11:18:59 (UTC-03:00) City of Buenos Aires	BOOK	Signed
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Affidavit:

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

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

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

(b) (6)	N/A	Nov-16-2020 10:31:04 (UTC-03:00) City of Buenos Aires		Edit - All signatures invalidated
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Affidavit:

N/A

(b) (6)	Approved	Nov-14-2020 12:11:23 (UTC-03:00) City of Buenos Aires	BOOK	Signed
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Affidavit:

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

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

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

090177e196ae2e71\Final\Final On: 01-Apr-2021 03:13 (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: 12312982

Subject Initials: ---

Generated By: (b) (4)

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

(b) (6)	N/A	Nov-12-2020 09:28:02 (UTC-03:00) City of Buenos Aires		Edit - All signatures invalidated
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Affidavit:

N/A

(b) (6)	Approved	Nov-10-2020 18:04:54 (UTC-03:00) City of Buenos Aires	BOOK	Signed
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Affidavit:

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

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

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

(b) (6)	N/A	Nov-10-2020 09:02:05 (UTC-03:00) City of Buenos Aires		Edit - All signatures invalidated
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Affidavit:

N/A

(b) (6)	Approved	Nov-04-2020 16:52:04 (UTC-03:00) City of Buenos Aires	BOOK	Signed
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Affidavit:

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

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

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

090177e196ae2e71\Final\Final On: 01-Apr-2021 03:13 (GMT)

Header Text: C4591001

Visit: COHORT_SELECTION

Form Version: 30-Jul-2020 21:29

Site No: 1231

Subject No: 12312982

Generated By: (b) (4)

Form: COHORT SELECTION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

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1. Select appropriate response - Protocol version

Date	Location	User	Value	Reason
Aug-22-2020 09:26:46 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> 30 JUN 2020	Initial Entry

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

Date	Location	User	Value	Reason
Aug-22-2020 09:26:46 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> STAGE 3 COHORTS	Initial Entry

090177e196ae2e71\Final\Final On: 01-Apr-2021 03:13 (GMT)

Header Text: C4591001

Visit: COHORT_SELECTION

Form Version: 22-Apr-2020 21:02

Site No: 1231

Subject No: 12312982

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

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I. Consent Was:

Date	Location	User	Value	Reason
Aug-22-2020 09:26:56 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: OBTAINED Date Written Consent Obtained Aug/21/2020	Initial Entry

Header Text: C4591001

Visit: COHORT_SELECTION

Form Version: 06-Jul-2020 21:55

Site No: 1231

Subject No: 12312982

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

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1. Subject ID

Date	Location	User	Value	Reason
Aug-21-2020 17:39:43 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 12312982	Item copied from previous form

2. Birth Date:

Date	Location	User	Value	Reason
Aug-21-2020 17:39:38 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: (b) (6) /1984	Enrollment Entry

3. Sex:

Date	Location	User	Value	Reason
Aug-22-2020 09:27:13 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: MALE	Initial Entry

4. Ethnicity:

Date	Location	User	Value	Reason
Aug-22-2020 09:27:13 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NOT HISPANIC OR LATINO(A) OR OF SPANISH ORIGIN	Initial Entry

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

Date	Location	User	Value	Reason
Aug-22-2020 09:27:13 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: WHITE	Initial Entry

090177e196ae2e71\Final\Final On: 01-Apr-2021 03:13 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:02

Site No: 1231

Subject No: 12312982

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

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I. Date of Visit

Date	Location	User	Value	Reason
Aug-28-2020 09:16:31 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Data updated
Aug-28-2020 04:08:46 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reissued:Candidate	Data updated
Aug-27-2020 11:00:02 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Electronic Sample Tracking Nasal Swab was collected and form was completed.
Aug-25-2020 07:49:29 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	DM Query: Please review and consider to complete "Electronic Sample Tracking-Nasal Swab" form. Thank you.
Aug-22-2020 09:27:24 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Aug/21/2020	Initial Entry

090177e196ae2e71\Final\Final On: 01-Apr-2021 03:13 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 21-Aug-2020 02:50

Site No: 1231

Subject No: 12312982

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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I.a

Date	Location	User	Value	Reason
Aug-22-2020 09:27:37 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Inclusi 1 on Nu mber: Criteria Male or female participants on Des between the ages of 18 and criptio 55 years, inclusive, 65 and 8 n: 5 years, inclusive, or 18 and 85 years, inclusive, at rando mization (dependent upon st udy stage) Criteria YES on met ?: Criteria IN01A00 on ID: (For P fizer u se only):	Initial Entry

I.a Inclusion Number:

Date	Location	User	Value	Reason
Aug-22-2020 09:27:37 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 1	Initial Entry

I.a Criterion Description:

Date	Location	User	Value	Reason
Aug-22-2020 09:27:37 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 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 randomizatio n (dependent upon study stage)	Initial Entry

I.a Criterion met?

090177e196ae2e71\Final\Final On: 01-Apr-2021 03:13 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 21-Aug-2020 02:50

Site No: 1231

Subject No: 12312982

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

Date	Location	User	Value	Reason
Aug-22-2020 09:27:37 (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-22-2020 09:27:37 (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-22-2020 09:27:37 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Inclusion Number: Participants who are willing and able to comply with a clinical scheduled visits, vaccination plan, laboratory tests, lifestyle considerations, and other study procedures Criterion met?: YES Criterion ID: (For Pfizer use only): IN02A00	Initial Entry

090177e196ae2e71\Final\Final On: 01-Apr-2021 03:13 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 21-Aug-2020 02:50

Site No: 1231

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 No: 12312982

Subject Initials: ---

Generated By: (b) (4)

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

I.b Inclusion Number:

Date	Location	User	Value	Reason
Aug-22-2020 09:27:37 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 2	Initial Entry

I.b Criterion Description:

Date	Location	User	Value	Reason
Aug-22-2020 09:27:37 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Participants who are willing and able to comply with all scheduled visits, v accination plan, laboratory tests, lifes tyle considerations, and other study p rocedures	Initial Entry

I.b Criterion met?

Date	Location	User	Value	Reason
Aug-22-2020 09:27:37 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

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

Date	Location	User	Value	Reason
Aug-22-2020 09:27:37 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: IN02A00	Initial Entry

I.c

Date	Location	User	Value	Reason
Aug-22-2020 09:27:37 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Inclusi 3 on Nu mber: Criteria Healthy participants who ar on Des e determined by medical his criptio tory, physical examination, n: and clinical judgment of the investigator to be eligible fo r inclusion in the study	Initial Entry

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Form Version: 21-Aug-2020 02:50

Site No: 1231

Subject No: 12312982

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

			Criteria on met?: Criteria on ID: (For Pfizer use only): IN03A00
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I.c Inclusion Number:

Date	Location	User	Value	Reason
Aug-22-2020 09:27:37 (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-22-2020 09:27:37 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Healthy participants who are determined by medical history, physical examination, and clinical judgment of the investigator to be eligible for inclusion in the study	Initial Entry

I.c Criterion met?:

Date	Location	User	Value	Reason
Aug-22-2020 09:27:37 (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)

Date	Location	User	Value	Reason
Aug-22-2020 09:27:37 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: IN03A00	Initial Entry

I.d

Date	Location	User	Value	Reason
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090177e196ae2e71\Final\Final On: 01-Apr-2021 03:13 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 21-Aug-2020 02:50

Site No: 1231

Subject No: 12312982

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

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Aug-22-2020 09:27:37 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 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: IN04A00 (For Publisher use only):	Initial Entry
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090177e196ae2e71\Final\Final On: 01-Apr-2021 03:13 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 21-Aug-2020 02:50

Site No: 1231

Subject No: 12312982

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

I.d Inclusion Number:

Date	Location	User	Value	Reason
Aug-22-2020 09:27:37 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 4	Initial Entry

I.d Criterion Description:

Date	Location	User	Value	Reason
Aug-22-2020 09:27:37 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Capable of giving personal signed informed consent, which includes compliance with the requirements and restrictions listed in the ICD and in this protocol	Initial Entry

I.d Criterion met?

Date	Location	User	Value	Reason
Aug-22-2020 09:27:37 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

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

Date	Location	User	Value	Reason
Aug-22-2020 09:27:37 (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-22-2020 09:27:37 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Exclusion Number: 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	Initial Entry

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Header Text: C4591001

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Site No: 1231

Subject No: 12312982

Generated By: (b) (4)

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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

			<p>Criteria NO on met?:</p> <p>Criteria EX01A00 on ID: (For Pfizer use only):</p>	
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2.a Exclusion Number:

Date	Location	User	Value	Reason
Aug-22-2020 09:27:37 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> 1	Initial Entry

2.a Criterion Description:

Date	Location	User	Value	Reason
Aug-22-2020 09:27:37 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> 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	Initial Entry

2.a Criterion met?

Date	Location	User	Value	Reason
Aug-22-2020 09:27:37 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NO	Initial Entry

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

Date	Location	User	Value	Reason
Aug-22-2020 09:27:37 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> EX01A00	Initial Entry

2.b

Date	Location	User	Value	Reason
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090177e196ae2e71\Final\Final On: 01-Apr-2021 03:13 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

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Site No: 1231

Subject No: 12312982

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

Aug-22-2020 09:27:37 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 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	Initial Entry
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Header Text: C4591001

Visit: V1_DAY1_VAX1_L

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Site No: 1231

Subject No: 12312982

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: ---

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2.b Exclusion Number:

Date	Location	User	Value	Reason
Aug-22-2020 09:27:37 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> 2	Initial Entry

2.b Criterion Description:

Date	Location	User	Value	Reason
Aug-22-2020 09:27:37 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Known infection with human immunodeficiency virus (HIV), hepatitis C virus (HCV), or hepatitis B virus (HBV)	Initial Entry

2.b Criterion met?

Date	Location	User	Value	Reason
Aug-22-2020 09:27:37 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NO	Initial Entry

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

Date	Location	User	Value	Reason
Aug-22-2020 09:27:37 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> EX02A00	Initial Entry

2.c

Date	Location	User	Value	Reason
Aug-22-2020 09:27:37 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Exclusion Number: 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)	Initial Entry

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Header Text: C4591001

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Subject No: 12312982

Generated By: (b) (4)

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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

			Criteria met?: NO Criteria ID: EX03A00 (For Pfizer use only):
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2.c Exclusion Number:

Date	Location	User	Value	Reason
Aug-22-2020 09:27:37 (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-22-2020 09:27:37 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: History of severe adverse reaction as 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-22-2020 09:27:37 (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
Aug-22-2020 09:27:37 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: EX03A00	Initial Entry

2.d

Date	Location	User	Value	Reason
Aug-22-2020 09:27:37	ACV0PFEINFP6000	(b) (6)	Data Entry:	Initial Entry

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Site No: 1231

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

Subject No: 12312982

Subject Initials: ---

Generated By: (b) (4)

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

(UTC-03:00) City of Buenos Aires		(b) (4), (b) (6)	Exclusion Number: 4 Criterion Description: Receipt of medications intended to prevent COVID-19 Criterion met?: NO Criterion ID: EX04A00 (For Pfizer use only):
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2.d Exclusion Number:

Date	Location	User	Value	Reason
Aug-22-2020 09:27:37 (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-22-2020 09:27:37 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Receipt of medications intended to prevent COVID-19	Initial Entry

2.d Criterion met?

Date	Location	User	Value	Reason
Aug-22-2020 09:27:37 (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-22-2020 09:27:37 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: EX04A00	Initial Entry

2.e

Date	Location	User	Value	Reason
Aug-22-2020 09:27:37 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (6)	Data Entry: Exclusion 8	Initial Entry

090177e196ae2e71\Final\Final On: 01-Apr-2021 03:13 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

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Site No: 1231

Subject No: 12312982

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

Buenos Aires		(b) (4)	on Number: 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	
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Header Text: C4591001

Visit: V1_DAY1_VAX1_L

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Site No: 1231

Subject No: 12312982

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

2.e Exclusion Number:

Date	Location	User	Value	Reason
Aug-22-2020 09:27:37 (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-22-2020 09:27:37 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Immunocompromised individuals with known or suspected immunodeficiency, as determined by history and/or laboratory/physical examination	Initial Entry

2.e Criterion met?

Date	Location	User	Value	Reason
Aug-22-2020 09:27:37 (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
Aug-22-2020 09:27:37 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: EX08A00	Initial Entry

2.f

Date	Location	User	Value	Reason
Aug-22-2020 09:27:37 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Exclusion Number: Criterion Description: Bleeding diathesis or condition associated with prolonged bleeding that would, in the opinion of the investigator, contraindicate intramuscular injection	Initial Entry

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Header Text: C4591001

Visit: V1_DAY1_VAX1_L

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Site No: 1231

Subject No: 12312982

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

			<p>Criteria NO on met?:</p> <p>Criteria EX10A00 on ID: (For Pfizer use only):</p>
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2.f Exclusion Number:

Date	Location	User	Value	Reason
Aug-22-2020 09:27:37 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> 10	Initial Entry

2.f Criterion Description:

Date	Location	User	Value	Reason
Aug-22-2020 09:27:37 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> 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-22-2020 09:27:37 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NO	Initial Entry

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

Date	Location	User	Value	Reason
Aug-22-2020 09:27:37 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> EX10A00	Initial Entry

2.g

Date	Location	User	Value	Reason
Aug-22-2020 09:27:37	ACV0PFEINFP6000	(b) (6)	<u>Data Entry:</u>	Initial Entry

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Header Text: C4591001

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Site No: 1231

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Form Status: Data Complete, Locked, Frozen, Verified

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

Subject No: 12312982

Subject Initials: ---

Generated By: (b) (4)

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

(UTC-03:00) City of Buenos Aires		(b) (4), (b) (6)	Exclusion Number: Criterion Description: Women who are pregnant or breastfeeding Criterion met?: NO Criterion ID: (For Pfizer use only): EX11A00
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2.g Exclusion Number:

Date	Location	User	Value	Reason
Aug-22-2020 09:27:37 (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-22-2020 09:27:37 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Women who are pregnant or breastfeeding	Initial Entry

2.g Criterion met?

Date	Location	User	Value	Reason
Aug-22-2020 09:27:37 (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-22-2020 09:27:37 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: EX11A00	Initial Entry

2.h

Date	Location	User	Value	Reason
Aug-22-2020 09:27:37 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Exclusion Number: 12	Initial Entry

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Header Text: C4591001

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Site No: 1231

Subject No: 12312982

Generated By: (b) (4)

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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 Description: Previous vaccination with any coronavirus vaccine Criterion met?: NO Criterion ID: EX12A00 (For Pfizer use only):
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2.h Exclusion Number:

Date	Location	User	Value	Reason
Aug-22-2020 09:27:37 (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-22-2020 09:27:37 (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-22-2020 09:27:37 (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-22-2020 09:27:37 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: EX12A00	Initial Entry

2.i

Date	Location	User	Value	Reason
Aug-22-2020 09:27:37 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Exclusion Number: 13	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: 12312982

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 Description: Subjects who receive immunosuppressive therapy, such as cytotoxic agents or systemic corticosteroids Criterion met?: NO Criterion ID: (For Pfizer use only): EX13A01
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2.i Exclusion Number:

Date	Location	User	Value	Reason
Aug-22-2020 09:27:37 (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-22-2020 09:27:37 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Subjects who receive immunosuppressive therapy, such as cytotoxic agents or systemic corticosteroids	Initial Entry

2.i Criterion met?

Date	Location	User	Value	Reason
Aug-22-2020 09:27:37 (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
Aug-22-2020 09:27:37 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: EX13A01	Initial Entry

2.j

Date	Location	User	Value	Reason
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090177e196ae2e71\Final\Final On: 01-Apr-2021 03:13 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 21-Aug-2020 02:50

Site No: 1231

Subject No: 12312982

Generated By: (b) (4)

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Aug-22-2020 09:27:37 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 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 Printer use only): EX14A01	Initial Entry
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090177e196ae2e71\Final\Final On: 01-Apr-2021 03:13 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 21-Aug-2020 02:50

Site No: 1231

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 No: 12312982

Subject Initials: ---

Generated By: (b) (4)

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

2.j Exclusion Number:

Date	Location	User	Value	Reason
Aug-22-2020 09:27:37 (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-22-2020 09:27:37 (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-22-2020 09:27:37 (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
Aug-22-2020 09:27:37 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: EX14A01	Initial Entry

090177e196ae2e71\Final\Final On: 01-Apr-2021 03:13 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 21-Aug-2020 02:50

Site No: 1231

Subject No: 12312982

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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2.k				
Date	Location	User	Value	Reason
Aug-22-2020 09:27:37 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Exclusion Number: 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: (Former Pfizer use only): EX15A01	Initial Entry

090177e196ae2e71\Final\Final On: 01-Apr-2021 03:13 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 21-Aug-2020 02:50

Site No: 1231

Subject No: 12312982

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

2.k Exclusion Number:

Date	Location	User	Value	Reason
Aug-22-2020 09:27:37 (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-22-2020 09:27:37 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Participation in other studies involving study intervention within 28 days prior to study entry and/or during study participation	Initial Entry

2.k Criterion met?

Date	Location	User	Value	Reason
Aug-22-2020 09:27:37 (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
Aug-22-2020 09:27:37 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: EX15A01	Initial Entry

2.l

Date	Location	User	Value	Reason
Aug-22-2020 09:27:37 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Exclusion Number: Criterion Description: Previous participation in other studies involving study intervention containing lipid nanoparticles Criterion met?: NO	Initial Entry

090177e196ae2e71\Final\Final On: 01-Apr-2021 03:13 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 21-Aug-2020 02:50

Site No: 1231

Subject No: 12312982

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 ID: (For Pfizer use only):	EX16A01
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2.l Exclusion Number:

Date	Location	User	Value	Reason
Aug-22-2020 09:27:37 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 17	Initial Entry

2.l Criterion Description:

Date	Location	User	Value	Reason
Aug-22-2020 09:27:37 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Previous participation in other studies involving study intervention containing lipid nanoparticles	Initial Entry

2.l Criterion met?

Date	Location	User	Value	Reason
Aug-22-2020 09:27:37 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

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

Date	Location	User	Value	Reason
Aug-22-2020 09:27:37 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: EX16A01	Initial Entry

2.m

Date	Location	User	Value	Reason
Aug-22-2020 09:27:37 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Exclus 22 ion Number:	Initial Entry

090177e196ae2e71\Final\Final On: 01-Apr-2021 03:13 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 21-Aug-2020 02:50

Site No: 1231

Subject No: 12312982

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

			<p>Criteria: 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</p> <p>Criteria met?:</p> <p>Criteria ID: EX21A01 (For Pfizer use only):</p>	
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090177e196ae2e71\Final\Final On: 01-Apr-2021 03:13 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 21-Aug-2020 02:50

Site No: 1231

Subject No: 12312982

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

2.m Exclusion Number:

Date	Location	User	Value	Reason
Aug-22-2020 09:27:37 (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-22-2020 09:27:37 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 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	Initial Entry

2.m Criterion met?

Date	Location	User	Value	Reason
Aug-22-2020 09:27:37 (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)

Date	Location	User	Value	Reason
Aug-22-2020 09:27:37 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: EX21A01	Initial Entry

090177e196ae2e71\Final\Final On: 01-Apr-2021 03:13 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1231

Subject No: 12312982

Generated By: (b) (4)

Form: DISPOSITION - SCREENING - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

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1. Date of Completion/Discontinuation/Death

Date	Location	User	Value	Reason
Aug-22-2020 09:27:46 (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-22-2020 09:27:46 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SCREENING	Initial Entry

3. Status:

Date	Location	User	Value	Reason
Aug-22-2020 09:27:46 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: COMPLETED	Initial Entry

090177e196ae2e71\Final\Final On: 01-Apr-2021 03:13 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 21-Aug-2020 02:51

Site No: 1231

Subject No: 12312982

Generated By: (b) (4)

Form: VITAL SIGNS - BASELINE - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

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1. Date:

Date	Location	User	Value	Reason
Aug-22-2020 09:28:17 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Aug/21/2020	Initial Entry

2. Weight:

Date	Location	User	Value	Reason
Aug-22-2020 09:28:17 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> 83.5	Initial Entry

3. Unit:

Date	Location	User	Value	Reason
Aug-22-2020 09:28:17 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> kg	Initial Entry

4. Height:

Date	Location	User	Value	Reason
Aug-22-2020 09:28:17 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> 182.0	Initial Entry

5. Unit:

Date	Location	User	Value	Reason
Aug-22-2020 09:28:17 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> cm	Initial Entry

6. Body Mass Index:

Date	Location	User	Value	Reason
Aug-22-2020 09:28:17 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> 25.2	Initial Entry

090177e196ae2e71\Final\Final On: 01-Apr-2021 03:13 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 21-Aug-2020 02:51

Site No: 1231

Subject No: 12312982

Generated By: (b) (4)

Form: VITAL SIGNS - BASELINE - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

7.a

Date	Location	User	Value	Reason
Aug-22-2020 09:28:17 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Record Identifier:: 1 Temperature: 36.7 Temperature Unit: C Temperature Location:: ORAL CAVITY	Initial Entry

7.a Record Identifier:

Date	Location	User	Value	Reason
Aug-22-2020 09:28:17 (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-22-2020 09:28:17 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 36.7	Initial Entry

7.a Unit:

Date	Location	User	Value	Reason
Aug-22-2020 09:28:17 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: C	Initial Entry

7.a Temperature Location:

Date	Location	User	Value	Reason
Aug-22-2020 09:28:17 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: ORAL CAVITY	Initial Entry

090177e196ae2e71\Final\Final On: 01-Apr-2021 03:13 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1231

Subject No: 12312982

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

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1. Randomization Date :

Date	Location	User	Value	Reason
Aug-22-2020 09:28:25 (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-22-2020 09:28:25 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 61389	Initial Entry

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1231

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

Subject No: 12312982

Subject Initials: ---

Generated By: (b) (4)

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

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1. Data Origin

Date	Location	User	Value	Reason
Aug-23-2020 18:53:22 (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-23-2020 18:53:22 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SERUM	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Aug-23-2020 18:54:25 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Aug-23-2020 18:53:22 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Aug-23-2020 18:53:22 (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-23-2020 18:54:25 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BHY61W	Initial Entry

5.a Sample ID

090177e196ae2e71\Final\Final On: 01-Apr-2021 03:13 (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: 12312982

Subject Initials: ---

Generated By: (b) (4)

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

Date	Location	User	Value	Reason
Aug-23-2020 18:54:25 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BHY61W	Initial Entry

5.b

Date	Location	User	Value	Reason
Aug-23-2020 18:54:58 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BHY61X	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Aug-23-2020 18:54:58 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BHY61X	Initial Entry

5.c

Date	Location	User	Value	Reason
Aug-23-2020 18:55:36 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BHY61Y	Initial Entry

5.c Sample ID

Date	Location	User	Value	Reason
Aug-23-2020 18:55:36 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BHY61Y	Initial Entry

5.d

Date	Location	User	Value	Reason
Sep-04-2020 18:45:24 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BJ4998	Initial Entry

090177e196ae2e71\Final\Final On: 01-Apr-2021 03:13 (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: 12312982

Subject Initials: ---

Generated By: (b) (4)

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

5.d Sample ID

Date	Location	User	Value	Reason
Sep-04-2020 18:45:24 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BJ4998	Initial Entry

5.e

Date	Location	User	Value	Reason
Sep-04-2020 18:45:32 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BJ4999	Initial Entry

5.e Sample ID

Date	Location	User	Value	Reason
Sep-04-2020 18:45:32 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BJ4999	Initial Entry

5.f

Date	Location	User	Value	Reason
Sep-25-2020 12:28:23 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BJ4997	Initial Entry

5.f Sample ID

Date	Location	User	Value	Reason
Sep-25-2020 12:28:23 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BJ4997	Initial Entry

090177e196ae2e71\Final\Final On: 01-Apr-2021 03:13 (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: 12312982

Subject Initials: ---

Generated By: (b) (4)

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

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1. Data Origin

Date	Location	User	Value	Reason
Aug-25-2020 13:54:17 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Aug-25-2020 13:54:17 (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
Aug-25-2020 13:54:35 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Aug-25-2020 13:54:17 (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.
Aug-25-2020 13:54:17 (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 13:54:35 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BHY64K	Initial Entry

5.a Sample ID

090177e196ae2e71\Final\Final On: 01-Apr-2021 03:13 (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: 12312982

Subject Initials: ---

Generated By: (b) (4)

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

Date	Location	User	Value	Reason
Aug-25-2020 13:54:35 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BHY64K	Initial Entry

090177e196ae2e71\Final\Final On: 01-Apr-2021 03:13 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:04

Site No: 1231

Subject No: 12312982

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

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1. Was there a temporary delay of vaccination?

Date	Location	User	Value	Reason
Aug-22-2020 09:28:36 (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-22-2020 09:28:36 (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-22-2020 09:28:36 (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-22-2020 09:28:36 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Aug/21/2020 18:50	Initial Entry

5. Anatomical Location:

Date	Location	User	Value	Reason
Aug-22-2020 09:28:36 (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-22-2020 09:28:36 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: LEFT	Initial Entry

090177e196ae2e71\Final\Final On: 01-Apr-2021 03:13 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:04

Site No: 1231

Subject No: 12312982

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

7. Route:

Date	Location	User	Value	Reason
Aug-22-2020 09:28:36 (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
Aug-22-2020 09:28:36 (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
Aug-22-2020 09:28:36 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

090177e196ae2e71\Final\Final On: 01-Apr-2021 03:13 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 06-Jul-2020 21:53

Site No: 1231

Subject No: 12312982

Generated By: (b) (4)

Form: REACTOGENICITY DIARY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

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1. Select appropriate response - Reactogenicity diary collection

Date	Location	User	Value	Reason
Aug-22-2020 09:28:42 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO - REACTOGENICITY E-DIAR Y NOT COLLECTED FOR THIS S UBJECT	Initial Entry

Header Text: C4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:02

Site No: 1231

Subject No: 12312982

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

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I. Date of Visit

Date	Location	User	Value	Reason
Sep-23-2020 01:25:17 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	Salim Bouguermouh (b) (4)	Query 1: Closed	Response satisfies query
Sep-22-2020 11:54:48 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	SAE was a febrile syndrome secondary to severe reactogenicity related to the investigational product. Thank you.
Sep-14-2020 11:30:37 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	Salim Bouguermouh (b) (4)	Query 1: Opened	Clin: Per PA-5 - Sections 8.3.7. and 8.13., please COVID-19 related event PNEUMONIA reported as a SAE to Safety should trigger a COVID Illness Visit regardless of other potential diagnosis and a NASAL SWAB needs to be collected ASAP.
Sep-09-2020 17:07:43 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	Martina Davalli (b) (4)	Data Entry: Sep/9/2020	Initial Entry

090177e196ae2e71\Final\Final On: 01-Apr-2021 03:13 (GMT)

Header Text: C4591001

Visit: V2_VAX2_L

Form Version: 21-Aug-2020 02:51

Site No: 1231

Subject No: 12312982

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

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I. Date:

Date	Location	User	Value	Reason
Sep-09-2020 17:07:59 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	Martina Davalli (b) (4)	Data Entry: Sep/9/2020	Initial Entry

2.a

Date	Location	User	Value	Reason
Sep-09-2020 17:07:59 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	Martina Davalli (b) (4)	Data Entry: Record Identifier:: 1 Temperature: 37.0 Temperature Unit: C Temperature Location: ORAL CAVITY	Initial Entry

2.a Record Identifier:

Date	Location	User	Value	Reason
Sep-09-2020 17:07:59 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	Martina Davalli (b) (4)	Data Entry: 1	Initial Entry

2.a Temperature:

Date	Location	User	Value	Reason
Sep-09-2020 17:07:59 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	Martina Davalli (b) (4)	Data Entry: 37.0	Initial Entry

2.a Unit:

Date	Location	User	Value	Reason
Sep-09-2020 17:07:59 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	Martina Davalli (b) (4)	Data Entry: C	Initial Entry

2.a Temperature Location:

Date	Location	User	Value	Reason
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090177e196ae2e71\Final\Final On: 01-Apr-2021 03:13 (GMT)

Header Text: C4591001

Visit: V2_VAX2_L

Form Version: 21-Aug-2020 02:51

Site No: 1231

Subject No: 12312982

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

Sep-09-2020 17:07:59 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	Martina Davalli (b) (4)	Data Entry: ORAL CAVITY	Initial Entry
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090177e196ae2e71\Final\Final On: 01-Apr-2021 03:13 (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: 12312982

Subject Initials: ---

Generated By: (b) (4)

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

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1. Data Origin

Date	Location	User	Value	Reason
Sep-09-2020 17:08:04 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Sep-09-2020 17:08:04 (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
Sep-10-2020 10:45:21 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Sep-10-2020 02:13:06 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Sep-09-2020 17:08:04 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Sep-09-2020 17:08:04 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	Martina Davalli (b) (4)	Data Entry: YES Date of Collection: Sep/9/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
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090177e196ae2e71\Final\Final On: 01-Apr-2021 03:13 (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: 12312982

Subject Initials: ---

Generated By: (b) (4)

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

Sep-10-2020 10:45:21 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	Romina Barrera (b) (4)	Data Entry: Sample ID: BP1YWS	Initial Entry
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5.a Sample ID

Date	Location	User	Value	Reason
Sep-10-2020 10:45:21 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	Romina Barrera (b) (4)	Data Entry: BP1YWS	Initial Entry

090177e196ae2e71\Final\Final On: 01-Apr-2021 03:13 (GMT)

Header Text: C4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:04

Site No: 1231

Subject No: 12312982

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

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1. Was there a temporary delay of vaccination?

Date	Location	User	Value	Reason
Sep-09-2020 17:08:20 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	Martina Davalli (b) (4)	Data Entry: NO	Initial Entry

2. Treatment Name

Date	Location	User	Value	Reason
Sep-09-2020 17:08:20 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: BLINDED THERAPY	Initial Entry

3. Formulation:

Date	Location	User	Value	Reason
Sep-09-2020 17:08:20 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: INJECTION	Initial Entry

4. Dose Date Time:

Date	Location	User	Value	Reason
Sep-09-2020 17:08:20 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	Martina Davalli (b) (4)	Data Entry: Sep/9/2020 14:00	Initial Entry

5. Anatomical Location:

Date	Location	User	Value	Reason
Sep-09-2020 17:08:20 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: DELTOID MUSCLE	Initial Entry

6. Body Side:

Date	Location	User	Value	Reason
Sep-09-2020 17:08:20 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	Martina Davalli (b) (4)	Data Entry: LEFT	Initial Entry

090177e196ae2e71\Final\Final On: 01-Apr-2021 03:13 (GMT)

Header Text: C4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:04

Site No: 1231

Subject No: 12312982

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

7. Route:

Date	Location	User	Value	Reason
Sep-09-2020 17:08:20 (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
Sep-09-2020 17:08:20 (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
Sep-09-2020 17:08:20 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	Martina Davalli (b) (4)	Data Entry: YES	Initial Entry

090177e196ae2e71\Final\Final On: 01-Apr-2021 03:13 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Sep/12/2020 **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: 12312982

Subject Initials: ---

Generated By: (b) (4)

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

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I. Date of Visit

Date	Location	User	Value	Reason
Oct-31-2020 04:07:16 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Closed	Response satisfies query
Oct-30-2020 09:52:26 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Answered	The subject needed hospitalization and the sample was taken on September 12, by his private medicine service. No more data is available. No home visit was made by protocol. Thanks you
Oct-30-2020 07:55:22 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Opened	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.
Oct-28-2020 11:05:42 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 3: Candidate	Date of Visit is completed but Date of Collection in both Nasal Swab Self and Nasal Swab are missing. Please review and update as appropriate.
Oct-27-2020 12:33:12 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Oct-27-2020 12:20:01 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Deleted	Close Auto Query
Oct-27-2020 12:17:46 (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

090177e196ae2e71\Final\Final On: 01-Apr-2021 03:13 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on **Form:** DATE OF VISIT - ILLNESS ONSET - eCRF Audit Trail History
Sep/12/2020

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1231

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

Subject No: 12312982

Subject Initials: ---

Generated By: (b) (4)

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

				Signs and Symptoms form is missing. Please review and update as appropriate.
Oct-27-2020 12:17:46 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	Date of Visit is completed but Date of Collection in both Nasal Swab Self and Nasal Swab are missing. Please review and update as appropriate.
Oct-27-2020 12:17:46 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sep/12/2020	Initial Entry

3. COVID-19 Illness Visit:

Date	Location	User	Value	Reason
Oct-27-2020 12:17:46 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: COVID_A	Initial Entry

090177e196ae2e71\Final\Final On: 01-Apr-2021 03:13 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Sep/12/2020 Form: SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - eCRF Audit Trail History

Form Version: 10-Oct-2020 16:02

Form Status: Data Complete, Frozen, Verified

Site No: 1231

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

Subject No: 12312982

Subject Initials: ---

Generated By: (b) (4)

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

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1. Date of Assessment:

Date	Location	User	Value	Reason
Oct-27-2020 12:20:01 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sep/12/2020	Initial Entry

2. Date of First Symptom Started:

Date	Location	User	Value	Reason
Oct-27-2020 12:20:01 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sep/9/2020	Initial Entry

3. Symptoms Ongoing?

Date	Location	User	Value	Reason
Nov-03-2020 12:53:01 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Nov-03-2020 08:10:35 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	The volunteer has a pending convalescence visit schedule for his probable covid disease, the date of the visit will be agreed as soon as possible.
Nov-02-2020 18:26:40 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reissued:Opened	Please update the form and enter "Not Done" for this visit.
Nov-02-2020 15:43:46 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	withdraw consent by subject.will not done this visit
Oct-31-2020 15:52:08 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	DM: Subject has completed illness Visit and symptoms are resolved,

090177e196ae2e71\Final\Final On: 01-Apr-2021 03:13 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Sep/12/2020

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

Form Version: 10-Oct-2020 16:02

Form Status: Data Complete, Frozen, Verified

Site No: 1231

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

Subject No: 12312982

Subject Initials: ---

Generated By: (b) (4)

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

				however corresponding Convalescent Visit not yet initiated. Please review and update as appropriate. Thank you.
Oct-27-2020 12:20:01 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO Date of Last Symptom Resolved : Sep/12/2020	Initial Entry

4.a

Date	Location	User	Value	Reason
Oct-27-2020 12:20:01 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptoms: FEVER Symptom Present: YES	Initial Entry

4.a Symptoms:

Date	Location	User	Value	Reason
Oct-27-2020 12:20:01 (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-27-2020 12:20:01 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

4.b

Date	Location	User	Value	Reason
Oct-27-2020 12:20:01 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptoms: NEW OR INCREASED COUGH	Initial Entry

090177e196ae2e71\Final\Final On: 01-Apr-2021 03:13 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Sep/12/2020

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

Form Version: 10-Oct-2020 16:02

Form Status: Data Complete, Frozen, Verified

Site No: 1231

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

Subject No: 12312982

Subject Initials: ---

Generated By: (b) (4)

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

			Symptom P NO resent:	
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4.b Symptoms:

Date	Location	User	Value	Reason
Oct-27-2020 12:20:01 (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
Oct-27-2020 12:20:01 (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-27-2020 12:20:01 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sympto NEW OR INCREASED ms: SHORTNESS OF BREA TH Sympto NO m Presen t:	Initial Entry

4.c Symptoms:

Date	Location	User	Value	Reason
Oct-27-2020 12:20:01 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NEW OR INCREASED SHORTNE SS OF BREATH	Initial Entry

4.c Was symptom present?

Date	Location	User	Value	Reason
Oct-27-2020 12:20:01 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

4.d

090177e196ae2e71\Final\Final On: 01-Apr-2021 03:13 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Sep/12/2020

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

Form Version: 10-Oct-2020 16:02

Form Status: Data Complete, Frozen, Verified

Site No: 1231

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

Subject No: 12312982

Subject Initials: ---

Generated By: (b) (4)

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

Date	Location	User	Value	Reason
Oct-27-2020 12:20:01 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptoms: CHILLS Symptom Present: NO	Initial Entry

4.d Symptoms:

Date	Location	User	Value	Reason
Oct-27-2020 12:20:01 (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-27-2020 12:20:01 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

4.e

Date	Location	User	Value	Reason
Oct-27-2020 12:20:01 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptoms NEW OR INCREASE : D MUSCLE PAIN Symptom YES Present:	Initial Entry

4.e Symptoms:

Date	Location	User	Value	Reason
Oct-27-2020 12:20:01 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NEW OR INCREASED MUSCLE P AIN	Initial Entry

4.e Was symptom present?

Date	Location	User	Value	Reason
Oct-27-2020 12:20:01 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

090177e196ae2e71\Final\Final On: 01-Apr-2021 03:13 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Sep/12/2020

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

Form Version: 10-Oct-2020 16:02

Form Status: Data Complete, Frozen, Verified

Site No: 1231

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

Subject No: 12312982

Subject Initials: ---

Generated By: (b) (4)

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

4.f

Date	Location	User	Value	Reason
Oct-27-2020 12:20:01 (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

4.f Symptoms:

Date	Location	User	Value	Reason
Oct-27-2020 12:20:01 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NEW LOSS OF TASTE OR SMELL	Initial Entry

4.f Was symptom present?

Date	Location	User	Value	Reason
Oct-27-2020 12:20:01 (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-27-2020 12:20:01 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptoms: NEW OR INCREASE : D SORE THROAT Symptom Present: NO	Initial Entry

090177e196ae2e71\Final\Final On: 01-Apr-2021 03:13 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Sep/12/2020

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

Form Version: 10-Oct-2020 16:02

Form Status: Data Complete, Frozen, Verified

Site No: 1231

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

Subject No: 12312982

Subject Initials: ---

Generated By: (b) (4)

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

4.g Symptoms:

Date	Location	User	Value	Reason
Oct-27-2020 12:20:01 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NEW OR INCREASED SORE THR OAT	Initial Entry

4.g Was symptom present?

Date	Location	User	Value	Reason
Oct-27-2020 12:20:01 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

4.h

Date	Location	User	Value	Reason
Oct-27-2020 12:20:01 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptoms: DIARRHEA Symptom Present: NO	Initial Entry

4.h Symptoms:

Date	Location	User	Value	Reason
Oct-27-2020 12:20:01 (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-27-2020 12:20:01 (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-27-2020 12:20:01 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptoms: VOMITING Symptom Present: NO	Initial Entry

090177e196ae2e71\Final\Final On: 01-Apr-2021 03:13 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Sep/12/2020

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

Form Version: 10-Oct-2020 16:02

Form Status: Data Complete, Frozen, Verified

Site No: 1231

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

Subject No: 12312982

Subject Initials: ---

Generated By: (b) (4)

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

4.i Symptoms:

Date	Location	User	Value	Reason
Oct-27-2020 12:20:01 (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-27-2020 12:20:01 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

5.a

Date	Location	User	Value	Reason
Oct-27-2020 12:20:12 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptoms - Other: HEADACHE	Initial Entry

5.a Symptoms - Other Text:

Date	Location	User	Value	Reason
Oct-27-2020 12:20:12 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: HEADACHE	Initial Entry

5.b

Date	Location	User	Value	Reason
Oct-29-2020 15:29:25 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptoms - Other: nausea	Transcription Error
Oct-27-2020 12:20:30 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptoms - Other: SICKNESS	Initial Entry

090177e196ae2e71\Final\Final On: 01-Apr-2021 03:13 (GMT)

Header Text: C4591001**Visit:** POT_COVID_ILL 1 - Unscheduled Visit on Sep/12/2020**Form Version:** 10-Oct-2020 16:02**Site No:** 1231**Subject No:** 12312982**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**5.b Symptoms - Other Text:**

Date	Location	User	Value	Reason
Oct-30-2020 14:06:25 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Oct-29-2020 15:29:25 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: nausea	Transcription Error
Oct-29-2020 15:29:14 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Changed data per query
Oct-29-2020 13:08:05 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	CRA: please note that medical note mentions as well Nausea, dark urine and dizziness. Verify and include accordingly. Thanks.
Oct-27-2020 12:20:30 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: SICKNESS	Initial Entry

5.c

Date	Location	User	Value	Reason
Oct-29-2020 15:27:00 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptoms - Other: dark urine	Initial Entry

5.c Symptoms - Other Text:

Date	Location	User	Value	Reason
Oct-29-2020 15:27:00 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: dark urine	Initial Entry

5.d

Date	Location	User	Value	Reason
Oct-29-2020 15:27:31 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (6)	Data Entry: Symptoms - Other: dizziness	Initial Entry

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Sep/12/2020 **Form:** SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - eCRF Audit Trail History

Form Version: 10-Oct-2020 16:02

Form Status: Data Complete, Frozen, Verified

Site No: 1231

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

Subject No: 12312982

Subject Initials: ---

Generated By: (b) (4)

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

Buenos Aires

(b) (4)

5.d Symptoms - Other Text:

Date	Location	User	Value	Reason
Oct-29-2020 15:27:31 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: dizziness	Initial Entry

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on **Form:** MICROBIOLOGY SPECIMEN - Audit Trail
Sep/12/2020

Form Version: 06-Jul-2020 21:54

Form Status:

Site No: 1231

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

Subject No: 12312982

Subject Initials: ---

Generated By: (b) (4)

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

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Date	Location	User	Value	Reason
Oct-27-2020 12:21:51 (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 Form: MICROBIOLOGY SPECIMEN - eCRF Audit Trail History
Sep/12/2020

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: 12312982

Subject Initials: ---

Generated By: (b) (4)

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

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1. Actual Date of Collection:

Date	Location	User	Value	Reason
Oct-27-2020 12:21:51 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sep/12/2020	Initial Entry

2. Specimen Type:

Date	Location	User	Value	Reason
Oct-27-2020 12:21:51 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: SWABBED MATERIAL	Initial Entry

3. Specimen Collection Location:

Date	Location	User	Value	Reason
Oct-27-2020 12:21:51 (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-27-2020 12:21:51 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SEVERE ACUTE RESP SYNDROM E CORONAVIRUS 2	Initial Entry

5. Device Type:

Date	Location	User	Value	Reason
Oct-27-2020 12:21:51 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SARS-COV-2 DIAGNOSTIC TEST	Initial Entry

6. Trade Name:

Date	Location	User	Value	Reason
Oct-27-2020 12:21:51 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: OTHER	Initial Entry

090177e196ae2e71\Final\Final On: 01-Apr-2021 03:13 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on **Form:** MICROBIOLOGY SPECIMEN - eCRF Audit Trail History
Sep/12/2020

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: 12312982

Subject Initials: ---

Generated By: (b) (4)

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

7. Test Result:

Date	Location	User	Value	Reason
Oct-27-2020 12:21:51 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NEGATIVE	Initial Entry

9. Trade Name Other, Specify:

Date	Location	User	Value	Reason
Oct-27-2020 12:21:51 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NALT Unknown	Initial Entry

090177e196ae2e71\Final\Final On: 01-Apr-2021 03:13 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Sep/12/2020 **Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB SELF - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1231

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

Subject No: 12312982

Subject Initials: ---

Generated By: (b) (4)

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

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1. Data Origin

Date	Location	User	Value	Reason
Oct-27-2020 12:31:42 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Oct-27-2020 12:31:42 (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
Oct-27-2020 12:31:42 (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
Oct-27-2020 12:31:42 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample collected by team physician	Initial Entry

090177e196ae2e71\Final\Final On: 01-Apr-2021 03:13 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Sep/12/2020 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: 12312982

Subject Initials: ---

Generated By: (b) (4)

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

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I. Data Origin

Date	Location	User	Value	Reason
Oct-29-2020 15:57:32 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry
Oct-28-2020 11:05:42 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry:	Transcription Error
Oct-27-2020 12:33:12 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Oct-29-2020 15:57:32 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: NASAL_SWAB	Initial Entry
Oct-28-2020 11:05:42 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry:	Transcription Error
Oct-27-2020 12:33:12 (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
Oct-30-2020 10:13:53 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Closed	Closing as other query open for missing sample
Oct-29-2020 15:57:32 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 3: Answered	Initial Entry
Oct-29-2020 15:57:32 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

090177e196ae2e71\Final\Final On: 01-Apr-2021 03:13 (GMT)

Header Text: C4591001**Visit:** POT_COVID_ILL 1 - Unscheduled Visit on Sep/12/2020**Form Version:** 22-Apr-2020 21:03**Site No:** 1231**Subject No:** 12312982**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

Oct-29-2020 03:55:51 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Opened	DM: Kindly review the form and update.
Oct-28-2020 11:05:42 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Closed	Close Auto Query
Oct-28-2020 11:05:42 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Oct-28-2020 11:05:42 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Transcription Error
Oct-28-2020 11:04:58 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Opened	Date of Collection 09/Sep/2020 is different from Date of Visit 12/Sep/2020. Please review and update as appropriate, else clarify.
Oct-28-2020 11:04:58 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Date of Collection: Sep/9/2020	Transcription Error
Oct-28-2020 07:38:29 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Oct-27-2020 12:33:12 (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.
Oct-27-2020 12:33:12 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Date of Collection:	Initial Entry

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Sep/12/2020 **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: 12312982

Subject Initials: ---

Generated By: (b) (4)

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

			Sep/12/2020	
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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 15:57:32 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not applicable	Initial Entry

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Sep/12/2020 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: 12312982

Subject Initials: ---

Generated By: (b) (4)

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

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I.a

Date	Location	User	Value	Reason
Oct-27-2020 12:34:26 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Type of Practitioner: SPECIALIST Occurrence of Visits or Contacts: NO	Initial Entry

I.a Physician or Healthcare Professional:

Date	Location	User	Value	Reason
Oct-27-2020 12:34:26 (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-27-2020 12:34:26 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

I.b

Date	Location	User	Value	Reason
Oct-27-2020 12:34:26 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Type of Practitioner: EMERGENCY ROOM Occurrence of Visits or Contacts: NO	Initial Entry

090177e196ae2e71\Final\Final On: 01-Apr-2021 03:13 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on **Form:** HEALTH CARE UTILIZATION - eCRF Audit Trail History
Sep/12/2020

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: 12312982

Subject Initials: ---

Generated By: (b) (4)

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

I.b Physician or Healthcare Professional:

Date	Location	User	Value	Reason
Oct-27-2020 12:34:26 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: EMERGENCY ROOM	Initial Entry

I.b Occurrence of Visits or Contacts:

Date	Location	User	Value	Reason
Oct-27-2020 12:34:26 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

I.c

Date	Location	User	Value	Reason
Oct-29-2020 15:33:11 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Type of Practitioner: PRIMARY CARE PHYSICIAN Occurrence of Visits or Contacts: YES <i>Number of Visits or Contacts:</i> 2	Transcription Error
Oct-27-2020 12:34:26 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Type of Practitioner: PRIMARY CARE PHYSICIAN Occurrence of Visits or Contacts: NO	Initial Entry

090177e196ae2e71\Final\Final On: 01-Apr-2021 03:13 (GMT)

Header Text: C4591001**Visit:** POT_COVID_ILL 1 - Unscheduled Visit on **Form:** HEALTH CARE UTILIZATION - eCRF Audit Trail History
Sep/12/2020**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:** 12312982**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 20:20**I.c Physician or Healthcare Professional:**

Date	Location	User	Value	Reason
Oct-27-2020 12:34:26 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: PRIMARY CARE PHYSICIAN	Initial Entry

I.c Occurrence of Visits or Contacts:

Date	Location	User	Value	Reason
Oct-30-2020 14:05:53 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Oct-29-2020 15:33:11 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Transcription Error
Oct-29-2020 15:33:11 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES <i>Number of Visits or Contacts:</i> 2	Transcription Error
Oct-29-2020 13:20:57 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	CRA: please note that medical chart refers that subject contacted his primary physician twice. Review and update accordingly. Thanks.
Oct-27-2020 12:34:26 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

I.d

Date	Location	User	Value	Reason
Oct-27-2020 12:34:26 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Type of Practitioner: URGENT CARE	Initial Entry

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on **Form:** HEALTH CARE UTILIZATION - eCRF Audit Trail History
Sep/12/2020

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: 12312982

Subject Initials: ---

Generated By: (b) (4)

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

			Occurrence of Visits or Contacts: YES <i>Number of Visits or Contacts:</i> 1	
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I.d Physician or Healthcare Professional:

Date	Location	User	Value	Reason
Oct-27-2020 12:34:26 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: URGENT CARE	Initial Entry

I.d Occurrence of Visits or Contacts:

Date	Location	User	Value	Reason
Oct-27-2020 12:34:26 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES <i>Number of Visits or Contacts:</i> 1	Initial Entry

I.e

Date	Location	User	Value	Reason
Oct-27-2020 12:34:26 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Type of Practitioner: TELEPHONE CONSULTATION Occurrence of Visits or Contacts: NO	Initial Entry

090177e196ae2e71\Final\Final On: 01-Apr-2021 03:13 (GMT)

Header Text: C4591001**Visit:** POT_COVID_ILL 1 - Unscheduled Visit on **Form:** HEALTH CARE UTILIZATION - eCRF Audit Trail History
Sep/12/2020**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:** 12312982**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 20:20***I.e Physician or Healthcare Professional:***

Date	Location	User	Value	Reason
Oct-27-2020 12:34:26 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: TELEPHONE CONSULTATION	Initial Entry

I.e Occurrence of Visits or Contacts:

Date	Location	User	Value	Reason
Oct-27-2020 12:34:26 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

I.f

Date	Location	User	Value	Reason
Oct-27-2020 12:34:26 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Type of Practitioner: OTH R Occurrence of Visits or Co ntacts: NO	Initial Entry

I.f Physician or Healthcare Professional:

Date	Location	User	Value	Reason
Oct-27-2020 12:34:26 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: OTHER	Initial Entry

I.f Occurrence of Visits or Contacts:

Date	Location	User	Value	Reason
Oct-27-2020 12:34:26 (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-27-2020 12:34:26 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Has the subject been in intensive ca	Initial Entry

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Sep/12/2020 **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: 12312982

Subject Initials: ---

Generated By: (b) (4)

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

			re due to potential COVID-19 illnesses?	
			NO	

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Sep/12/2020 **Form:** HOSPITALIZATION DETAILS - 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: 12312982

Subject Initials: ---

Generated By: (b) (4)

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

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Date	Location	User	Value	Reason
Oct-27-2020 13:13:26 (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/12/2020 Form: HOSPITALIZATION DETAILS - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen, Verified

Site No: 1231

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

Subject No: 12312982

Subject Initials: ---

Generated By: (b) (4)

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

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1. Hospitalization Category:

Date	Location	User	Value	Reason
Oct-27-2020 13:13:26 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: HOSPITALIZATION STATUS	Initial Entry

2. Hospitalization Term:

Date	Location	User	Value	Reason
Nov-30-2020 17:15:44 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	Rupal N Shah (b) (4)	Query 1: Closed	Response satisfies query
Nov-29-2020 19:11:36 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	The subject had no probable clinical signs of severe systemic disease at rest during his Covid-19 illness. It did not require respiratory treatment. Images and lab results were uploaded. Some lab results are unknown
Nov-29-2020 14:09:32 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	Rupal N Shah (b) (4)	Query 1: Opened	CLIQUEY: This subject was hospitalized. Please enter on the CRF form any available information (vital signs, pulse oxymet, respiratory treatment, lab results, imaging...). Please make every effort to obtain these information
Oct-27-2020 13:13:26 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: HOSPITAL	Initial Entry

090177e196ae2e71\Final\Final On: 01-Apr-2021 03:13 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on **Form:** HOSPITALIZATION DETAILS - eCRF Audit Trail History
Sep/12/2020

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen, Verified

Site No: 1231

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

Subject No: 12312982

Subject Initials: ---

Generated By: (b) (4)

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

3. Admission Date:

Date	Location	User	Value	Reason
Oct-27-2020 13:13:26 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sep/12/2020	Initial Entry

4. Ongoing?

Date	Location	User	Value	Reason
Oct-27-2020 13:13:26 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO Discharge Date: Sep/13/2020	Initial Entry

090177e196ae2e71\Final\Final On: 01-Apr-2021 03:13 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on **Form:** ILLNESS DETAILS - eCRF Audit Trail History
Sep/12/2020

Form Version: 06-Jul-2020 21:52

Form Status: Data Complete, Frozen, Verified

Site No: 1231

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

Subject No: 12312982

Subject Initials: ---

Generated By: (b) (4)

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

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1. Category of Clinical Event:

Date	Location	User	Value	Reason
Oct-27-2020 12:35:47 (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-27-2020 12:35:47 (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-27-2020 12:35:47 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 2	Initial Entry

090177e196ae2e71\Final\Final On: 01-Apr-2021 03:13 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Sep/12/2020 **Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY - Audit Trail

Form Version: 21-Aug-2020 02:49

Form Status:

Site No: 1231

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

Subject No: 12312982

Subject Initials: ---

Generated By: (b) (4)

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

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Date	Location	User	Value	Reason
Oct-29-2020 15:36:37 (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/12/2020

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:49

Form Status: Data Complete, Frozen, Verified

Site No: 1231

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

Subject No: 12312982

Subject Initials: ---

Generated By: (b) (4)

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

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1. Lab Panel:

Date	Location	User	Value	Reason
Oct-29-2020 15:37:38 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: CLINICAL CHEMISTRY	Initial Entry

2. Laboratory Name and Address

Date	Location	User	Value	Reason
Oct-30-2020 14:08:06 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Oct-29-2020 15:38:36 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Initial Entry
Oct-29-2020 15:38:36 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Hospital Aleman, Av. Pueyrredon 1640, C1118 AAT, Buenos Aires, Argentina	Initial Entry
Oct-29-2020 13:22:35 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	CRA: please update this CRF as per medical note. Thanks.

3. Collection Date:

Date	Location	User	Value	Reason
Oct-29-2020 15:37:38 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sep/12/2020	Initial Entry

4. Specimen Type:

Date	Location	User	Value	Reason
Oct-29-2020 15:37:38 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: BLOOD	Initial Entry

5.a

090177e196ae2e71\Final\Final On: 01-Apr-2021 03:13 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Sep/12/2020

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:49

Form Status: Data Complete, Frozen, Verified

Site No: 1231

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

Subject No: 12312982

Subject Initials: ---

Generated By: (b) (4)

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

Date	Location	User	Value	Reason
Oct-29-2020 15:34:06 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sponsor-Defined Identifier: Unknwn Test: Unknwn Result: Unknwn Not Done: Unknwn Lab Normal Range: Unknwn	Initial Entry

5.a Sponsor ID:

Date	Location	User	Value	Reason
Oct-29-2020 15:34:06 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Unknown	Initial Entry

5.a Test:

Date	Location	User	Value	Reason
Oct-29-2020 15:34:06 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Unknown	Initial Entry

5.a Result:

Date	Location	User	Value	Reason
Oct-29-2020 15:34:06 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Unknown	Initial Entry

5.a Not Done:

Date	Location	User	Value	Reason
Oct-29-2020 15:34:06 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Unknown	Initial Entry

5.a LNMT

090177e196ae2e71\Final\Final On: 01-Apr-2021 03:13 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Sep/12/2020

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:49

Form Status: Data Complete, Frozen, Verified

Site No: 1231

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

Subject No: 12312982

Subject Initials: ---

Generated By: (b) (4)

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

Date	Location	User	Value	Reason
Oct-29-2020 15:34:06 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Unknown	Initial Entry

5.b

Date	Location	User	Value	Reason
Oct-29-2020 15:34:24 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sponsor-Defined Identifier: Unknown Test:: Alanine Aminotransferase_PX30 Result:: Unknown Not Done:: Unknown Lab Normal Range: Unknown	Initial Entry
Oct-29-2020 15:34:06 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sponsor-Defined Identifier: Test:: Alanine Aminotransferase_PX30 Result:: Not Done:: Lab Normal Range:	Initial Entry

090177e196ae2e71\Final\Final On: 01-Apr-2021 03:13 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Sep/12/2020

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:49

Form Status: Data Complete, Frozen, Verified

Site No: 1231

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

Subject No: 12312982

Subject Initials: ---

Generated By: (b) (4)

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

5.b Sponsor ID:

Date	Location	User	Value	Reason
Oct-29-2020 15:34:24 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Unknown	Initial Entry

5.b Test:

Date	Location	User	Value	Reason
Oct-29-2020 15:34:06 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Alanine Aminotransferase_PX30	Initial Entry

5.b Result:

Date	Location	User	Value	Reason
Oct-29-2020 15:34:24 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Unknown	Initial Entry

5.b Not Done:

Date	Location	User	Value	Reason
Oct-29-2020 15:34:24 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Unknown	Initial Entry

5.b LNMT

Date	Location	User	Value	Reason
Oct-29-2020 15:34:24 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Unknown	Initial Entry

5.c

Date	Location	User	Value	Reason
Oct-29-2020 15:34:52 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Sponsor-Defined Identifier : Unknown	Initial Entry

090177e196ae2e71\Final\Final On: 01-Apr-2021 03:13 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Sep/12/2020

Form Version: 21-Aug-2020 02:49

Site No: 1231

Subject No: 12312982

Generated By: (b) (4)

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY - 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

			Test:: Aspartate Aminotransferase_PX28 Result:: Unknown Not Done:: Unknown Lab Normal Range: Unknown	
Oct-29-2020 15:34:06 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sponsor-Defined Identifier: Test:: Aspartate Aminotransferase_PX28 Result:: Not Done:: Lab Normal Range:	Initial Entry

090177e196ae2e71\Final\Final On: 01-Apr-2021 03:13 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Sep/12/2020

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:49

Form Status: Data Complete, Frozen, Verified

Site No: 1231

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

Subject No: 12312982

Subject Initials: ---

Generated By: (b) (4)

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

5.c Sponsor ID:

Date	Location	User	Value	Reason
Oct-29-2020 15:34:52 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Unknown	Initial Entry

5.c Test:

Date	Location	User	Value	Reason
Oct-29-2020 15:34:06 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Aspartate Aminotransferase_PX2 8	Initial Entry

5.c Result:

Date	Location	User	Value	Reason
Oct-29-2020 15:34:52 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Unknown	Initial Entry

5.c Not Done:

Date	Location	User	Value	Reason
Oct-29-2020 15:34:52 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Unknown	Initial Entry

5.c LNMT

Date	Location	User	Value	Reason
Oct-29-2020 15:34:52 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Unknown	Initial Entry

5.d

Date	Location	User	Value	Reason
Oct-29-2020 15:35:19 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sponsor-Defined Identifier: Test:: Alkaline Phosphatase_PX35	Initial Entry

090177e196ae2e71\Final\Final On: 01-Apr-2021 03:13 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Sep/12/2020

Form Version: 21-Aug-2020 02:49

Site No: 1231

Subject No: 12312982

Generated By: (b) (4)

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY - 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

			Result:: Unknown Not Done:: Unknown Lab Normal Range: Unknown	
Oct-29-2020 15:34:06 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sponsor-Defined Identifier: Test:: Alkaline Phosphatase_PX35 Result:: Not Done:: Lab Normal Range:	Initial Entry

090177e196ae2e71\Final\Final On: 01-Apr-2021 03:13 (GMT)

Header Text: C4591001**Visit:** POT_COVID_ILL 1 - Unscheduled Visit on Sep/12/2020**Form Version:** 21-Aug-2020 02:49**Site No:** 1231**Subject No:** 12312982**Generated By:** (b) (4)**Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY - 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.d Sponsor ID:**

Date	Location	User	Value	Reason
Oct-29-2020 15:35:19 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Unknown	Initial Entry

5.d Test:

Date	Location	User	Value	Reason
Oct-29-2020 15:34:06 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Alkaline Phosphatase_PX35	Initial Entry

5.d Result:

Date	Location	User	Value	Reason
Oct-29-2020 15:35:19 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Unknown	Initial Entry

5.d Not Done:

Date	Location	User	Value	Reason
Oct-29-2020 15:35:19 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Unknown	Initial Entry

5.d LNMT

Date	Location	User	Value	Reason
Oct-29-2020 15:35:19 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Unknown	Initial Entry

5.e

Date	Location	User	Value	Reason
Oct-29-2020 15:35:34 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sponsor-Defined Id Unknown Test:: Bilirubin_P X21	Initial Entry

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Sep/12/2020

Form Version: 21-Aug-2020 02:49

Site No: 1231

Subject No: 12312982

Generated By: (b) (4)

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY - 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

			Result:: Unknown Not Done:: Unknown Lab Normal Range: Unknown	
Oct-29-2020 15:34:06 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sponsor-Defined Identifier: Test:: Bilirubin_P X21 Result:: Not Done:: Lab Normal Range:	Initial Entry

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Sep/12/2020

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:49

Form Status: Data Complete, Frozen, Verified

Site No: 1231

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

Subject No: 12312982

Subject Initials: ---

Generated By: (b) (4)

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

5.e Sponsor ID:

Date	Location	User	Value	Reason
Oct-29-2020 15:35:34 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Unknown	Initial Entry

5.e Test:

Date	Location	User	Value	Reason
Oct-29-2020 15:34:06 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Bilirubin_PX21	Initial Entry

5.e Result:

Date	Location	User	Value	Reason
Oct-29-2020 15:35:34 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Unknown	Initial Entry

5.e Not Done:

Date	Location	User	Value	Reason
Oct-29-2020 15:35:34 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Unknown	Initial Entry

5.e LNMT

Date	Location	User	Value	Reason
Oct-29-2020 15:35:34 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Unknown	Initial Entry

5.f

Date	Location	User	Value	Reason
Oct-29-2020 15:35:47 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sponsor-Defined Identifier: Test:: Blood Urea Nitrogen_PX47	Initial Entry

090177e196ae2e71\Final\Final On: 01-Apr-2021 03:13 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Sep/12/2020

Form Version: 21-Aug-2020 02:49

Site No: 1231

Subject No: 12312982

Generated By: (b) (4)

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY - 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

			Result:: Unknown Not Done:: Unknown Lab Normal Range: Unknown	
Oct-29-2020 15:34:06 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sponsor-Defined Identifier: Test:: Blood Urea Nitrogen_PX47 Result:: Not Done:: Lab Normal Range:	Initial Entry

090177e196ae2e71\Final\Final On: 01-Apr-2021 03:13 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Sep/12/2020

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:49

Form Status: Data Complete, Frozen, Verified

Site No: 1231

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

Subject No: 12312982

Subject Initials: ---

Generated By: (b) (4)

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

5.f Sponsor ID:

Date	Location	User	Value	Reason
Oct-29-2020 15:35:47 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Unknown	Initial Entry

5.f Test:

Date	Location	User	Value	Reason
Oct-29-2020 15:34:06 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Blood Urea Nitrogen_PX47	Initial Entry

5.f Result:

Date	Location	User	Value	Reason
Oct-29-2020 15:35:47 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Unknown	Initial Entry

5.f Not Done:

Date	Location	User	Value	Reason
Oct-29-2020 15:35:47 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Unknown	Initial Entry

5.f LNMT

Date	Location	User	Value	Reason
Oct-29-2020 15:35:47 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Unknown	Initial Entry

5.g

Date	Location	User	Value	Reason
Oct-30-2020 09:41:49 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sponsor-Defined I 48 Test:: Creatinine_PX48	New Information

090177e196ae2e71\Final\Final On: 01-Apr-2021 03:13 (GMT)

Header Text: C4591001**Visit:** POT_COVID_ILL 1 - Unscheduled Visit on Sep/12/2020**Form Version:** 21-Aug-2020 02:49**Site No:** 1231**Subject No:** 12312982**Generated By:** (b) (4)**Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY - 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

			Result:: 1.21 Not Done:: Lab Normal Range: <i>Low</i> e: 0.7 <i>High</i> 1.3 <i>Unit</i> mg/dL	
Oct-30-2020 09:34:38 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sponsor-Defined Identifier: 48 Test:: Creatinine_PX48 Result:: 1.21 Not Done:: Lab Normal Range: <i>Unit</i> e: mg/dL	Transcription Error
Oct-30-2020 09:31:55 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sponsor-Defined Identifier: 48 Test:: Creatinine_PX48 Result:: 1.21 mg / dl Not Done:: Lab Normal Range: <i>Unit</i> e: mg/dL	Transcription Error
Oct-29-2020 15:36:37 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sponsor-Defined Identifier: 48 Test:: Creatinine_PX48 Result:: 1.21 Not Done:: Lab Normal Range: <i>Unit</i> e: mg/dL	Initial Entry
Oct-29-2020 15:34:06 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sponsor-Defined Identifier:	Initial Entry

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Sep/12/2020

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:49

Form Status: Data Complete, Frozen, Verified

Site No: 1231

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

Subject No: 12312982

Subject Initials: ---

Generated By: (b) (4)

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

			Test:: Creatinine_PX48	
			Result::	
			Not Done::	
			Lab Normal Range:	

5.g Sponsor ID:

Date	Location	User	Value	Reason
Oct-29-2020 15:36:37 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 48	Initial Entry

5.g Test:

Date	Location	User	Value	Reason
Oct-29-2020 15:34:06 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Creatinine_PX48	Initial Entry

5.g Result:

Date	Location	User	Value	Reason
Oct-30-2020 09:41:49 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Oct-30-2020 09:34:38 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 1.21	Transcription Error

090177e196ae2e71\Final\Final On: 01-Apr-2021 03:13 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Sep/12/2020

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:49

Form Status: Data Complete, Frozen, Verified

Site No: 1231

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

Subject No: 12312982

Subject Initials: ---

Generated By: (b) (4)

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

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5.g Result:

Date	Location	User	Value	Reason
Oct-30-2020 09:31:55 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	Result is present, but lab normal range (Low, high or Unit) is missing. Please correct or confirm.
Oct-30-2020 09:31:55 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 1.21 mg / dl	Transcription Error
Oct-30-2020 04:41:52 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reissued:Opened	DM: Thank you for your response. Please check to update lab normal range (low, high) as per available unit.
Oct-29-2020 15:37:28 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	laboratory data were collected from the patient's epicirisis. There is no lab report specifying the normal ranges or the method they used. The values of th leukocyte formula are not known either since they are not reported in epicirisis.
Oct-29-2020 15:36:37 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	Result is present, but lab normal range (Low, high or Unit) is missing. Please correct or confirm.
Oct-29-2020 15:36:37 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 1.21	Initial Entry

5.g LNMT

Date	Location	User	Value	Reason
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090177e196ae2e71\Final\Final On: 01-Apr-2021 03:13 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Sep/12/2020

Form Version: 21-Aug-2020 02:49

Site No: 1231

Subject No: 12312982

Generated By: (b) (4)

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY - 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-30-2020 09:41:49 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: <i>Low</i> 0.7 <i>High</i> 1.3 <i>Unit</i> mg/dL	New Information
Oct-29-2020 15:36:37 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: <i>Unit</i> mg/dL	Initial Entry

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Sep/12/2020 **Form:** LOCAL LABORATORY DATA - REPEATING Hematology - Audit Trail

Form Version: 21-Aug-2020 02:51

Form Status:

Site No: 1231

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

Subject No: 12312982

Subject Initials: ---

Generated By: (b) (4)

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

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Date	Location	User	Value	Reason
Oct-29-2020 15:54:41 (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/12/2020**Form Version:** 21-Aug-2020 02:51**Site No:** 1231**Subject No:** 12312982**Generated By:** (b) (4)**Form:** LOCAL LABORATORY DATA - REPEATING Hematology - 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. Lab Panel:**

Date	Location	User	Value	Reason
Oct-29-2020 15:54:41 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: HEMATOLOGY	Initial Entry

2. Laboratory Name and Address

Date	Location	User	Value	Reason
Oct-30-2020 14:08:32 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Oct-29-2020 15:54:41 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Initial Entry
Oct-29-2020 15:54:41 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Hospital Aleman, Av. Pueyrredon 1640, C1118 AAT, Buenos Aires, Argentina	Initial Entry
Oct-29-2020 13:23:22 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	CRA: please update this CRF as per medical note although all results are unknown. Thanks.

3. Collection Date:

Date	Location	User	Value	Reason
Oct-29-2020 15:54:41 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sep/12/2020	Initial Entry

4. Specimen Type:

Date	Location	User	Value	Reason
Oct-29-2020 15:54:41 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: BLOOD	Initial Entry

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Sep/12/2020

Form: LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:51

Form Status: Data Complete, Frozen, Verified

Site No: 1231

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

Subject No: 12312982

Subject Initials: ---

Generated By: (b) (4)

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

5.a

Date	Location	User	Value	Reason
Oct-29-2020 15:55:24 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sponsor-Defined Identifier: Unknown Test:: Hemoglobin_PX1 Result:: Unknown Not Done:: Unknown Lab Normal Range: Unknown	Initial Entry
Oct-29-2020 15:54:41 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sponsor-Defined Identifier: Test:: Hemoglobin_PX1 Result:: Not Done:: Lab Normal Range:	Initial Entry

5.a Sponsor ID:

Date	Location	User	Value	Reason
Oct-29-2020 15:55:24 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Unknown	Initial Entry

5.a Test:

Date	Location	User	Value	Reason
Oct-29-2020 15:54:41 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Hemoglobin_PX1	Initial Entry

5.a Result:

Date	Location	User	Value	Reason
Oct-29-2020 15:55:24 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Unknown	Initial Entry

090177e196ae2e71\Final\Final On: 01-Apr-2021 03:13 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Sep/12/2020

Form: LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:51

Form Status: Data Complete, Frozen, Verified

Site No: 1231

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

Subject No: 12312982

Subject Initials: ---

Generated By: (b) (4)

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

5.a Not Done:

Date	Location	User	Value	Reason
Oct-29-2020 15:55:24 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Unknown	Initial Entry

5.a LNMT

Date	Location	User	Value	Reason
Oct-29-2020 15:55:24 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Unknown	Initial Entry

5.b

Date	Location	User	Value	Reason
Oct-29-2020 15:55:34 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sponsor-Defined Identifier: Unknown Test:: Hematocrit_PX2 Result:: Unknown Not Done:: Unknown Lab Normal Range Unknown :	Initial Entry
Oct-29-2020 15:54:41 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sponsor-Defined Identifier: Unknown Test:: Hematocrit_PX2 Result:: Not Done:: Lab Normal Range :	Initial Entry

090177e196ae2e71\Final\Final On: 01-Apr-2021 03:13 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Sep/12/2020

Form: LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:51

Form Status: Data Complete, Frozen, Verified

Site No: 1231

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

Subject No: 12312982

Subject Initials: ---

Generated By: (b) (4)

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

5.b Sponsor ID:

Date	Location	User	Value	Reason
Oct-29-2020 15:55:34 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Unknown	Initial Entry

5.b Test:

Date	Location	User	Value	Reason
Oct-29-2020 15:54:41 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Hematocrit_PX2	Initial Entry

5.b Result:

Date	Location	User	Value	Reason
Oct-29-2020 15:55:34 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Unknown	Initial Entry

5.b Not Done:

Date	Location	User	Value	Reason
Oct-29-2020 15:55:34 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Unknown	Initial Entry

5.b LNMT

Date	Location	User	Value	Reason
Oct-29-2020 15:55:34 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Unknown	Initial Entry

5.c

Date	Location	User	Value	Reason
Oct-29-2020 15:56:19 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sponsor-Defined I Unknown Test:: Erythrocytes_PX3	Initial Entry

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Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Sep/12/2020

Form: LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:51

Form Status: Data Complete, Frozen, Verified

Site No: 1231

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

Subject No: 12312982

Subject Initials: ---

Generated By: (b) (4)

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

			Result:: Unknown Not Done:: Unknown Lab Normal Range: Unknown	
Oct-29-2020 15:54:41 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sponsor-Defined Identifier: Test:: Erythrocytes_PX3 Result:: Not Done:: Lab Normal Range:	Initial Entry

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Sep/12/2020

Form: LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

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Form Status: Data Complete, Frozen, Verified

Site No: 1231

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

Subject No: 12312982

Subject Initials: ---

Generated By: (b) (4)

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

5.c Sponsor ID:

Date	Location	User	Value	Reason
Oct-29-2020 15:56:19 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Unknown	Initial Entry

5.c Test:

Date	Location	User	Value	Reason
Oct-29-2020 15:54:41 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Erythrocytes_PX3	Initial Entry

5.c Result:

Date	Location	User	Value	Reason
Oct-29-2020 15:56:19 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Unknown	Initial Entry

5.c Not Done:

Date	Location	User	Value	Reason
Oct-29-2020 15:56:19 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Unknown	Initial Entry

5.c LNMT

Date	Location	User	Value	Reason
Oct-29-2020 15:56:19 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Unknown	Initial Entry

5.d

Date	Location	User	Value	Reason
Oct-29-2020 15:56:32 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sponsor-Defined Identifier: Unknown Test:: Platelets_PX5	Initial Entry

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Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Sep/12/2020

Form Version: 21-Aug-2020 02:51

Site No: 1231

Subject No: 12312982

Generated By: (b) (4)

Form: LOCAL LABORATORY DATA - REPEATING Hematology - 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

			Result:: Unknown Not Done:: Unknown Lab Normal Range: Unknown	
Oct-29-2020 15:54:41 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sponsor-Defined Identifier: Test:: Platelets_PX5 Result:: Not Done:: Lab Normal Range:	Initial Entry

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Sep/12/2020

Form: LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

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Form Status: Data Complete, Frozen, Verified

Site No: 1231

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

Subject No: 12312982

Subject Initials: ---

Generated By: (b) (4)

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

5.d Sponsor ID:

Date	Location	User	Value	Reason
Oct-29-2020 15:56:32 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Unknown	Initial Entry

5.d Test:

Date	Location	User	Value	Reason
Oct-29-2020 15:54:41 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Platelets_PX5	Initial Entry

5.d Result:

Date	Location	User	Value	Reason
Oct-29-2020 15:56:32 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Unknown	Initial Entry

5.d Not Done:

Date	Location	User	Value	Reason
Oct-29-2020 15:56:32 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Unknown	Initial Entry

5.d LNMT

Date	Location	User	Value	Reason
Oct-29-2020 15:56:32 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Unknown	Initial Entry

5.e

Date	Location	User	Value	Reason
Oct-29-2020 15:56:42 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sponsor-Defined Id Unknown Test:: Leukocytes_PX7	Initial Entry

090177e196ae2e71\Final\Final On: 01-Apr-2021 03:13 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Sep/12/2020

Form Version: 21-Aug-2020 02:51

Site No: 1231

Subject No: 12312982

Generated By: (b) (4)

Form: LOCAL LABORATORY DATA - REPEATING Hematology - 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

			Result:: Unknown Not Done:: Unknown Lab Normal Range Unknown :	
Oct-29-2020 15:54:41 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sponsor-Defined Identifier: Test:: Leukocytes _PX7 Result:: Not Done:: Lab Normal Range :	Initial Entry

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Sep/12/2020

Form: LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

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Form Status: Data Complete, Frozen, Verified

Site No: 1231

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

Subject No: 12312982

Subject Initials: ---

Generated By: (b) (4)

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

5.e Sponsor ID:

Date	Location	User	Value	Reason
Oct-29-2020 15:56:42 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Unknown	Initial Entry

5.e Test:

Date	Location	User	Value	Reason
Oct-29-2020 15:54:41 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Leukocytes_PX7	Initial Entry

5.e Result:

Date	Location	User	Value	Reason
Oct-29-2020 15:56:42 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Unknown	Initial Entry

5.e Not Done:

Date	Location	User	Value	Reason
Oct-29-2020 15:56:42 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Unknown	Initial Entry

5.e LNMT

Date	Location	User	Value	Reason
Oct-29-2020 15:56:42 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Unknown	Initial Entry

5.f

Date	Location	User	Value	Reason
Oct-29-2020 15:56:57 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sponsor-Defined I Unknown Test:: Neutrophils_PX608	Initial Entry

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Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Sep/12/2020

Form Version: 21-Aug-2020 02:51

Site No: 1231

Subject No: 12312982

Generated By: (b) (4)

Form: LOCAL LABORATORY DATA - REPEATING Hematology - 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

			Result:: Unknown Not Done:: Unknown Lab Normal Range: Unknown	
Oct-29-2020 15:54:41 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sponsor-Defined Identifier: Test:: Neutrophils_PX608 Result:: Not Done:: Lab Normal Range:	Initial Entry

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Sep/12/2020

Form: LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:51

Form Status: Data Complete, Frozen, Verified

Site No: 1231

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

Subject No: 12312982

Subject Initials: ---

Generated By: (b) (4)

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

5.f Sponsor ID:

Date	Location	User	Value	Reason
Oct-29-2020 15:56:57 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Unknown	Initial Entry

5.f Test:

Date	Location	User	Value	Reason
Oct-29-2020 15:54:41 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Neutrophils_PX608	Initial Entry

5.f Result:

Date	Location	User	Value	Reason
Oct-29-2020 15:56:57 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Unknown	Initial Entry

5.f Not Done:

Date	Location	User	Value	Reason
Oct-29-2020 15:56:57 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Unknown	Initial Entry

5.f LNMT

Date	Location	User	Value	Reason
Oct-29-2020 15:56:57 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Unknown	Initial Entry

5.g

Date	Location	User	Value	Reason
Oct-29-2020 15:57:09 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sponsor-Defined I Unknown Test:: Eosinophils_PX609 identifier:	Initial Entry

090177e196ae2e71\Final\Final On: 01-Apr-2021 03:13 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Sep/12/2020

Form Version: 21-Aug-2020 02:51

Site No: 1231

Subject No: 12312982

Generated By: (b) (4)

Form: LOCAL LABORATORY DATA - REPEATING Hematology - 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

			Result:: Unknown Not Done:: Unknown Lab Normal Range: Unknown	
Oct-29-2020 15:54:41 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sponsor-Defined Identifier: Test:: Eosinophils_PX609 Result:: Not Done:: Lab Normal Range:	Initial Entry

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Sep/12/2020

Form: LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:51

Form Status: Data Complete, Frozen, Verified

Site No: 1231

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

Subject No: 12312982

Subject Initials: ---

Generated By: (b) (4)

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

5.g Sponsor ID:

Date	Location	User	Value	Reason
Oct-29-2020 15:57:09 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Unknown	Initial Entry

5.g Test:

Date	Location	User	Value	Reason
Oct-29-2020 15:54:41 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Eosinophils_PX609	Initial Entry

5.g Result:

Date	Location	User	Value	Reason
Oct-29-2020 15:57:09 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Unknown	Initial Entry

5.g Not Done:

Date	Location	User	Value	Reason
Oct-29-2020 15:57:09 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Unknown	Initial Entry

5.g LNMT

Date	Location	User	Value	Reason
Oct-29-2020 15:57:09 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Unknown	Initial Entry

5.h

Date	Location	User	Value	Reason
Oct-29-2020 15:57:35 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sponsor-Defined I Unknown Test:: Monocytes_PX612	Initial Entry

090177e196ae2e71\Final\Final On: 01-Apr-2021 03:13 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Sep/12/2020

Form: LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:51

Form Status: Data Complete, Frozen, Verified

Site No: 1231

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

Subject No: 12312982

Subject Initials: ---

Generated By: (b) (4)

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

			Result:: Unknown	
			Not Done:: Unknown	
			Lab Normal Range: Unknown	

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Sep/12/2020

Form: LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:51

Form Status: Data Complete, Frozen, Verified

Site No: 1231

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

Subject No: 12312982

Subject Initials: ---

Generated By: (b) (4)

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

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5.h				
Date	Location	User	Value	Reason
Oct-29-2020 15:54:41 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sponsor-Defined Identifier: Test:: Monocytes_PX612 Result:: Not Done:: Lab Normal Range:	Initial Entry

090177e196ae2e71\Final\Final On: 01-Apr-2021 03:13 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Sep/12/2020

Form: LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:51

Form Status: Data Complete, Frozen, Verified

Site No: 1231

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

Subject No: 12312982

Subject Initials: ---

Generated By: (b) (4)

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

5.h Sponsor ID:

Date	Location	User	Value	Reason
Oct-29-2020 15:57:35 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Unknown	Initial Entry

5.h Test:

Date	Location	User	Value	Reason
Oct-29-2020 15:54:41 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Monocytes_PX612	Initial Entry

5.h Result:

Date	Location	User	Value	Reason
Oct-29-2020 15:57:35 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Unknown	Initial Entry

5.h Not Done:

Date	Location	User	Value	Reason
Oct-29-2020 15:57:35 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Unknown	Initial Entry

5.h LNMT

Date	Location	User	Value	Reason
Oct-29-2020 15:57:35 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Unknown	Initial Entry

5.i

Date	Location	User	Value	Reason
Oct-29-2020 15:57:46 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sponsor-Defined I Unknown Test:: Basophils_P X610	Initial Entry

090177e196ae2e71\Final\Final On: 01-Apr-2021 03:13 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Sep/12/2020

Form Version: 21-Aug-2020 02:51

Site No: 1231

Subject No: 12312982

Generated By: (b) (4)

Form: LOCAL LABORATORY DATA - REPEATING Hematology - 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

			Result:: Unknown Not Done:: Unknown Lab Normal Range: Unknown	
Oct-29-2020 15:54:41 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sponsor-Defined Identifier: Test:: Basophils_P X610 Result:: Not Done:: Lab Normal Range:	Initial Entry

090177e196ae2e71\Final\Final On: 01-Apr-2021 03:13 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Sep/12/2020

Form: LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:51

Form Status: Data Complete, Frozen, Verified

Site No: 1231

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

Subject No: 12312982

Subject Initials: ---

Generated By: (b) (4)

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

5.i Sponsor ID:

Date	Location	User	Value	Reason
Oct-29-2020 15:57:46 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Unknown	Initial Entry

5.i Test:

Date	Location	User	Value	Reason
Oct-29-2020 15:54:41 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Basophils_PX610	Initial Entry

5.i Result:

Date	Location	User	Value	Reason
Oct-29-2020 15:57:46 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Unknown	Initial Entry

5.i Not Done:

Date	Location	User	Value	Reason
Oct-29-2020 15:57:46 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Unknown	Initial Entry

5.i LNMT

Date	Location	User	Value	Reason
Oct-29-2020 15:57:46 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Unknown	Initial Entry

5.j

Date	Location	User	Value	Reason
Oct-29-2020 15:58:03 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sponsor-Defined Identifier: Test:: Lymphocytes_PX611	Initial Entry

090177e196ae2e71\Final\Final On: 01-Apr-2021 03:13 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Sep/12/2020

Form Version: 21-Aug-2020 02:51

Site No: 1231

Subject No: 12312982

Generated By: (b) (4)

Form: LOCAL LABORATORY DATA - REPEATING Hematology - 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

			Result:: Unknown Not Done:: Unknown Lab Normal Range: Unknown	
Oct-29-2020 15:54:41 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sponsor-Defined Identifier: Test:: Lymphocytes _PX611 Result:: Not Done:: Lab Normal Range:	Initial Entry

090177e196ae2e71\Final\Final On: 01-Apr-2021 03:13 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Sep/12/2020

Form: LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:51

Form Status: Data Complete, Frozen, Verified

Site No: 1231

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

Subject No: 12312982

Subject Initials: ---

Generated By: (b) (4)

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

5.j Sponsor ID:

Date	Location	User	Value	Reason
Oct-29-2020 15:58:03 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Unknown	Initial Entry

5.j Test:

Date	Location	User	Value	Reason
Oct-29-2020 15:54:41 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Lymphocytes_PX611	Initial Entry

5.j Result:

Date	Location	User	Value	Reason
Oct-29-2020 15:58:03 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Unknown	Initial Entry

5.j Not Done:

Date	Location	User	Value	Reason
Oct-29-2020 15:58:03 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Unknown	Initial Entry

5.j LNMT

Date	Location	User	Value	Reason
Oct-29-2020 15:58:03 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Unknown	Initial Entry

090177e196ae2e71\Final\Final On: 01-Apr-2021 03:13 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on **Form:** IMAGING - Audit Trail
Sep/12/2020

Form Version: 06-Jul-2020 21:53

Form Status:

Site No: 1231

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

Subject No: 12312982

Subject Initials: ---

Generated By: (b) (4)

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

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Date	Location	User	Value	Reason
Oct-29-2020 15:33:00 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	Adolfo Gonzalez (b) (4)	Form Created	

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on **Form:** IMAGING - Audit Trail
Sep/12/2020

Form Version: 06-Jul-2020 21:53

Form Status:

Site No: 1231

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

Subject No: 12312982

Subject Initials: ---

Generated By: (b) (4)

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

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Date	Location	User	Value	Reason
Oct-29-2020 15:33:27 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	Adolfo Gonzalez (b) (4)	Form Created	

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Form: IMAGING - eCRF Audit Trail History
Sep/12/2020

Form Version: 06-Jul-2020 21:53

Form Status: Data Complete, Frozen, Verified

Site No: 1231

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

Subject No: 12312982

Subject Initials: ---

Generated By: (b) (4)

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

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I. Date of Assessment:

Date	Location	User	Value	Reason
Oct-30-2020 14:09:47 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Oct-29-2020 15:33:00 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Initial Entry
Oct-29-2020 15:33:00 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	Adolfo Gonzalez (b) (4)	Data Entry: Sep/12/2020	Initial Entry
Oct-29-2020 13:25:23 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	CRA: per medical note, subject undergone an Xray and CT of chest. Please update accordingly using one row for each one of the images taken. Thanks.

2. Location of Assessment:

Date	Location	User	Value	Reason
Oct-29-2020 15:33:00 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	Adolfo Gonzalez (b) (4)	Data Entry: CHEST	Initial Entry

3. Type of Imaging Exam:

Date	Location	User	Value	Reason
Oct-29-2020 15:33:00 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	Adolfo Gonzalez (b) (4)	Data Entry: X-RAY	Initial Entry

4. Assessment:

Date	Location	User	Value	Reason
Oct-29-2020 15:33:00 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	Adolfo Gonzalez (b) (4)	Data Entry: ABNORMAL	Initial Entry

090177e196ae2e71\Final\Final On: 01-Apr-2021 03:13 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on **Form:** IMAGING - eCRF Audit Trail History
Sep/12/2020

Form Version: 06-Jul-2020 21:53

Form Status: Data Complete, Frozen, Verified

Site No: 1231

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

Subject No: 12312982

Subject Initials: ---

Generated By: (b) (4)

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

Buenos Aires

If abnormal, specify findings:

right lung consolidation

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on **Form:** IMAGING - eCRF Audit Trail History
Sep/12/2020

Form Version: 06-Jul-2020 21:53

Form Status: Data Complete, Frozen, Verified

Site No: 1231

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

Subject No: 12312982

Subject Initials: ---

Generated By: (b) (4)

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

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1. Date of Assessment:

Date	Location	User	Value	Reason
Oct-29-2020 15:33:27 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	Adolfo Gonzalez (b) (4)	Data Entry: Sep/12/2020	Initial Entry

2. Location of Assessment:

Date	Location	User	Value	Reason
Oct-29-2020 15:33:27 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	Adolfo Gonzalez (b) (4)	Data Entry: CHEST	Initial Entry

3. Type of Imaging Exam:

Date	Location	User	Value	Reason
Oct-29-2020 15:33:27 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	Adolfo Gonzalez (b) (4)	Data Entry: CT SCAN	Initial Entry

4. Assessment:

Date	Location	User	Value	Reason
Oct-29-2020 15:33:27 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	Adolfo Gonzalez (b) (4)	Data Entry: NORMAL	Initial Entry

090177e196ae2e71\Final\Final On: 01-Apr-2021 03:13 (GMT)

Header Text: C4591001

Visit: End of Treatment - Unscheduled

Form Version: 15-Sep-2020 21:55

Site No: 1231

Subject No: 12312982

Generated By: (b) (4)

Form: DISPOSITION - TREATMENT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

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1. Date of Completion/Discontinuation/Death :

Date	Location	User	Value	Reason
Oct-06-2020 16:00:10 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sep/23/2020	Initial Entry

2. Phase of Disposition:

Date	Location	User	Value	Reason
Oct-06-2020 16:00:10 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: VACCINATION	Initial Entry

3. Status:

Date	Location	User	Value	Reason
Nov-19-2020 18:31:32 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Closed	Response satisfies query
Nov-19-2020 15:38:45 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Answered	The subject reports that the decision to stop participating in the study is of a personal nature. It is not a discontinuation for AE, it is a WITHDRAWAL BY SUBJECT
Nov-19-2020 14:14:27 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Opened	CLINQUERY: it appears that the subject was unblinded and discontinued due to the event of severe anxiety. Please clarify if the disposition treatment status should be updated to ADVERSE EVENT
Oct-13-2020 09:26:53 (UTC-03:00) City of	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query

090177e196ae2e71\Final\Final On: 01-Apr-2021 03:13 (GMT)

Header Text: C4591001

Visit: End of Treatment - Unscheduled

Form: DISPOSITION - TREATMENT - eCRF Audit Trail History

Form Version: 15-Sep-2020 21:55

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1231

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

Subject No: 12312982

Subject Initials: ---

Generated By: (b) (4)

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

Buenos Aires				
Oct-13-2020 09:19:47 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	The subject will have follow-up visits
Oct-13-2020 09:05:25 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reissued:Opened	CLINQUERY: Please clarify if the subject will have follow-up visits. If not, please complete the disposition Follow-up form. If the subject will have follow-up visits, please indicate this in query response. The data was entered but has since been removed
Oct-12-2020 21:17:58 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	The disposition follow-up form was completed.
Oct-12-2020 12:59:15 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reissued:Opened	CLINQUERY: Please clarify if the subject will have follow-up visits. If not, please complete the disposition Follow-up form, and indicate WITHDRAWAL BY SUBJECT. If the subject will have follow-up visits, please indicate this in query response.
Oct-11-2020 13:22:11 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	The form is already loaded. Thank you
Oct-07-2020 16:29:25 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	CLINQUERY: Withdrawal of Consent Date of 23/Sep/2020 is provided. Please clarify if the subject will have follow-up visits. If not, please

090177e196ae2e71\Final\Final On: 01-Apr-2021 03:13 (GMT)

Header Text: C4591001

Visit: End of Treatment - Unscheduled

Form: DISPOSITION - TREATMENT - eCRF Audit Trail History

Form Version: 15-Sep-2020 21:55

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1231

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

Subject No: 12312982

Subject Initials: ---

Generated By: (b) (4)

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

				complete the disposition follow-up form, and indicate WITHDRAWAL BY SUBJECT
Oct-07-2020 16:24:29 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Candidate	CLINQUERY: Withdrawal of Consent Date of 23/Sep/2020 is provided. Please clarify if the subject will have follow-up visits. If not, please complete the disposition follow-up form, and indicate WITHDRAWAL BY SUBJECT
Oct-06-2020 16:00:10 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: WITHDRAWAL BY SUBJECT	Initial Entry

4. Specify Status:

Date	Location	User	Value	Reason
Oct-06-2020 16:00:10 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: The subject reports that the decision to stop participating in the study is of a personal nature	Initial Entry

090177e196ae2e71\Final\Final On: 01-Apr-2021 03:13 (GMT)

Header Text: C4591001

Visit: Follow-Up - Unscheduled

Form Version: 15-Sep-2020 21:53

Site No: 1231

Subject No: 12312982

Generated By: (b) (4)

Form: DISPOSITION - FOLLOW-UP - 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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1. Date of Completion/Discontinuation/Death :

Date	Location	User	Value	Reason
Nov-10-2020 13:48:03 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Closed	Response satisfies query
Nov-10-2020 09:07:35 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 4: Closed	Close Auto Query
Nov-10-2020 09:07:35 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sep/23/2020	Changed Information
Nov-10-2020 09:02:05 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 4: Opened	Date of Completion/Discontinuation/Death on the Follow-Up Disposition form is after "Withdrawal of consent" date. Please review and correct as appropriate.
Nov-10-2020 09:02:05 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 3: Answered	New Information
Nov-10-2020 09:02:05 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Oct/29/2020	New Information
Nov-10-2020 04:27:48 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	Balaji Prabu R (b) (4)	Query 3: Opened	Based on previous response if subject was contacted on 14Oct2020, please update disposition date to reflect the same. Else clarify.
Nov-02-2020 18:44:18 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Closed	Response satisfies query
Nov-02-2020 16:22:56 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	Adolfo Gonzalez (b) (4)	Query 2: Answered	original value is correct, per sponsor request this information was collected by the PI
Nov-02-2020 05:48:27	ACV0PFEINFP6000	Balaji Prabu R	Query 2: Opened	Subject withdrew consent

090177e196ae2e71\Final\Final On: 01-Apr-2021 03:13 (GMT)

Header Text: C4591001**Visit:** Follow-Up - Unscheduled**Form Version:** 15-Sep-2020 21:53**Site No:** 1231**Subject No:** 12312982**Generated By:** (b) (4)**Form:** DISPOSITION - FOLLOW-UP - 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)		on 23Sep2020, but for the Adverse event 'Severe Anxiety' has resolved date of '14-Oct-2020'. Please verify and update this date in case subject was contacted and obtained stop date. Last contact date should be entered here.
Oct-30-2020 04:02:49 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Oct-29-2020 17:11:19 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Initial Entry
Oct-29-2020 17:11:19 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	Adolfo Gonzalez (b) (4)	Data Entry: Sep/23/2020	Initial Entry
Oct-29-2020 03:55:03 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	DM: Subject withdrew consent kindly consider updating this for with appropriate reason. Thank you.
Oct-12-2020 21:29:26 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Transcription Error
Oct-12-2020 21:17:33 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sep/23/2020	Initial Entry

2. Phase of Disposition:

Date	Location	User	Value	Reason
Oct-29-2020 17:11:19 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: FOLLOW-UP	Initial Entry
Oct-12-2020 21:29:26 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry:	Transcription Error
Oct-12-2020 21:17:33 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: FOLLOW-UP	Initial Entry

Header Text: C4591001

Visit: Follow-Up - Unscheduled

Form: DISPOSITION - FOLLOW-UP - eCRF Audit Trail History

Form Version: 15-Sep-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: 12312982

Subject Initials: ---

Generated By: (b) (4)

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

3. Status:

Date	Location	User	Value	Reason
Nov-19-2020 18:34:35 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Closed	Response satisfies query
Nov-19-2020 15:39:02 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Answered	The subject reports that the decision to stop participating in the study is of a personal nature. It is not a discontinuation for AE, it is a WITHDRAWAL BY SUBJECT
Nov-19-2020 13:18:49 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Opened	CLINQUERY: for the AE of severe anxiety the question, "Did the adverse event cause the subject to be discontinued from the study?" is YES. Please confirm that the status for the disposition follow-up should be updated to Adverse Event.
Oct-29-2020 17:12:22 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Closed	Close Auto Query
Oct-29-2020 17:11:19 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Opened	Response to "Status" is WITHDRAWAL BY SUBJECT but "Specify Status" is missing.
Oct-29-2020 17:11:19 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	Adolfo Gonzalez (b) (4)	Data Entry: WITHDRAWAL BY SUBJECT	Initial Entry
Oct-12-2020 21:29:16 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Oct-12-2020 21:29:16 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Transcription Error

090177e196ae2e71\Final\Final On: 01-Apr-2021 03:13 (GMT)

Header Text: C4591001

Visit: Follow-Up - Unscheduled

Form: DISPOSITION - FOLLOW-UP - eCRF Audit Trail History

Form Version: 15-Sep-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: 12312982

Subject Initials: ---

Generated By: (b) (4)

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

Buenos Aires				
Oct-12-2020 21:29:04 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	Response to "Status" is WITHDRAWAL BY SUBJECT but "Specify Status" is missing.
Oct-12-2020 21:17:33 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: WITHDRAWAL BY SUBJECT	Initial Entry

4. Specify Status:

Date	Location	User	Value	Reason
Nov-12-2020 09:57:23 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Nov-12-2020 09:28:02 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Transcription Error
Nov-12-2020 09:28:02 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Withdrawal of consent for personal reasons	Transcription Error
Nov-11-2020 13:00:07 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	CLINQUERY: per the disposition treatment CRF, "The subject reports that the decision to stop participating in the study is of a personal nature". Please clarify if the disposition follow-up CRF should be updated to reflect this information.
Oct-29-2020 17:12:22 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	Adolfo Gonzalez (b) (4)	Data Entry: subject withdrew his consent	Initial Entry
Oct-12-2020 21:29:04 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Transcription Error

090177e196ae2e71\Final\Final On: 01-Apr-2021 03:13 (GMT)

Header Text: C4591001

Visit: Follow-Up - Unscheduled

Form Version: 15-Sep-2020 21:53

Site No: 1231

Subject No: 12312982

Generated By: (b) (4)

Form: DISPOSITION - FOLLOW-UP - 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-12-2020 21:17:33 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: the volunteer's own decision to le ave the study	Initial Entry
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Header Text: C4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1231

Subject No: 12312982

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: ---

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Date	Location	User	Value	Reason
Sep-14-2020 19:31:49 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Created	

Header Text: C4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1231

Subject No: 12312982

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

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Date	Location	User	Value	Reason
Sep-15-2020 10:06:51 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Created	

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Header Text: C4591001

Visit: Logs - Unscheduled

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Site No: 1231

Subject No: 12312982

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: ---

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Date	Location	User	Value	Reason
Oct-08-2020 20:50:33 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Created	

Header Text: C4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1231

Subject No: 12312982

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

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

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I. Category:

Date	Location	User	Value	Reason
Sep-14-2020 19:31:49 (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
Sep-14-2020 19:31:49 (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-27-2020 18:12:34 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	Salim Bouguermouh (b) (4)	Query 6: Closed	Response satisfies query
Oct-27-2020 18:10:10 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	Salim Bouguermouh (b) (4)	Query 6: Re issued: Opened	Clin: Per protocol section 8.3.7., this Suspected COVID-19 Illness event does not qualify as AE and please should be documented only on the COVID Illness CRF SOD form and should not be captured on the AE CRF page.
Oct-21-2020 17:11:16 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 6: Answered	Taking into account the data of the epicrisis, having ruled out Sars-Cov2 disease, the clinical picture of fever, myalgia, headache and general malaise is interpreted as a febrile syndrome secondary to

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Site No: 1231

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

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

Subject No: 12312982

Subject Initials: ---

Generated By: (b) (4)

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				severe reactogenicity related to the product under in
Oct-21-2020 10:49:15 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	Salim Bouguermouh (b) (4)	Query 6: Opened	Clin: Per protocol section 8.1., COVID-19 related event should have please triggered a potential COVID Illness Visit, should be added to the COVID SOD CRF Form and removed from the AE form.
Oct-13-2020 00:30:15 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000.InFormAdapter.Discrepancy	PFETMS Oracle (b) (4)	Query 4: Closed	Discrepancy has been closed.
Oct-12-2020 22:29:38 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	Mabel Berrueta (b) (4)	Query 5: Deleted	Transcription Error
Oct-12-2020 22:29:38 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	Mabel Berrueta (b) (4)	Data Entry Suspected COVID-19 Illness	Transcription Error
Oct-12-2020 21:42:04 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 5: Re issued:Candidate	SAE Recon: Pending SDB update
Oct-12-2020 21:24:53 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 5: Answered	Transcription Error
Oct-12-2020 21:24:53 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 4: Answered	Transcription Error

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Header Text: C4591001

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Form Version: 22-Apr-2020 21:02

Site No: 1231

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

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

Subject No: 12312982

Subject Initials: ---

Generated By: (b) (4)

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

Oct-12-2020 21:24:53 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry i suspected COVID Illness	Transcription Error
Oct-12-2020 20:59:34 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 5: Opened	SAE RECON: AER#2020354694,term was updated to COVID Illness however,per Clinical subject had been ruled out for covid illness.Please clarify.If reporting for Febrile Syndrome,update AE CRF and safety database as appropriate.
Oct-12-2020 11:51:19 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000.InFormAdapter.Discrepancy	PFETMS Oracle (b) (4)	Query 4: Opened	Clarify COVID ILLNESS as follows...The term appears incomplete. Are you reporting COVID-19 ILLNESS? If so, edit the term as such. Otherwise, clarify and edit the term as appropriate. Thank you.
Oct-12-2020 10:16:44 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry i COVID Illness	New Information
Oct-11-2020 23:10:18 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Closed	Response satisfies query
Oct-11-2020 10:19:49 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 3: Answered	New Information

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Header Text: C4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1231

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

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

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

Subject No: 12312982

Subject Initials: ---

Generated By: (b) (4)

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

Oct-11-2020 10:19:49 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	Mabel Berrueta (b) (4)	Data Entry : Suspected COVID Illness	New Information
Oct-04-2020 22:15:21 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Re issued: Opened	CLINICAL This adverse event needs to have the same name on both the AE CRF (which is now Febrile Syndrome) and the SAE report (which is now Suspected COVID Illness); please review and update one accordingly.
Oct-03-2020 14:08:54 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	Mabel Berrueta (b) (4)	Query 3: Answered	Febrile Syndrome is correct based on medical chart.
Sep-24-2020 15:43:48 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Opened	CLINQUERY AER#2020354694, The term in SDB was updated to 'Suspected COVID Illness' while retained as 'FEBRILE SYNDROME' in AE CRF. Please confirm correct term. If safety update is required, please submit a follow-up SAE form'
Sep-24-2020 10:45:32 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Candidate	CLINQUERY AER#2020354694, The term in SDB was updated to 'Suspected COVID Illness' while retained as 'FEBRILE SYNDROME' in AE CRF. Please confirm correct term. If safety update is required, please submit a follow-up SAE form'

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Subject No: 12312982

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

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

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

Sep-23-2020 01:25:30 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	Salim Bouguermouh (b) (4)	Query 2: Closed	Response satisfies query
Sep-23-2020 01:23:39 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	Salim Bouguermouh (b) (4)	Query 2: Re issued: Opened	Clin: Please the COVID-19 related event Febrile syndrome (the related symptoms and all the relevant information's) should be also documented on the COVID Illness CRF forms.
Sep-22-2020 22:34:39 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Sep-22-2020 11:51:41 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Answered	Changed Information
Sep-22-2020 11:51:41 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Changed Information
Sep-22-2020 11:51:41 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry : febrile syndrome	Changed Information
Sep-21-2020 14:38:08 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	Salim Bouguermouh (b) (4)	Query 2: Opened	Clin: Please the COVID-19 related event Febrile syndrome (the related symptoms and all the relevant information's) should be also documented on the COVID Illness CRF forms.

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

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

Subject No: 12312982

Subject Initials: ---

Generated By: (b) (4)

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

Sep-18-2020 07:13:48 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	SAE RECON: AER#2020354694, The term in SDB was updated to 'FEBRILE SYNDROME while retained as 'Bilateral Pneumonia' in AE CRF. Please confirm correct term. If safety update is required, please submit a follow-up SAE form'
Sep-14-2020 19:31:49 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry</u> : bilateral pneumonia	Initial Entry

4. Start Date Time:

Date	Location	User	Value	Reason
Oct-27-2020 18:12:48 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	Salim Bouguermouh (b) (4)	Query 2: Closed	Response satisfies query
Oct-27-2020 12:23:02 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Answered	A COVID form was added. Thank you.
Oct-19-2020 05:05:21 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Opened	Clin: Please complete the potential COVID Illness Visit CRF forms with all information available. The nasal swab taken in clinic at V2 can count for these symptoms please enter the same barcode on the potential COVID illness CRF TRACKING - NASAL SWAB
Oct-17-2020 12:33:54 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	Salim Bouguermouh (b) (4)	Query 2: Candidate	Clin: Please complete the potential COVID Illness Visit CRF forms with all information available.

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Header Text: C4591001**Visit:** Logs - Unscheduled**Form Version:** 22-Apr-2020 21:02**Site No:** 1231**Subject No:** 12312982**Generated By:** (b) (4)**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History**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

				The nasal swab taken in clinic at V2 can count for these symptoms please enter the same barcode on the potential COVID illness CRF TRACKING - NASAL SWAB
Sep-16-2020 13:33:58 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sep/9/2020 21:00	New Information
Sep-15-2020 09:02:21 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	issue resolved
Sep-15-2020 08:46:35 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Transcription Error
Sep-15-2020 08:46:35 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sep/12/2020 21:00	Transcription Error
Sep-15-2020 07:12:08 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	SAE RECON: AER#2020354694 ,onset date was reported as 12Sep2020 in SDB however reported as 09Sep2020 on AE CRF. Please confirm correct Onset Date. If safety update is required, please submit a follow-up SAE form.
Sep-14-2020 19:31:49 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sep/9/2020 20:00	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Sep-16-2020 13:34:23 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO End Date Time:	New Information

Header Text: C4591001**Visit:** Logs - Unscheduled**Form Version:** 22-Apr-2020 21:02**Site No:** 1231**Subject No:** 12312982**Generated By:** (b) (4)**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History**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

			Sep/14/2020 11:00	
Sep-15-2020 09:25:02 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Sep-15-2020 09:25:02 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Transcription Error
Sep-15-2020 09:23:36 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	For bilateral pneumonia End Date & Time 25/Aug/2020 14:47 is before the Start Date & Time 12/Sep/2020 21:00.
Sep-15-2020 09:23:36 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO End Date Time: Aug/25/2020 14:47	New Information
Sep-14-2020 19:31:49 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

6. Toxicity Grade:

Date	Location	User	Value	Reason
Sep-14-2020 19:31:49 (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-28-2020 01:28:13 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Closed	Response satisfies query

Header Text: C4591001

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Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

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

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

Subject Initials: ---

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7. Is the adverse event serious?

If Yes, NOTIFY PFIZER IMMEDIATELY.

Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).

Date	Location	User	Value	Reason
Oct-27-2020 12:24:11 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Answered	The COVID form with te 12SEPT2020 SWAB was loaded. Thank you.
Oct-21-2020 13:27:00 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Opened	CLINICAL Please send a SAE safety update with the date of the COVID test lab test during Hospital stay (admitted Sep 12), if known
Sep-15-2020 07:09:39 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Sep-14-2020 19:31:49 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	For AE bilateral pneumonia: Response to "Is the adverse event serious?" is 'Yes' but "Serious Adverse Event Number" is blank.
Sep-14-2020 19:31:49 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Is this serious event associated with congenital anomaly or birth defect? NO Did this serious event result in death?	Initial Entry

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			NO	
			Did this serious event require or prolong hospitalization?	
			YES	
			Did this serious event result in persistent or significant disability/incapacity?	
			NO	
			Is this serious event life threatening?	
			NO	
			Other medically important serious event	
			NO	

8. Is this adverse event the result of a study Medication Error?
If Yes, record the type of medication error on the Medication Error Log.

Date	Location	User	Value	Reason
Sep-14-2020 19:31:49 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

9. Is this event related to study treatment:

Date	Location	User	Value	Reason
Oct-08-2020 21:10:28 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Closed	Response satisfies query
Oct-08-2020 20:39:06 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Answered	New Information
Oct-08-2020 20:39:06 (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:	New Information

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			OTHER <i>If Other, specify:</i> unknown	
Oct-05-2020 14:23:34 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Reissued:Opened	CLINQUERY: per response, "Based on medical Record, Dr Polack PI of the study wrote on 17SET2020 that 'Hospitalization is an SAE not related to the vaccine, due to suspicion of COVID-19'. Cause is unknown." please update the specify field as appropriate.
Oct-03-2020 14:06:45 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	Mabel Berrueta (b) (4)	Query 2: Answered	Based on medical Record, Dr Polack PI of the study wrote on 17SET2020 that "Hospitalization is an SAE not related to the vaccine, due to suspicion of COVID-19". Cause is unknown.
Oct-01-2020 15:03:30 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Opened	CLINQUERY: If the AE is determined not to be related to study treatment, please indicate what this event is due to. Options are Concomitant Drug treatment, Concomitant non-drug treatment and Other. If other, please specify
Sep-24-2020 05:56:45 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Sep-23-2020 08:35:02 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Transcription Error
Sep-23-2020 08:35:02 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NOT RELATED If Not Related to study treat	Transcription Error

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			ment(s), this event is due to:	
Sep-23-2020 06:53:26 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reissued:Opened	SAE RECON 1: Per previous query response 'SAE is not related to the research product' however, causality was updated to RELATED in AE CRF. Please update back to NOT RELATED.
Sep-22-2020 11:55:49 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: RELATED	New Information
Sep-22-2020 11:47:17 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	SAE is not related to the research product. An explanatory follow-up form was sent.
Sep-18-2020 07:15:52 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	SAE RECON:AER#2020354694 Causality was reported as RELATED in SAE form however, recorded as NOT RELATED on AE CRF. Please confirm correct causality. If safety update is required, please submit a follow-up form.
Sep-14-2020 19:31:49 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NOT RELATED If Not Related to study treatment(s), this event is due to: OTHER <i>If Other, specify:</i> unknown	Initial Entry

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Sep-14-2020 19:31:49 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NOT APPLICABLE	Initial Entry

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11. Was a Concomitant Medication given?

Date	Location	User	Value	Reason
Sep-14-2020 19:31:49 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Sep-14-2020 19:31:49 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

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

Date	Location	User	Value	Reason
Sep-16-2020 13:35:41 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Closed	Close Auto Query
Sep-16-2020 13:35:41 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: RECOVERED/RESOLVED	New Information
Sep-16-2020 13:34:23 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Opened	For AE bilateral pneumonia: Response to "What was the outcome of this adverse event?" is 'Not Recovered/Not Resolved' but AE End Date/Time is present.
Sep-15-2020 09:25:02 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Sep-15-2020 09:23:36 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	For AE bilateral pneumonia: Response to "What was the outcome of this adverse event?" is 'Not Recovered/Not Resolved' but AE End Date/Time is

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				present.
Sep-14-2020 19:31:49 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NOT RECOVERED/NOT RESOLVED	Initial Entry

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

Date	Location	User	Value	Reason
Sep-14-2020 19:31:49 (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
Sep-15-2020 07:09:39 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 2020354694	Initial Entry

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1. Category:

Date	Location	User	Value	Reason
Sep-15-2020 10:06:51 (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
Sep-15-2020 10:06:51 (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
Sep-15-2020 10:06:51 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: mild pain at the injection site	Initial Entry

4. Start Date Time:

Date	Location	User	Value	Reason
Sep-15-2020 10:06:51 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Aug/23/2020 11:17	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Sep-15-2020 10:06:51 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO End Date Time: Aug/25/2020 14:47	Initial Entry

6. Toxicity Grade:

Date	Location	User	Value	Reason
Sep-15-2020 10:06:51	ACV0PFEINFP6000	(b) (6)	Data Entry:	Initial Entry

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

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7. Is the adverse event serious?

If Yes, NOTIFY PFIZER IMMEDIATELY.

Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).

Date	Location	User	Value	Reason
Sep-15-2020 10:06:51 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

8. Is this adverse event the result of a study Medication Error?

If Yes, record the type of medication error on the Medication Error Log.

Date	Location	User	Value	Reason
Sep-15-2020 10:06:51 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

9. Is this event related to study treatment:

Date	Location	User	Value	Reason
Sep-16-2020 18:45:48 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Sep-16-2020 12:48:34 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Transcription Error
Sep-16-2020 12:48:34 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: RELATED	Transcription Error
Sep-15-2020 11:06:53 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	Per medical records, (HC EVENTO ADVERSO) this event was related with the investigational product. Please review and amend if

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				appropriate. Thank you!
Sep-15-2020 10:06:51 (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 If Other, specify: unknown	Initial Entry

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Sep-15-2020 10:06:51 (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
Sep-15-2020 10:06:51 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Sep-15-2020 10:06:51 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

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

Date	Location	User	Value	Reason
Sep-15-2020 10:06:51 (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
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Sep-15-2020 10:06:51 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry
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1. Category:

Date	Location	User	Value	Reason
Oct-08-2020 20:50:33 (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-08-2020 20:50:33 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 3	Initial Entry

3. Adverse Event:

(If possible specify diagnosis, not individual symptoms)

Date	Location	User	Value	Reason
Oct-15-2020 17:54:45 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Oct-15-2020 17:12:44 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	Maria Beretta (b) (4)	Query 1: Answered	The patient has no history of anxiety. By constitutive features we mean his baseline personality. The anxiety was an adverse event, not part of his medical history
Oct-13-2020 09:16:56 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reissued:Opened	CLINQUERY: based on the response, "Based on medical history, severe anxiety is mentioned - constitutive features" please update the medical history form to include this history. Request to unfreeze medical history form has been submitted.

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Oct-12-2020 21:09:51 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Based on medical history, severe anxiety is mentioned - constitutive features
Oct-09-2020 16:25:55 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	CLINQUERY: please clarify if the subject has a history of anxiety.
Oct-08-2020 20:50:33 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: severe anxiety	Initial Entry

4. Start Date Time:

Date	Location	User	Value	Reason
Oct-12-2020 21:05:32 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sep/23/2020 23:00	New Information
Oct-08-2020 20:50:33 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sep/23/2020 UNK:UNK	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Feb-19-2021 09:42:49 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	Balaji Prabu R (b) (4)	Query 8: Closed	Response satisfies query
Feb-18-2021 14:51:07 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 8: Answered	I clarify that although the DISPOSITION - FOLLOW-UP date is SEP 23, 2020, at the request of the sponsor the information on the end date was compiled by the PI
Feb-18-2021 03:49:29 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 8: Reissued: Opened	DM:AE End date (14/Oct/2020) is after the Date of Completion/Discontinuation/Death (23/Sep/2020) on DISPOSITION - FOLLOW-UP CRF in FUP

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				visit. AE END DATE cannot be greater than DISP F/U DATE. Thus, please review and update. Else, clarify.
Feb-17-2021 10:17:35 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 8: Answered	Original value is correct, per sponsor request this information was collected by the PI. Thank you
Feb-17-2021 03:05:48 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	Balaji Prabu R (b) (4)	Query 8: Opened	End Date (14Oct2020) is after Date of Completion/Discontinuation /Death (23Sep2020) on the Disposition-Follow-up eCRF. Hence, please review and update as ongoing if this AE was ongoing at the time subject ended the study participation. Else clarify.
Nov-17-2020 12:29:23 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 7: Closed	Response satisfies query
Nov-17-2020 09:59:18 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 7: Answered	according to medical record, the 14/oct/20 was the date that the volunteer went to the hospital to sign the receipt of the certified letter that details his branch of treatment, retiring in excellent spirits, constituting your last contact, thank you
Nov-17-2020 00:05:08 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (b) (4)	Query 7: Opened	DMW5391373; 'End Date' is after 'Date of Completion/Discontinuation /Death' on the Disposition - Follow-up eCRF. Please clarify or correct.
Nov-16-2020 19:01:55 (UTC-03:00)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry :	New Information

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City of Buenos Aires			NO End Date Time: Oct/14/2021 01:53:00	
Nov-16-2020 12:50:06 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 6: Closed	Response satisfies query
Nov-16-2020 12:49:54 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 5: Closed	Response satisfies query
Nov-16-2020 10:33:14 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 6: Answered	Subject withdraws consent. The resolution date is after the FUP date, therefore it does not register in this form. Thank you.
Nov-16-2020 10:31:04 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 6: Opened	'Disposition Follow-up form is completed and this Adverse Event is still ongoing. Please review and update as appropriate.
Nov-16-2020 10:31:04 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 5: Answered	New Information
Nov-16-2020 10:31:04 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry : YES	New Information

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Header Text: C4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1231

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

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

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

Subject No: 12312982

Subject Initials: ---

Generated By: (b) (4)

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

Nov-15-2020 18:50:28 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 5: Reissued: Opened	This new information can only reside in source data only - please change back to ongoing and also change question #13. In the database there can be no data after consent was withdrawn. Thank You!
Nov-15-2020 18:12:29 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 5: Answered	On 14OCT, the participant went to the center to deliver the electronic diary and sign the follow-up receipt of the certified letter that was sent to him in a timely manner, in order to inform him of the result of his blindness. During that visit, he repor
Nov-15-2020 11:23:48 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 5: Reissued: Opened	There cannot be a date in the database that is greater than the Date of Completion/Discontinuation /Death on the DISP FUP form. Please update AE to reflect the status of the AE at the time of discontinuation, which is AE Ongoing and Outcome Not Resolved.
Nov-12-2020 18:23:30 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 5: Reissued: Candidate	Sent to Triad team to review.
Nov-12-2020 09:21:49 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 5: Answered	In a subject's note delivered 13OCT it states "I authorize you to initiate all the checks of the medical history and other data that are necessary for the clarification of the events that occurred in the events that occurred in the study". Thank you.
Nov-11-2020 16:49:16 (UTC-03:00)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 5: Reissued:	Subject withdrew consent to collect further information on 23SEP2020. Therefore

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Header Text: C4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1231

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

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

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

Subject No: 12312982

Subject Initials: ---

Generated By: (b) (4)

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

City of Buenos Aires			Opened	the End Date has to be changed back to ONGOING and the OUTCOME has to be changed back to NOT RESOLVED'. Data can not be collected after consent withdrawn! Thank You.
Nov-02-2020 19:10:18 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 5: Reissued: Candidate	send query to TRIAD team so CRA can contact site - the stop date needs to be changed to ongoing as no further information can be collected once subject withdraws consent.
Nov-02-2020 16:21:55 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	Adolfo Gonzalez (b) (4)	Query 5: Answered	original value is correct, per sponsor request this information was collected by the PI
Nov-02-2020 14:47:12 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 5: Reissued: Opened	'End Date' is after 'Date of Discontinuation'. Once a subject withdrew consent no further information can be collected. Please remove any information collected after 23SEP2020 if event was ongoing at the time consent was withdrawn it must remain as such.
Oct-30-2020 20:15:37 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 5: Answered	Although the subject withdraws informed consent on 09/23/2020 and based on everything that has evolved in the subject's CH, the AE in question is correct. Thank you
Oct-30-2020 16:25:06 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (b) (4)	Query 5: Opened	DMW5230651;'End Date' is after 'Date of Completion/Discontinuation /Death' on the Disposition - Follow-up eCRF. Please clarify or correct.

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Header Text: C4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1231

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

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

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

Subject No: 12312982

Subject Initials: ---

Generated By: (b) (4)

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

Oct-30-2020 12:52:43 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry : NO End Date Time: Oc t/1 4/2 02 0 U N K: U N K	New Information
Oct-30-2020 12:45:25 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 4: Clo sed	Response satisfies query
Oct-29-2020 19:18:24 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 4: Ans wered	Original value is correct
Oct-29-2020 17:11:19 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 4: Op ened	'Disposition Follow-up form is completed and this Adverse Event is still ongoing. Please review and update as appropriate.
Oct-22-2020 19:48:21 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Clo sed	Response satisfies query
Oct-22-2020 19:36:30 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	Adolfo Gonzalez (b) (4)	Query 3: Ans wered	this AE is still ongoing

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Header Text: C4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1231

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

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

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

Subject No: 12312982

Subject Initials: ---

Generated By: (b) (4)

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

Oct-21-2020 13:35:22 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Op ened	CLINQUERY: please clarify if this event has resolved. If so, please provide the stop date.
Oct-13-2020 09:21:17 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Clo sed	Response satisfies query
Oct-12-2020 21:30:45 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Ans wered	Severe anxiety is ongoing.
Oct-12-2020 21:29:26 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Clo sed	Close Auto Query
Oct-12-2020 21:17:33 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Op ened	'Disposition Follow-up form is completed and this Adverse Event is still ongoing. Please review and update as appropriate.
Oct-12-2020 17:31:03 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Op ened	CLINQUERY: please clarify if the subject is still experiencing severe anxiety. If resolved, please provide a stop date.
Oct-08-2020 20:50:33 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry : YES	Initial Entry

6. Toxicity Grade:

Date	Location	User	Value	Reason
Oct-08-2020 20:50:33 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 3	Initial Entry

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Header Text: C4591001

Visit: Logs - Unscheduled

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Site No: 1231

Subject No: 12312982

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

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

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

Subject Initials: ---

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7. Is the adverse event serious?

If Yes, NOTIFY PFIZER IMMEDIATELY.

Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).

Date	Location	User	Value	Reason
Oct-08-2020 20:50:33 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

8. Is this adverse event the result of a study Medication Error?

If Yes, record the type of medication error on the Medication Error Log.

Date	Location	User	Value	Reason
Oct-08-2020 20:50:33 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

9. Is this event related to study treatment:

Date	Location	User	Value	Reason
Oct-29-2020 15:55:05 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	Adolfo Gonzalez (b) (4)	Data Entry: NOT RELATED If Not Related to study treatment(s), this event is due to: OTHER <i>If Other, specify:</i> constitutive features	Transcription Error
Oct-29-2020 15:54:34 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	Adolfo Gonzalez (b) (4)	Data Entry: NOT RELATED If Not Related to study treatment(s), this event is due to: OTHER <i>If Other, specify:</i> unknown	Transcription Error

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Header Text: C4591001

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Site No: 1231

Subject No: 12312982

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

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

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Oct-12-2020 21:09:07 (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> constitutive features	New Information
Oct-08-2020 21:07:11 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NOT RELATED If Not Related to study treatment(s), this event is due to: OTHER <i>If Other, specify:</i> unknown	New Information
Oct-08-2020 20:50:33 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NOT RELATED	Initial Entry

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Nov-19-2020 18:34:54 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Nov-19-2020 15:37:41 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	The subject is not a study discontinuation. Is a withdraw consent by subject
Nov-19-2020 14:11:42 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	CLINQUERY: it appears that the subject was unblinded and discontinued due to the event of severe anxiety. Please clarify if "Latest Action Taken with Study Treatment" should be updated to DRUG

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Site No: 1231

Subject No: 12312982

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

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

				WITHDRAWN.
Oct-08-2020 20:59:47 (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-30-2020 04:03:39 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Oct-29-2020 16:46:20 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	New Information
Oct-29-2020 16:46:20 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	New Information
Oct-29-2020 16:45:52 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Initial Entry
Oct-29-2020 14:20:04 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	Balaji Prabu R (b) (4)	Query 1: Opened	Please remove comment and report "Was a concomitant medication given?" and "Was a Non-drug treatment given?" question with appropriate response. Thank you.
Oct-08-2020 21:01:10 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Unknown	Initial Entry

12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Oct-29-2020 15:53:09 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	Adolfo Gonzalez (b) (4)	Data Entry: NO	Initial Entry
Oct-29-2020 15:52:45 (UTC-03:00) City of	ACV0PFEINFP6000	Adolfo Gonzalez (b) (4)	Data Entry:	Initial Entry

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Header Text: C4591001

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Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

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

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

Subject No: 12312982

Subject Initials: ---

Generated By: (b) (4)

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

Buenos Aires				
Oct-08-2020 21:07:21 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Unknown	Initial Entry

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

Date	Location	User	Value	Reason
Nov-16-2020 20:59:02 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2 : Closed	Response satisfies query
Nov-16-2020 19:00:37 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2 : Answered	Anxiety as an AE finished the 14th of October.
Nov-16-2020 17:24:50 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (b) (4)	Query 2 : Opened	DMW5388807;Response to "What was the outcome of this adverse event?" is 'Recovered/Resolved' or 'Recovered/Resolved with Sequelae' but End Date/Time is missing. Please review and update as appropriate.
Oct-30-2020 12:52:56 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1 : Closed	Close Auto Query
Oct-30-2020 12:52:56 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: RECOVERED/RESOLVED	New Information
Oct-30-2020 12:52:43 (UTC-03:00)	ACV0PFEINFP6000	auto query (autoquery)	Query 1 : Opened	For AE severe anxiety: Response to "What was the outcome of this

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Header Text: C4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1231

Subject No: 12312982

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

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

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

Subject Initials: ---

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City of Buenos Aires				adverse event?" is 'Not Recovered/Not Resolved' but AE End Date/Time is present.
Oct-08-2020 20:50:33 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NOT RECOVERED/NOT RESOLVED	Initial Entry

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

Date	Location	User	Value	Reason
Nov-19-2020 15:35:17 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Transcription Error
Nov-16-2020 10:31:28 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	New Information
Oct-08-2020 20:59:47 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

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Header Text: C4591001

Visit: Disposition - Unscheduled

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Site No: 1231

Subject No: 12312982

Generated By: (b) (4)

Form: TREATMENT UNBLINDED - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

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

Subject Initials: ---

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

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I. Date Treatment Unblinded :

Date	Location	User	Value	Reason
Mar-02-2021 03:43:31 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Closed	Closed per data updated by site.
Mar-01-2021 14:45:21 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry : Not Applicable	Initial Entry
Mar-01-2021 14:44:05 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Answered	Changed Information
Mar-01-2021 14:44:05 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry :	Changed Information
Feb-27-2021 14:35:24 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	Saumitra Dubey (b) (4)	Query 2: Opened	P21 Review: Date Treatment Unblinded (09Oct2020) is after Disposition - Follow-Up date (23Sep2020). If dates are confirmed to be correct, please remove all the data from this page and provide form level comment as "Not Applicable". Else clarify.
Nov-02-2020 12:04:33 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Oct-30-2020 13:48:56	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Although the subject withdraws informed consent

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Header Text: C4591001

Visit: Disposition - Unscheduled

Form: TREATMENT UNBLINDED - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1231

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

Subject No: 12312982

Subject Initials: ---

Generated By: (b) (4)

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

(UTC-03:00) City of Buenos Aires			wered	on 09/23/2020 for everything that has evolved in the HC, the blind is opened and he is informed on 10/09/2020. Thank you.
Oct-29-2020 22:35:19 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (b) (4)	Query 1: Op ened	DMW5223319; 'Date Treatment Unblinded' is after 'Date of Completion/Discontinuation /Death' on the Disposition - Follow-up eCRF. Please clarify or correct.
Oct-09-2020 13:52:32 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry : Oct/9/ 2020	Initial Entry

2. Primary Reason for Unblinding:

Date	Location	User	Value	Reason
Mar-01-2021 14:45:21 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry
Mar-01-2021 14:44:42 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Changed Information
Oct-09-2020 13:52:32 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: SUBJECT SAFETY CONCERN	Initial Entry

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Header Text: C4591001

Visit: Disposition - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1231

Subject No: 12312982

Generated By: (b) (4)

Form: WITHDRAWAL OF CONSENT - 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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I. Withdrawal of Consent Date :

Date	Location	User	Value	Reason
Oct-06-2020 15:59:54 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sep/23/2020	Initial Entry

Header Text: C4591001**Visit:** Subject Status - Unscheduled**Form Version:** 22-Apr-2020 21:03**Site No:** 1231**Subject No:** 12312982**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](#)**I. Subject Status**

Date	Location	User	Value	Reason
Oct-29-2020 17:11:19 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: DISCONTINUED	Initial Entry
Oct-12-2020 21:29:16 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: DISCONTINUED	Transcription Error
Oct-12-2020 21:17:33 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: DISCONTINUED	Initial Entry
Oct-06-2020 16:00:10 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: DISCONTINUED	Initial Entry
Aug-22-2020 09:28:25 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: ENROLLED/RANDOMIZED	Initial Entry
Aug-22-2020 09:27:46 (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-10-2020 09:07:35 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sep/23/2020	Changed Information
Nov-10-2020 09:02:05 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Oct/29/2020	New Information
Oct-29-2020 17:11:19 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sep/23/2020	Initial Entry
Oct-12-2020 21:29:26 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sep/23/2020	Transcription Error

Header Text: C4591001

Visit: Subject Status - Unscheduled

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Site No: 1231

Subject No: 12312982

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

Oct-12-2020 21:29:16 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sep/23/2020	Transcription Error
Oct-12-2020 21:17:33 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sep/23/2020	Initial Entry
Oct-06-2020 16:00:10 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sep/23/2020	Initial Entry
Aug-22-2020 09:28:25 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Aug/21/2020	Initial Entry
Aug-22-2020 09:27:46 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Aug/21/2020	Initial Entry

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Form Version: 22-Apr-2020 21:04

Site No: 1231

Subject No: 12312982

Generated By: (b) (4)

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

Subject Initials: ---

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I. Casebook Signature

Date	Location	User	Value	Reason
Nov-04-2020 16:51:54 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Click Here to Enable	Initial Entry

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