

Header Text: C4591001

Visit: COHORT_SELECTION

Form: COHORT_SELECTION

Form Version: 30-Jul-2020 21:29

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1231

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

Subject No: 12314197

Subject Initials: ---

Generated By:

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

(b) (4)

[eCRF Audit Trail History](#)

Cohort Selection

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

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

090177e196ae2e43\Final\Final On: 01-Apr-2021 03:09 (GMT)

Header Text: C4591001

Visit: COHORT_SELECTION

Form Version: 22-Apr-2020 21:02

Site No: 1231

Subject No: 12314197

Generated By:

(b) (4)

Form: MAIN INFORMED CONSENT

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Informed Consent

1.	Consent Was:	OBTAINED Date Written Consent Obtained Aug/26/2020
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Header Text: C4591001

Visit: COHORT_SELECTION

Form: DEMOGRAPHY

Form Version: 06-Jul-2020 21:55

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1231

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

Subject No: 12314197

Subject Initials: ---

Generated By:

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

(b) (4)

[eCRF Audit Trail History](#)

Demography

1.	Subject ID	[12314197]
2.	Birth Date:	(b) (6)/1943
3.	Sex:	MALE
4.	Ethnicity:	HISPANIC OR LATINO(A) OR OF SPANISH ORIGIN
5.	Race: (Check X all that apply):	WHITE
6.	Racial Designation:	

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Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:02

Site No: 1231

Subject No: 12314197

Generated By:

(b) (4)

Form: DATE OF VISIT

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Date of Visit

1.	Date of Visit	Aug/26/2020
2.	Erroneous Visit	

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 30-Jul-2020 21:29

Site No: 1231

Subject No: 12314197

Generated By:

(b) (4)

Form: INCLUSION/EXCLUSION CRITERIA

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

Form Comments

Inclusion Criteria Not Met

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

Exclusion Criteria Met

2.	Description of Exclusion Criterion Met	Not Applicable _____
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090177e196ae2e43\Final\Final On: 01-Apr-2021 03:09 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1231

Subject No: 12314197

Generated By:

(b) (4)

Form: DISPOSITION - SCREENING

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Disposition - Screening

1.	Date of Completion/Discontinuation /Death	Aug/26/2020
2.	Phase of Disposition:	SCREENING
3.	Status:	COMPLETED
4.	Specify Status:	[]

090177e196ae2e43\Final\Final On: 01-Apr-2021 03:09 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1231

Subject No: 12314197

Generated By:

(b) (4)

Form: GENERAL MEDICAL HISTORY

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Medical History Details

1.a	Line/MH Number:	[1]
	Disease/Syndrome /Surgery/Non-Drug Allergies/Drug Allergies:	[prostatic hyperplasia]
	Start Date:	Aug/31/2018
	Ongoing:	YES
1.b	Line/MH Number:	[2]
	Disease/Syndrome /Surgery/Non-Drug Allergies/Drug Allergies:	[arterial hypertension]
	Start Date:	Aug/25/2018
	Ongoing:	YES

090177e196ae2e43\Final\Final On: 01-Apr-2021 03:09 (GMT)

Header Text: C4591001**Visit:** V1_DAY1_VAX1_L**Form Version:** 21-Aug-2020 02:51**Site No:** 1231**Subject No:** 12314197**Generated By:**

(b) (4)

Form: VITAL SIGNS - BASELINE**Form Status:** Data Complete, Locked, Frozen, Verified**Site Name:** (1231) Hospital Militar Central Cirujano
Mayor Dr. Cosme Argerich**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 20:34[eCRF Audit Trail History](#)**Vital Signs**

1.	Date:	Aug/26/2020
2.	Weight:	[89.0]
3.	Unit:	kg
4.	Height:	[169.0]
5.	Unit:	cm
6.	Body Mass Index:	[31.2]

Vital Signs Details

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

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1231

Subject No: 12314197

Generated By:

(b) (4)

Form: RANDOMIZATION

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Disposition

1.	Randomization Date :	Aug/26/2020
2.	Randomization Number:	[241376]
3.	Randomization Group:	[]

Header Text: C4591001**Visit:** V1_DAY1_VAX1_L**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY**Form Version:** 22-Apr-2020 21:03**Form Status:** Data Complete, Locked, Frozen, Verified**Site No:** 1231**Site Name:** (1231) Hospital Militar Central Cirujano Mayor Dr. Cosme Argerich**Subject No:** 12314197**Subject Initials:** ---**Generated By:****Generated Time (GMT):** 29-Mar-2021 20:34

(b) (4)

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

1.	Data Origin	SITE
2.	Sample Type	SERUM
3.	Sample Collected?	YES Date of Collection: Aug/26/2020
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[]

Aliquot

Please enter barcode for each aliquot.

5.a	Sample ID	[]
5.b	Sample ID	[BPT98H]
5.c	Sample ID	[BPT98J]
5.d	Sample ID	[BNTYDR]
5.e	Sample ID	[BNTYDS]
5.f	Sample ID	[BPTF90]

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1231

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

Subject No: 12314197

Subject Initials: ---

Generated By:

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

(b) (4)

5.g	Sample ID	[BPTF91]
5.h	Sample ID	[BPTF92]

Header Text: C4591001**Visit:** V1_DAY1_VAX1_L**Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB**Form Version:** 22-Apr-2020 21:03**Form Status:** Data Complete, Locked, Frozen, Verified**Site No:** 1231**Site Name:** (1231) Hospital Militar Central Cirujano Mayor Dr. Cosme Argerich**Subject No:** 12314197**Subject Initials:** ---**Generated By:****Generated Time (GMT):** 29-Mar-2021 20:34

(b) (4)

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

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB
3.	Sample Collected?	YES Date of Collection: Aug/26/2020
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	[BPT9PS]
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Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:04

Site No: 1231

Subject No: 12314197

Generated By:

(b) (4)

Form: VACCINATION

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Vaccination

1.	Was there a temporary delay of vaccination?	NO
2.	Treatment Name	[BLINDED THERAPY]
3.	Formulation:	INJECTION
4.	Dose Date Time:	Aug/26/2020 13:38
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

090177e196ae2e43\Final\Final On: 01-Apr-2021 03:09 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 06-Jul-2020 21:53

Site No: 1231

Subject No: 12314197

Generated By:

(b) (4)

Form: REACTOGENICITY DIARY

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Reactogenicity Diary

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

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:02

Site No: 1231

Subject No: 12314197

Generated By:

(b) (4)

Form: DATE OF VISIT

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Date of Visit

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

Header Text: C4591001

Visit: V2_VAX2_L

Form: VITAL SIGNS - TEMP

Form Version: 15-Sep-2020 21:54

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1231

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

Subject No: 12314197

Subject Initials: ---

Generated By:

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

(b) (4)

[eCRF Audit Trail History](#)

Vital Signs

1.	Date:	Sep/14/2020
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Vital Signs Details

2.a	Record Identifier:	1
	Temperature:	[36.1]
	Unit:	C
	Temperature Location:	ORAL CAVITY

Header Text: C4591001

Visit: V2_VAX2_L

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1231

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

Subject No: 12314197

Subject Initials: ---

Generated By:

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

(b) (4)

[eCRF Audit Trail History](#)

Electronic Sample Tracking

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB
3.	Sample Collected?	YES Date of Collection: Sep/14/2020
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[]

Aliquot

Please enter barcode for each aliquot.

5.a	Sample ID	[BP2FHZ]
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Header Text: C4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:04

Site No: 1231

Subject No: 12314197

Generated By:

(b) (4)

Form: VACCINATION

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Vaccination

1.	Was there a temporary delay of vaccination?	NO
2.	Treatment Name	[BLINDED THERAPY]
3.	Formulation:	INJECTION
4.	Dose Date Time:	Sep/14/2020 09:00
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

090177e196ae2e43\Final\Final On: 01-Apr-2021 03:09 (GMT)

Header Text: C4591001

Visit: V3_MONTH1_POSTVAX2_L **Form:** DATE OF VISIT

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

Site No: 1231

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

Subject No: 12314197

Subject Initials: ---

Generated By:

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

(b) (4)

[eCRF Audit Trail History](#)

Date of Visit

1.	Date of Visit	Oct/16/2020
2.	Erroneous Visit	

Header Text: C4591001

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

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

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

Subject No: 12314197 **Subject Initials:** ---

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

[eCRF Audit Trail History](#)

Electronic Sample Tracking

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

Aliquot

Please enter barcode for each aliquot.

5.a	Sample ID	[BLBX7F]
5.b	Sample ID	[BPW654]
5.c	Sample ID	[BLBX6K]

Header Text: C4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Oct/26/2020

Form Version: 22-Apr-2020 21:03

Site No: 1231

Subject No: 12314197

Generated By:

(b) (4)

Form: DATE OF VISIT - ILLNESS ONSET

Form Status: Data Complete, Frozen, Verified

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

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Date of Visit

1.	Date of Visit	Oct/26/2020
2.	Erroneous Visit	

COVID-19 Illness Visit

3.	COVID-19 Illness Visit:	COVID_A
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090177e196ae2e43\Final\Final On: 01-Apr-2021 03:09 (GMT)

Header Text: C4591001**Visit:** POT_COVID_ILL 1 -
Unscheduled Visit on Oct/26/2020**Form Version:** 10-Oct-2020 16:02**Site No:** 1231**Subject No:** 12314197**Generated By:**

(b) (4)

Form: SIGNS AND SYMPTOMS OF POTENTIAL
COVID-19**Form Status:** Data Complete, Frozen, Not Complete**Site Name:** (1231) Hospital Militar Central Cirujano
Mayor Dr. Cosme Argerich**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 20:34[eCRF Audit Trail History](#)**Signs and Symptoms**

1.	Date of Assessment:	Oct/26/2020
2.	Date of First Symptom Started:	Oct/26/2020
3.	Symptoms Ongoing?	NO Date of Last Symptom Resolved: Nov/1/2020

Symptoms

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

Header Text: C4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Oct/26/2020

Form Version: 10-Oct-2020 16:02

Site No: 1231

Subject No: 12314197

Generated By:

(b) (4)

Form: SIGNS AND SYMPTOMS OF POTENTIAL
COVID-19

Form Status: Data Complete, Frozen, Not Complete

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

Subject Initials: ---

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

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

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Header Text: C4591001

Visit: POT_COVID_ILL 1

Form: MICROBIOLOGY SPECIMEN

Form Version: 06-Jul-2020 21:54

Site No: 1231

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

Subject No: 12314197

Subject Initials: ---

Generated By:

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

(b) (4)

#	Date of Collection	Specimen Type	Specimen Collection Location	Assay Code and Description	Device Type	Form Instance
1.	Oct/26/2020	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 Oct/26/2020

Form: MICROBIOLOGY SPECIMEN

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen, Verified

Site No: 1231

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

Subject No: 12314197

Subject Initials: ---

Generated By:

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

(b) (4)

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[Form Audit Trail](#)

Microbiology Specimen

1.	Actual Date of Collection:	Oct/26/2020
2.	Specimen Type:	SWABBED MATERIAL
3.	Specimen Collection Location:	NASOPHARYNX
4.	Assay Code and Description:	SEVERE ACUTE RESP SYNDROME CORONAVIRUS 2
5.	Device Type:	SARS-COV-2 DIAGNOSTIC TEST
6.	Trade Name:	ATILA BIOSYSTEMS IAMP COVID-19 DETECTION KIT
7.	Test Result:	NEGATIVE
8.	Comments/Findings /Details:	[]
9.	Trade Name Other, Specify:	[]

090177e196ae2e43\Final\Final On: 01-Apr-2021 03:09 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Oct/26/2020

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: 12314197

Subject Initials: ---

Generated By:

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

(b) (4)

[eCRF Audit Trail History](#)

Electronic Sample Tracking

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

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 Oct/26/2020

Form Version: 22-Apr-2020 21:03

Site No: 1231

Subject No: 12314197

Generated By:

(b) (4)

Form: ELECTRONIC SAMPLE TRACKING - NASAL
SWAB

Form Status: Data Complete, Frozen, Verified

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

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Electronic Sample Tracking

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB
3.	Sample Collected?	YES Date of Collection: Oct/26/2020
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	[BPT7ZB]
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Header Text: C4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Oct/26/2020

Form: HEALTH CARE UTILIZATION

Form Version: 10-Oct-2020 15:59

Form Status: Data Complete, Frozen, Verified

Site No: 1231

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

Subject No: 12314197

Subject Initials: ---

Generated By:

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

(b) (4)

[eCRF Audit Trail History](#)

Health Care Utilization

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

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Header Text: C4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Oct/26/2020

Form: HEALTH CARE UTILIZATION

Form Version: 10-Oct-2020 15:59

Form Status: Data Complete, Frozen, Verified

Site No: 1231

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

Subject No: 12314197

Subject Initials: ---

Generated By:

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

(b) (4)

1.f	Physician or Healthcare Professional:	OTHER
	Occurrence of Visits or Contacts:	NO
Health Care Utilization Other		
2.	Other Type of Practitioner Specify:	[]
Health Care Utilization		
3.	Has the subject been hospitalized due to potential COVID-19 illness?	NO

090177e196ae2e43\Final\Final On: 01-Apr-2021 03:09 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1

Form: RESPIRATORY TREATMENT

Form Version: 06-Jul-2020 21:53

Site No: 1231

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

Subject No: 12314197

Subject Initials: ---

Generated By:

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

(b) (4)

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

Header Text: C4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Oct/26/2020

Form: RESPIRATORY TREATMENT

Form Version: 06-Jul-2020 21:53

Form Status: Not Started

Site No: 1231

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

Subject No: 12314197

Subject Initials: ---

Generated By:

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

(b) (4)

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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?	

090177e196ae2e43\Final\Final On: 01-Apr-2021 03:09 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Oct/26/2020

Form Version: 06-Jul-2020 21:52

Site No: 1231

Subject No: 12314197

Generated By:

(b) (4)

Form: ILLNESS DETAILS

Form Status: Data Complete, Frozen, Verified

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

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Illness Details

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

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: 12314197

Subject Initials: ---

Generated By:

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

(b) (4)

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

Header Text: C4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Oct/26/2020

Form: ILLNESS DETAILS - SEVERE

Form Version: 17-Jul-2020 21:55

Form Status: Not Started

Site No: 1231

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

Subject No: 12314197

Subject Initials: ---

Generated By:

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

(b) (4)

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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: 12314197

Subject Initials: ---

Generated By:

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

(b) (4)

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

090177e196ae2e43\Final\Final On: 01-Apr-2021 03:09 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Oct/26/2020

Form: LOCAL LABORATORY DATA - REPEATING
CHEMISTRY

Form Version: 21-Aug-2020 02:49

Form Status: Not Started

Site No: 1231

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

Subject No: 12314197

Subject Initials: ---

Generated By:

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

(b) (4)

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Lab Chemistry Details

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

Lab Result

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

090177e196ae2e43\Final\Final On: 01-Apr-2021 03:09 (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: 12314197

Subject Initials: ---

Generated By:

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

(b) (4)

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

090177e196ae2e43\Final\Final On: 01-Apr-2021 03:09 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Oct/26/2020

Form: LOCAL LABORATORY DATA - REPEATING
Hematology

Form Version: 21-Aug-2020 02:51

Form Status: Not Started

Site No: 1231

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

Subject No: 12314197

Subject Initials: ---

Generated By:

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

(b) (4)

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Laboratory Data Hematology

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

Lab Result

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

090177e196ae2e43\Final\Final On: 01-Apr-2021 03:09 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1

Form: VITAL SIGNS - COVID

Form Version: 21-Aug-2020 02:50

Site No: 1231

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

Subject No: 12314197

Subject Initials: ---

Generated By:

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

(b) (4)

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

090177e196ae2e43\Final\Final On: 01-Apr-2021 03:09 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Oct/26/2020

Form: VITAL SIGNS - COVID

Form Version: 21-Aug-2020 02:50

Form Status: Not Started

Site No: 1231

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

Subject No: 12314197

Subject Initials: ---

Generated By:

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

(b) (4)

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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: 12314197

Subject Initials: ---

Generated By:

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

(b) (4)

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

Header Text: C4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Oct/26/2020

Form: VITAL SIGNS - PULSE OX ROOM AIR

Form Version: 21-Aug-2020 02:51

Form Status: Not Started

Site No: 1231

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

Subject No: 12314197

Subject Initials: ---

Generated By:

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

(b) (4)

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Vital Signs

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

Vital Signs Details

2.	Record Identifier:	
	SPO2 Pulse Oximetry %	[]

Header Text: C4591001

Visit: POT_COVID_ILL 1

Form: OXYGENATION PARAMETERS

Form Version: 06-Jul-2020 21:52

Site No: 1231

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

Subject No: 12314197

Subject Initials: ---

Generated By:

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

(b) (4)

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

090177e196ae2e43\Final\Final On: 01-Apr-2021 03:09 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Oct/26/2020

Form: OXYGENATION PARAMETERS

Form Version: 06-Jul-2020 21:52

Form Status: Not Started

Site No: 1231

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

Subject No: 12314197

Subject Initials: ---

Generated By:

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

(b) (4)

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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: 12314197

Subject Initials: ---

Generated By:

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

(b) (4)

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

090177e196ae2e43\Final\Final On: 01-Apr-2021 03:09 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Oct/26/2020

Form Version: 06-Jul-2020 21:55

Site No: 1231

Subject No: 12314197

Generated By:

(b) (4)

Form: CONCOMITANT MEDICATIONS -
VASOPRESSORS

Form Status: Not Started

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

Subject Initials: ---

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

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Concomitant Medications

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

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Header Text: C4591001

Visit: POT_COVID_ILL 1

Form: IMAGING

Form Version: 06-Jul-2020 21:53

Site No: 1231

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

Subject No: 12314197

Subject Initials: ---

Generated By:

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

(b) (4)

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

Header Text: C4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Oct/26/2020

Form: IMAGING

Form Version: 06-Jul-2020 21:53

Form Status: Not Started

Site No: 1231

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

Subject No: 12314197

Subject Initials: ---

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Imaging

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

Header Text: C4591001

Visit: POT_COVID_ILL 2 -
Unscheduled Visit on Jan/27/2021

Form Version: 22-Apr-2020 21:03

Site No: 1231

Subject No: 12314197

Generated By:

(b) (4)

Form: DATE OF VISIT - ILLNESS ONSET

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Date of Visit

1.	Date of Visit	Jan/27/2021
2.	Erroneous Visit	

COVID-19 Illness Visit

3.	COVID-19 Illness Visit:	COVID_B
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090177e196ae2e43\Final\Final On: 01-Apr-2021 03:09 (GMT)

Header Text: C4591001**Visit:** POT_COVID_ILL 2 -
Unscheduled Visit on Jan/27/2021**Form Version:** 14-Jan-2021 02:23**Site No:** 1231**Subject No:** 12314197**Generated By:**

(b) (4)

Form: SIGNS AND SYMPTOMS OF POTENTIAL
COVID-19**Form Status:** Data Complete, Locked, Frozen**Site Name:** (1231) Hospital Militar Central Cirujano
Mayor Dr. Cosme Argerich**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 20:34[eCRF Audit Trail History](#)**Signs and Symptoms**

1.	Date of Assessment:	Jan/27/2021
2.	Date of First Symptom Started:	Jan/25/2021
3.	Symptoms Ongoing?	NO Date of Last Symptom Resolved: Jan/27/2021

Symptoms

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

Header Text: C4591001

Visit: POT_COVID_ILL 2 -
Unscheduled Visit on Jan/27/2021

Form: SIGNS AND SYMPTOMS OF POTENTIAL
COVID-19

Form Version: 14-Jan-2021 02:23

Form Status: Data Complete, Locked, Frozen

Site No: 1231

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

Subject No: 12314197

Subject Initials: ---

Generated By:

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

(b) (4)

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		
5.	Symptoms - Other Text:	[]

090177e196ae2e43\Final\Final On: 01-Apr-2021 03:09 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 2

Form: MICROBIOLOGY SPECIMEN

Form Version: 06-Jul-2020 21:54

Site No: 1231

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

Subject No: 12314197

Subject Initials: ---

Generated By:

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

(b) (4)

#	Date of Collection	Specimen Type	Specimen Collection Location	Assay Code and Description	Device Type	Form Instance
1.	Jan/27/2021	SWABBED MATERIAL	NASOPHARYNX	SEVERE ACUTE RESPIRATORY SYNDROME CORONAVIRUS 2	SARS-COV-2 DIAGNOSTIC TEST	Repeating Pages

090177e196ae2e43\Final\Final On: 01-Apr-2021 03:09 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 2 -
Unscheduled Visit on Jan/27/2021

Form: MICROBIOLOGY SPECIMEN

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Locked, Frozen

Site No: 1231

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

Subject No: 12314197

Subject Initials: ---

Generated By:

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

(b) (4)

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[Form Audit Trail](#)

Microbiology Specimen		
1.	Actual Date of Collection:	Jan/27/2021
2.	Specimen Type:	SWABBED MATERIAL
3.	Specimen Collection Location:	NASOPHARYNX
4.	Assay Code and Description:	SEVERE ACUTE RESP SYNDROME CORONAVIRUS 2
5.	Device Type:	SARS-COV-2 DIAGNOSTIC TEST
6.	Trade Name:	ATILA BIOSYSTEMS IAMP COVID-19 DETECTION KIT
7.	Test Result:	NEGATIVE
8.	Comments/Findings /Details:	[]
9.	Trade Name Other, Specify:	[]

090177e196ae2e43\Final\Final On: 01-Apr-2021 03:09 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 2 -
Unscheduled Visit on Jan/27/2021

Form Version: 22-Apr-2020 21:03

Site No: 1231

Subject No: 12314197

Generated By:

(b) (4)

Form: ELECTRONIC SAMPLE TRACKING - NASAL
SWAB SELF

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Electronic Sample Tracking

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB_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	[]
----	-----------	-----

Header Text: C4591001**Visit:** POT_COVID_ILL 2 -
Unscheduled Visit on Jan/27/2021**Form Version:** 22-Apr-2020 21:03**Site No:** 1231**Subject No:** 12314197**Generated By:**

(b) (4)

Form: ELECTRONIC SAMPLE TRACKING - NASAL
SWAB**Form Status:** Data Complete, Locked, Frozen, Verified**Site Name:** (1231) Hospital Militar Central Cirujano
Mayor Dr. Cosme Argerich**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 20:34[eCRF Audit Trail History](#)**Electronic Sample Tracking**

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB
3.	Sample Collected?	YES Date of Collection: Jan/27/2021
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[]

Aliquot

Please enter barcode for each aliquot.

5.a	Sample ID	[BPW6J8]
-----	-----------	----------

Header Text: C4591001

Visit: POT_COVID_ILL 2 -
Unscheduled Visit on Jan/27/2021

Form: HEALTH CARE UTILIZATION

Form Version: 14-Jan-2021 02:24

Form Status: Data Complete, Locked, Frozen

Site No: 1231

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

Subject No: 12314197

Subject Initials: ---

Generated By:

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

(b) (4)

[eCRF Audit Trail History](#)

Health Care Utilization

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

090177e196ae2e43\Final\Final On: 01-Apr-2021 03:09 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 2 -
Unscheduled Visit on Jan/27/2021

Form: HEALTH CARE UTILIZATION

Form Version: 14-Jan-2021 02:24

Form Status: Data Complete, Locked, Frozen

Site No: 1231

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

Subject No: 12314197

Subject Initials: ---

Generated By:

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

(b) (4)

1.f	Physician or Healthcare Professional:	OTHER
	Occurrence of Visits or Contacts:	NO
Health Care Utilization Other		
2.	Other Type of Practitioner Specify:	[]
Health Care Utilization		
3.	Has the subject been hospitalized due to potential COVID-19 illness?	NO

090177e196ae2e43\Final\Final On: 01-Apr-2021 03:09 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 2

Form: RESPIRATORY TREATMENT

Form Version: 06-Jul-2020 21:53

Site No: 1231

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

Subject No: 12314197

Subject Initials: ---

Generated By:

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

(b) (4)

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

Header Text: C4591001

Visit: POT_COVID_ILL 2 -
Unscheduled Visit on Jan/27/2021

Form Version: 06-Jul-2020 21:53

Site No: 1231

Subject No: 12314197

Generated By:

(b) (4)

Form: RESPIRATORY TREATMENT

Form Status: Not Started

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

Subject Initials: ---

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

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Respiratory Treatment

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

090177e196ae2e43\Final\Final On: 01-Apr-2021 03:09 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 2 -
Unscheduled Visit on Jan/27/2021

Form Version: 06-Jul-2020 21:52

Site No: 1231

Subject No: 12314197

Generated By:

(b) (4)

Form: ILLNESS DETAILS

Form Status: Data Complete, Locked, Frozen

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

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Illness Details

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

Header Text: C4591001

Visit: POT_COVID_ILL 2

Form: ILLNESS DETAILS - SEVERE

Form Version: 17-Jul-2020 21:55

Site No: 1231

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

Subject No: 12314197

Subject Initials: ---

Generated By:

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

(b) (4)

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

Header Text: C4591001

Visit: POT_COVID_ILL 2 -
Unscheduled Visit on Jan/27/2021

Form Version: 17-Jul-2020 21:55

Site No: 1231

Subject No: 12314197

Generated By:

(b) (4)

Form: ILLNESS DETAILS - SEVERE

Form Status: Not Started

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

Subject Initials: ---

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

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Illness Details

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

090177e196ae2e43\Final\Final On: 01-Apr-2021 03:09 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 2

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY

Form Version: 21-Aug-2020 02:49

Site No: 1231

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

Subject No: 12314197

Subject Initials: ---

Generated By:

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

(b) (4)

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

090177e196ae2e43\Final\Final On: 01-Apr-2021 03:09 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 2 -
Unscheduled Visit on Jan/27/2021

Form: LOCAL LABORATORY DATA - REPEATING
CHEMISTRY

Form Version: 21-Aug-2020 02:49

Form Status: Not Started

Site No: 1231

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

Subject No: 12314197

Subject Initials: ---

Generated By:

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

(b) (4)

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Lab Chemistry Details

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

Lab Result

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

090177e196ae2e43\Final\Final On: 01-Apr-2021 03:09 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 2

Form: LOCAL LABORATORY DATA - REPEATING Hematology

Form Version: 21-Aug-2020 02:51

Site No: 1231

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

Subject No: 12314197

Subject Initials: ---

Generated By:

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

(b) (4)

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

090177e196ae2e43\Final\Final On: 01-Apr-2021 03:09 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 2 -
Unscheduled Visit on Jan/27/2021

Form: LOCAL LABORATORY DATA - REPEATING
Hematology

Form Version: 21-Aug-2020 02:51

Form Status: Not Started

Site No: 1231

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

Subject No: 12314197

Subject Initials: ---

Generated By:

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

(b) (4)

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Laboratory Data Hematology

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

Lab Result

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

090177e196ae2e43\Final\Final On: 01-Apr-2021 03:09 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 2

Form: VITAL SIGNS - COVID

Form Version: 21-Aug-2020 02:50

Site No: 1231

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

Subject No: 12314197

Subject Initials: ---

Generated By:

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

(b) (4)

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

Header Text: C4591001

Visit: POT_COVID_ILL 2 -
Unscheduled Visit on Jan/27/2021

Form: VITAL SIGNS - COVID

Form Version: 21-Aug-2020 02:50

Form Status: Not Started

Site No: 1231

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

Subject No: 12314197

Subject Initials: ---

Generated By:

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

(b) (4)

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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:	[]

090177e196ae2e43\Final\Final On: 01-Apr-2021 03:09 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 2

Form: VITAL SIGNS - PULSE OX ROOM AIR

Form Version: 21-Aug-2020 02:51

Site No: 1231

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

Subject No: 12314197

Subject Initials: ---

Generated By:

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

(b) (4)

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

090177e196ae2e43\Final\Final On: 01-Apr-2021 03:09 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 2 -
Unscheduled Visit on Jan/27/2021

Form: VITAL SIGNS - PULSE OX ROOM AIR

Form Version: 21-Aug-2020 02:51

Form Status: Not Started

Site No: 1231

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

Subject No: 12314197

Subject Initials: ---

Generated By:

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

(b) (4)

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Vital Signs

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

Vital Signs Details

2.	Record Identifier:	
	SPO2 Pulse Oximetry %	[]

Header Text: C4591001

Visit: POT_COVID_ILL 2

Form: OXYGENATION PARAMETERS

Form Version: 06-Jul-2020 21:52

Site No: 1231

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

Subject No: 12314197

Subject Initials: ---

Generated By:

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

(b) (4)

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

Header Text: C4591001

Visit: POT_COVID_ILL 2 -
Unscheduled Visit on Jan/27/2021

Form: OXYGENATION PARAMETERS

Form Version: 06-Jul-2020 21:52

Form Status: Not Started

Site No: 1231

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

Subject No: 12314197

Subject Initials: ---

Generated By:

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

(b) (4)

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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 2

Form: CONCOMITANT MEDICATIONS -
VASOPRESSORS

Form Version: 06-Jul-2020 21:55

Site No: 1231

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

Subject No: 12314197

Subject Initials: ---

Generated By:

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

(b) (4)

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

090177e196ae2e43\Final\Final On: 01-Apr-2021 03:09 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 2 -
Unscheduled Visit on Jan/27/2021

Form Version: 06-Jul-2020 21:55

Site No: 1231

Subject No: 12314197

Generated By:

(b) (4)

Form: CONCOMITANT MEDICATIONS -
VASOPRESSORS

Form Status: Not Started

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

Subject Initials: ---

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

[Back to Form](#)

Concomitant Medications

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

090177e196ae2e43\Final\Final On: 01-Apr-2021 03:09 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 2

Form: IMAGING

Form Version: 06-Jul-2020 21:53

Site No: 1231

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

Subject No: 12314197

Subject Initials: ---

Generated By:

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

(b) (4)

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

Header Text: C4591001

Visit: POT_COVID_ILL 2 -
Unscheduled Visit on Jan/27/2021

Form: IMAGING

Form Version: 06-Jul-2020 21:53

Form Status: Not Started

Site No: 1231

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

Subject No: 12314197

Subject Initials: ---

Generated By:

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

(b) (4)

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Imaging

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

Header Text: C4591001

Visit: POT_COVID_CONVA 1 -
Unscheduled Visit on Nov/26/2020

Form Version: 22-Apr-2020 21:04

Site No: 1231

Subject No: 12314197

Generated By:

(b) (4)

Form: DATE OF VISIT - ILLNESS CONVALESCENT

Form Status: Data Complete, Frozen, Verified

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

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Date of Visit

1.	Date of Visit	Nov/26/2020
2.	Erroneous Visit	

COVID-19 Illness Visit

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

090177e196ae2e43\Final\Final On: 01-Apr-2021 03:09 (GMT)

Header Text: C4591001**Visit:** POT_COVID_CONVA 1 -
Unscheduled Visit on Nov/26/2020**Form Version:** 22-Apr-2020 21:03**Site No:** 1231**Subject No:** 12314197**Generated By:**

(b) (4)

Form: ELECTRONIC SAMPLE TRACKING -
IMMUNOGENICITY**Form Status:** Data Complete, Frozen, Verified**Site Name:** (1231) Hospital Militar Central Cirujano
Mayor Dr. Cosme Argerich**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 20:34[eCRF Audit Trail History](#)**Electronic Sample Tracking**

1.	Data Origin	SITE
2.	Sample Type	SERUM
3.	Sample Collected?	YES Date of Collection: Nov/26/2020
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	[BRVMHH]
5.b	Sample ID	[BRVMH5]
5.c	Sample ID	[BPWSPZ]

Header Text: C4591001

Visit: POT_COVID_CONVA 2 -
Unscheduled Visit on Mar/26/2021

Form: DATE OF VISIT - ILLNESS CONVALESCENT

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Verified

Site No: 1231

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

Subject No: 12314197

Subject Initials: ---

Generated By:

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

(b) (4)

[eCRF Audit Trail History](#)

Date of Visit

1.	Date of Visit	Mar/26/2021
2.	Erroneous Visit	

COVID-19 Illness Visit

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

090177e196ae2e43\Final\Final On: 01-Apr-2021 03:09 (GMT)

Header Text: C4591001**Visit:** POT_COVID_CONVA 2 -
Unscheduled Visit on Mar/26/2021**Form Version:** 22-Apr-2020 21:03**Site No:** 1231**Subject No:** 12314197**Generated By:**

(b) (4)

Form: ELECTRONIC SAMPLE TRACKING -
IMMUNOGENICITY**Form Status:** Data Complete, Verified**Site Name:** (1231) Hospital Militar Central Cirujano
Mayor Dr. Cosme Argerich**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 20:34[eCRF Audit Trail History](#)**Electronic Sample Tracking**

1.	Data Origin	SITE
2.	Sample Type	SERUM
3.	Sample Collected?	YES Date of Collection: Mar/26/2021
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[]

Aliquot

Please enter barcode for each aliquot.

5.a	Sample ID	[BS1RFB]
5.b	Sample ID	[BS1RDZ]
5.c	Sample ID	[BPW7TZ]

Header Text: C4591001

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

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

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

Subject No: 12314197 **Subject Initials:** ---

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

Date of Visit

1.	Date of Visit	//
2.	Erroneous Visit	

Header Text: C4591001

Visit: Unplanned - New Unscheduled Visit **Form:** UNPLANNED VISIT

Form Version: 22-Apr-2020 21:04 **Form Status:** Not Started

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

Subject No: 12314197 **Subject Initials:** ---

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

Unplanned Assessments

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

Header Text: C4591001

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

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

Site No: 1231

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

Subject No: 12314197

Subject Initials: ---

Generated By:

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

(b) (4)

[eCRF Audit Trail History](#)

Disposition - Treatment

1.	Date of Completion/Discontinuation/Death :	Oct/16/2020
2.	Phase of Disposition:	VACCINATION
3.	Status:	COMPLETED
4.	Specify Status:	[]

090177e196ae2e43\Final\Final On: 01-Apr-2021 03:09 (GMT)

Header Text: C4591001

Visit: Follow-Up - Unscheduled

Form Version: 15-Sep-2020 21:53

Site No: 1231

Subject No: 12314197

Generated By:

(b) (4)

Form: DISPOSITION - FOLLOW-UP

Form Status: Not Started

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

Subject Initials: ---

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

Disposition - Follow-Up

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

Header Text: C4591001

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

Form Version: 10-Oct-2020 15:57

Form Status: Not Started

Site No: 1231

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

Subject No: 12314197

Subject Initials: ---

Generated By:

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

(b) (4)

Date of Visit

1.	Date of Visit	//
2.	Erroneous Visit	

COVID-19 Repeat Swab

3.	COVID-19 Repeat Swab:	
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090177e196ae2e43\Final\Final On: 01-Apr-2021 03:09 (GMT)

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:** 12314197**Subject Initials:** ---**Generated By:****Generated Time (GMT):** 29-Mar-2021 20:34

(b) (4)

Electronic Sample Tracking

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

Aliquot

Please enter barcode for each aliquot.

5.	Sample ID	[]
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Header Text: C4591001

Visit: Unplanned Vaccination -
Unscheduled

Form: DATE OF VISIT

Form Version: 22-Apr-2020 21:02

Form Status: Not Started

Site No: 1231

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

Subject No: 12314197

Subject Initials: ---

Generated By:

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

(b) (4)

Date of Visit

1.	Date of Visit	//
2.	Erroneous Visit	

Header Text: C4591001

Visit: Unplanned Vaccination -
Unscheduled

Form: VITAL SIGNS - TEMP

Form Version: 28-Mar-2021 02:28

Form Status: Not Started

Site No: 1231

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

Subject No: 12314197

Subject Initials: ---

Generated By:

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

(b) (4)

Vital Signs

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

Vital Signs Details

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

Header Text: C4591001

Visit: Unplanned Vaccination -
Unscheduled

Form: VACCINATION

Form Version: 10-Dec-2020 02:26

Form Status: Not Started

Site No: 1231

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

Subject No: 12314197

Subject Initials: ---

Generated By:

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

(b) (4)

Vaccination

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

090177e196ae2e43\Final\Final On: 01-Apr-2021 03:09 (GMT)

Header Text: C4591001

Visit: Unplanned Vaccination -
Unscheduled

Form Version: 10-Oct-2020 15:57

Site No: 1231

Subject No: 12314197

Generated By:

(b) (4)

Form: CONTACT OUTCOME - MONTH 1

Form Status: Not Started

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

Subject Initials: ---

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

Contact Outcome

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

Header Text: C4591001

Visit: Unplanned Vaccination -
Unscheduled

Form Version: 10-Oct-2020 16:01

Site No: 1231

Subject No: 12314197

Generated By:

(b) (4)

Form: CONTACT OUTCOME - MONTH 6

Form Status: Not Started

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

Subject Initials: ---

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

Contact Outcome

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

Header Text: C4591001

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

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1231

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

Subject No: 12314197

Subject Initials: ---

Generated By:

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

(b) (4)

[eCRF Audit Trail History](#)

Date of Visit

1.	Date of Visit	Jan/26/2021
2.	Erroneous Visit	

Header Text: C4591001

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

Form Version: 10-Dec-2020 02:25

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1231

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

Subject No: 12314197

Subject Initials: ---

Generated By:

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

(b) (4)

[eCRF Audit Trail History](#)

Further Vaccination Confirmation

1.	Select appropriate response - Is participant willing to return for Vaccination 3?	Participant is willing to return for Vaccination 3 Participant is: eligible per local/national recommendations and confirmed to have received only placebo at Vaccination 1/2
----	---	--

090177e196ae2e43\Final\Final On: 01-Apr-2021 03:09 (GMT)

Header Text: C4591001

Visit: V101_VAX3

Form Version: 22-Apr-2020 21:02

Site No: 1231

Subject No: 12314197

Generated By:

(b) (4)

Form: DATE OF VISIT

Form Status: Data Complete, Verified

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

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Date of Visit

1.	Date of Visit	Mar/26/2021
2.	Erroneous Visit	

Header Text: C4591001

Visit: V101_VAX3

Form: INFORMED CONSENT - FURTHER VACCINATION

Form Version: 10-Dec-2020 02:31

Form Status: Data Complete, Verified

Site No: 1231

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

Subject No: 12314197

Subject Initials: ---

Generated By:

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

(b) (4)

[eCRF Audit Trail History](#)

Informed Consent - Further Vaccination

1.	Consent Was:	OBTAINED Date Written Consent Obtained Mar/26/2021
----	--------------	--

Header Text: C4591001

Visit: V101_VAX3

Form: INCLUSION/EXCLUSION CRITERIA - FURTHER VACCINATION

Form Version: 10-Dec-2020 02:30

Form Status: Data Complete, Verified

Site No: 1231

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

Subject No: 12314197

Subject Initials: ---

Generated By:

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

(b) (4)

Form Comments

Inclusion Criteria Not Met

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

Exclusion Criteria Met

2.	Description of Exclusion Criterion Met	Not Applicable _____
----	--	-------------------------

090177e196ae2e43\Final\Final On: 01-Apr-2021 03:09 (GMT)

Header Text: C4591001

Visit: V101_VAX3

Form: DISPOSITION - SCREENING FOR FURTHER VACCINATION

Form Version: 10-Dec-2020 02:31

Form Status: Data Complete, Verified

Site No: 1231

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

Subject No: 12314197

Subject Initials: ---

Generated By:

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

(b) (4)

[eCRF Audit Trail History](#)

Disposition - Screening for Further Vaccination

1.	Date of Completion/Discontinuation/Death :	Mar/26/2021
2.	Phase of Disposition:	REPEAT SCREENING 1
3.	Status:	COMPLETED
4.	Specify Status:	[]

090177e196ae2e43\Final\Final On: 01-Apr-2021 03:09 (GMT)

Header Text: C4591001

Visit: V101_VAX3

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Verified

Site No: 1231

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

Subject No: 12314197

Subject Initials: ---

Generated By:

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

(b) (4)

[eCRF Audit Trail History](#)

Electronic Sample Tracking

1.	Data Origin	SITE
2.	Sample Type	SERUM
3.	Sample Collected?	NO
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[Sample was captured in the convalescent visit which was carried out the same day]

Aliquot

Please enter barcode for each aliquot.

5.	Sample ID	[]
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090177e196ae2e43\Final\Final On: 01-Apr-2021 03:09 (GMT)

Header Text: C4591001

Visit: V101_VAX3

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Verified

Site No: 1231

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

Subject No: 12314197

Subject Initials: ---

Generated By:

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

(b) (4)

[eCRF Audit Trail History](#)

Electronic Sample Tracking

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB
3.	Sample Collected?	YES Date of Collection: Mar/26/2021
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[]

Aliquot

Please enter barcode for each aliquot.

5.a	Sample ID	[BPT8W5]
-----	-----------	----------

Header Text: C4591001

Visit: V101_VAX3

Form Version: 10-Dec-2020 02:26

Site No: 1231

Subject No: 12314197

Generated By:

(b) (4)

Form: VACCINATION

Form Status: Data Complete, Verified

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

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Vaccination

1.	Was there a temporary delay of vaccination?	NO
2.	Treatment Name	[BNT162b2]
3.	Formulation:	INJECTION
4.	Dose Date Time:	Mar/26/2021 11:09
5.	Anatomical Location:	DELTOID MUSCLE
6.	Body Side:	RIGHT
7.	Route:	INTRAMUSCULAR
8.	Actual Dose:	[30.0]
9.	Unit:	ug
10.	Timeframe Subject Was Observed	30 MINUTES
11.	Was the subject observed for at least the protocol specified observation period after investigational product administration?	YES

090177e196ae2e43\Final\Final On: 01-Apr-2021 03:09 (GMT)

Header Text: C4591001

Visit: V102_VAX4

Form Version: 22-Apr-2020 21:02

Site No: 1231

Subject No: 12314197

Generated By:

(b) (4)

Form: DATE OF VISIT

Form Status: Not Started

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

Subject Initials: ---

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

Date of Visit		
1.	Date of Visit	//
2.	Erroneous Visit	

Header Text: C4591001

Visit: V102_VAX4

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1231

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

Subject No: 12314197

Subject Initials: ---

Generated By:

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

(b) (4)

Electronic Sample Tracking

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

Aliquot

Please enter barcode for each aliquot.

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

Header Text: C4591001

Visit: V102_VAX4

Form: VACCINATION

Form Version: 10-Dec-2020 02:26

Form Status: Not Started

Site No: 1231

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

Subject No: 12314197

Subject Initials: ---

Generated By:

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

(b) (4)

Vaccination

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

090177e196ae2e43\Final\Final On: 01-Apr-2021 03:09 (GMT)

Header Text: C4591001

Visit: V103_MONTH1

Form Version: 22-Apr-2020 21:02

Site No: 1231

Subject No: 12314197

Generated By:

(b) (4)

Form: DATE OF VISIT

Form Status: Not Started

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

Subject Initials: ---

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

Date of Visit

1.	Date of Visit	//
2.	Erroneous Visit	

Header Text: C4591001

Visit: V103_MONTH1

Form Version: 22-Apr-2020 21:04

Site No: 1231

Subject No: 12314197

Generated By:

(b) (4)

Form: CONTACT OUTCOME

Form Status: Not Started

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

Subject Initials: ---

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

Contact Outcome

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

Header Text: C4591001

Visit: V104_MONTH6

Form Version: 22-Apr-2020 21:02

Site No: 1231

Subject No: 12314197

Generated By:

(b) (4)

Form: DATE OF VISIT

Form Status: Not Started

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

Subject Initials: ---

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

Date of Visit

1.	Date of Visit	//
2.	Erroneous Visit	

Header Text: C4591001

Visit: V104_MONTH6

Form Version: 22-Apr-2020 21:04

Site No: 1231

Subject No: 12314197

Generated By:

(b) (4)

Form: CONTACT OUTCOME

Form Status: Not Started

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

Subject Initials: ---

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

Contact Outcome

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

Header Text: C4591001

Visit: V105_MONTH18

Form Version: 22-Apr-2020 21:02

Site No: 1231

Subject No: 12314197

Generated By:

(b) (4)

Form: DATE OF VISIT

Form Status: Not Started

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

Subject Initials: ---

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

Date of Visit

1.	Date of Visit	//
2.	Erroneous Visit	

Header Text: C4591001

Visit: V105_MONTH18

Form Version: 22-Apr-2020 21:04

Site No: 1231

Subject No: 12314197

Generated By:

(b) (4)

Form: CONTACT OUTCOME

Form Status: Not Started

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

Subject Initials: ---

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

Contact Outcome

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

Header Text: C4591001

Visit:
FURTHER_VACCINATION_EOT -
Unscheduled

Form: DISPOSITION - TREATMENT

Form Version: 20-Feb-2021 02:26

Form Status: Not Started

Site No: 1231

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

Subject No: 12314197

Subject Initials: ---

Generated By:

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

(b) (4)

Disposition - Treatment

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

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: 12314197

Subject Initials: ---

Generated By:

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

(b) (4)

#	Category	AE Identifier	Adverse Event	Start Date	Is the Adverse Event Still Ongoing	Form Instance
1.	ADVERSE EVENT	1	hip osteoarthritis	Nov/11/2020 20:30	NO End Date Time: Nov/26/2020 17:47	Repeating Pages
2.	ADVERSE EVENT	2	Worsening of left hip osteoarthritis	Jan/23/2021 08:00	NO End Date Time: Mar/15/2021 10:00	Repeating Pages
3. DELETED	ADVERSE EVENT	3	Worsening of left hip osteoarthritis	Jan/23/2021 08:00	YES	Repeating Pages
4.	ADVERSE EVENT	4	Left hip osteoarthritis	Nov/13/2020 09:00	NO End Date Time: Mar/26/2021 10:00	Repeating Pages

090177e196ae2e43\Final\Final On: 01-Apr-2021 03:09 (GMT)

Header Text: C4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Locked, Frozen

Site No: 1231

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

Subject No: 12314197

Subject Initials: ---

Generated By:

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

(b) (4)

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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)	[hip osteoarthritis]
4.	Start Date Time:	Nov/11/2020 20:30
5.	Is the adverse event still ongoing?	NO End Date Time: Nov/26/2020 17:47
6.	Toxicity Grade:	1

090177e196ae2e43\Final\Final On: 01-Apr-2021 03:09 (GMT)

Header Text: C4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1231

Subject No: 12314197

Generated By:

(b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Locked, Frozen

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

Subject Initials: ---

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

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

090177e196ae2e43\Final\Final On: 01-Apr-2021 03:09 (GMT)

Header Text: C4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Locked, Frozen

Site No: 1231

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

Subject No: 12314197

Subject Initials: ---

Generated By:

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

(b) (4)

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	[]

090177e196ae2e43\Final\Final On: 01-Apr-2021 03:09 (GMT)

Header Text: C4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1231

Subject No: 12314197

Generated By:

(b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete

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

Subject Initials: ---

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

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Adverse Event Report

1.	Category:	ADVERSE EVENT
2.	AE ID:	[2]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[Worsening of left hip osteoarthritis]
4.	Start Date Time:	Jan/23/2021 08:00
5.	Is the adverse event still ongoing?	NO End Date Time: Mar/15/2021 10:00
6.	Toxicity Grade:	3

090177e196ae2e43\Final\Final On: 01-Apr-2021 03:09 (GMT)

Header Text: C4591001**Visit:** Logs - Unscheduled**Form Version:** 22-Apr-2020 21:02**Site No:** 1231**Subject No:** 12314197**Generated By:**

(b) (4)

Form: ADVERSE EVENT REPORT**Form Status:** Data Complete**Site Name:** (1231) Hospital Militar Central Cirujano
Mayor Dr. Cosme Argerich**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 20:34

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

Header Text: C4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete

Site No: 1231

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

Subject No: 12314197

Subject Initials: ---

Generated By:

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

(b) (4)

10.	Latest Action Taken with Study Treatment:	NOT APPLICABLE
11.	Was a Concomitant Medication given?	YES
12.	Was a Non-Drug Treatment given?	YES
13.	What was the outcome of this adverse event?:	RECOVERED/RESOLVED WITH SEQUELAE
14.	Did the adverse event cause the subject to be discontinued from the study?	NO
15.	Serious Adverse Event Number: For Pfizer Use Only	[2021251319]

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Header Text: C4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1231

Subject No: 12314197

Generated By:

(b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Deleted, Locked, Frozen

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

Subject Initials: ---

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

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

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Adverse Event Report

1.	Category:	ADVERSE EVENT
2.	AE ID:	[3]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[Worsening of left hip osteoarthritis]
4.	Start Date Time:	Jan/23/2021 08:00
5.	Is the adverse event still ongoing?	YES
6.	Toxicity Grade:	3

090177e196ae2e43\Final\Final On: 01-Apr-2021 03:09 (GMT)

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

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

Header Text: C4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1231

Subject No: 12314197

Generated By:

(b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete

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

Subject Initials: ---

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Adverse Event Report

1.	Category:	ADVERSE EVENT
2.	AE ID:	[4]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[Left hip osteoarthritis]
4.	Start Date Time:	Nov/13/2020 09:00
5.	Is the adverse event still ongoing?	NO End Date Time: Mar/26/2021 10:00
6.	Toxicity Grade:	3

090177e196ae2e43\Final\Final On: 01-Apr-2021 03:09 (GMT)

Header Text: C4591001**Visit:** Logs - Unscheduled**Form Version:** 22-Apr-2020 21:02**Site No:** 1231**Subject No:** 12314197**Generated By:**

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Form: ADVERSE EVENT REPORT**Form Status:** Data Complete**Site Name:** (1231) Hospital Militar Central Cirujano
Mayor Dr. Cosme Argerich**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 20:34

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

Header Text: C4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete

Site No: 1231

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

Subject No: 12314197

Subject Initials: ---

Generated By:

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

(b) (4)

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

090177e196ae2e43\Final\Final On: 01-Apr-2021 03:09 (GMT)

Header Text: C4591001

Visit: Logs

Form: MEDICATION ERROR

Form Version: 17-Jul-2020 21:54

Site No: 1231

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

Subject No: 12314197

Subject Initials: ---

Generated By:

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

(b) (4)

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

Header Text: C4591001

Visit: Logs - Unscheduled

Form: MEDICATION ERROR

Form Version: 17-Jul-2020 21:54

Form Status: Not Started

Site No: 1231

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

Subject No: 12314197

Subject Initials: ---

Generated By:

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

(b) (4)

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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	[]

090177e196ae2e43\Final\Final On: 01-Apr-2021 03:09 (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: 12314197

Subject Initials: ---

Generated By:

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

(b) (4)

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

Header Text: C4591001

Visit: 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: 12314197

Subject Initials: ---

Generated By:

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

(b) (4)

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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:	//

090177e196ae2e43\Final\Final On: 01-Apr-2021 03:09 (GMT)

Header Text: C4591001

Visit: Logs

Form: CONCOMITANT MEDICATIONS - PROHIBITED

Form Version: 22-Apr-2020 21:03

Site No: 1231

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

Subject No: 12314197

Subject Initials: ---

Generated By:

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

(b) (4)

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

Header Text: C4591001

Visit: Logs - Unscheduled

Form: CONCOMITANT MEDICATIONS - PROHIBITED

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1231

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

Subject No: 12314197

Subject Initials: ---

Generated By:

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

(b) (4)

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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?	

090177e196ae2e43\Final\Final On: 01-Apr-2021 03:09 (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: 12314197

Subject Initials: ---

Generated By:

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

(b) (4)

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

Header Text: C4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1231

Subject No: 12314197

Generated By:

(b) (4)

Form: RADIATION TREATMENT

Form Status: Not Started

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

Subject Initials: ---

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

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Radiation Treatment

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

090177e196ae2e43\Final\Final On: 01-Apr-2021 03:09 (GMT)

Header Text: C4591001

Visit: Logs

Form: TRANSFUSIONS

Form Version: 22-Apr-2020 21:03

Site No: 1231

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

Subject No: 12314197

Subject Initials: ---

Generated By:

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

(b) (4)

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

Header Text: C4591001

Visit: Logs - Unscheduled

Form: TRANSFUSIONS

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1231

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

Subject No: 12314197

Subject Initials: ---

Generated By:

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

(b) (4)

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

Header Text: C4591001

Visit: Disposition - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1231

Subject No: 12314197

Generated By:

(b) (4)

Form: TREATMENT UNBLINDED

Form Status: Data Complete, Frozen, Verified

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

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Treatment Unblinded

1.	Date Treatment Unblinded :	Jan/26/2021
2.	Primary Reason for Unblinding:	ASSESS ELIGIBILITY FOR ADDITIONAL VACCINATION

Header Text: C4591001

Visit: Disposition - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1231

Subject No: 12314197

Generated By:

(b) (4)

Form: WITHDRAWAL OF CONSENT

Form Status: Not Started

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

Subject Initials: ---

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

Withdrawal Of Consent

1.	Withdrawal of Consent Date :	//
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090177e196ae2e43\Final\Final On: 01-Apr-2021 03:09 (GMT)

Header Text: C4591001

Visit: Disposition - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1231

Subject No: 12314197

Generated By:

(b) (4)

Form: DEATH DETAILS CODED

Form Status: Not Started

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

Subject Initials: ---

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

Death Details

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

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

Header Text: C4591001

Visit: Subject Status - Unscheduled

Form: SUBJECT STATUS

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Verified

Site No: 1231

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

Subject No: 12314197

Subject Initials: ---

Generated By:

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

(b) (4)

[eCRF Audit Trail History](#)

Subject Status

1.	Subject Status	FOLLOW-UP
2.	Subject Status Date	Oct/16/2020

Header Text: C4591001

Visit: Investigator Signature -
Unscheduled

Form: CASEBOOK SIGNATURE FORM

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Verified

Site No: 1231

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

Subject No: 12314197

Subject Initials: ---

Generated By:

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

(b) (4)

[eCRF Audit Trail History](#)

Casebook Signature Form

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

Visit: Investigator Signature -
Unscheduled

Form: CASEBOOK SIGNATURE FORM

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Verified

Site No: 1231

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

Subject No: 12314197

Subject Initials: ---

Generated By:

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

(b) (4)

[Audit Trail](#)

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

- CRF_Sign
- CRF_Sign_1

Name	Signature Meaning	Date	Type	Action
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Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form: INCLUSION/EXCLUSION CRITERIA -
Comments

Form Version: 30-Jul-2020 21:29

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1231

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

Subject No: 12314197

Subject Initials: ---

Generated By:

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

(b) (4)

[Back to Form](#)

Item	Date	User	Comment
Form	Aug-26-2020 15:16:39 (UTC-03:00) City of Buenos Aires	(b) (4), (b) (6)	Not Applicable

Header Text: C4591001

Visit: V101_VAX3

Form: INCLUSION/EXCLUSION CRITERIA - FURTHER VACCINATION - Comments

Form Version: 10-Dec-2020 02:30

Form Status: Data Complete, Verified

Site No: 1231

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

Subject No: 12314197

Subject Initials: ---

Generated By:

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

(b) (4)

[Back to Form](#)

Item	Date	User	Comment
Form	Mar-26-2021 12:57:01 (UTC-03:00) City of Buenos Aires	(b) (4), (b) (6)	Not Applicable

Header Text: C4591001

Visit: Investigator Signature -
Unscheduled

Form: CASEBOOK SIGNATURE FORM - Signature
History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Verified

Site No: 1231

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

Subject No: 12314197

Subject Initials: ---

Generated By:

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

(b) (4)

[Back to Form](#)

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

- CRF_Sign
- CRF_Sign_1

Name	Signature Meaning	Date	Type	Action
(b) (6)	N/A	Mar-26-2021 11:19:38 (UTC-03:00) City of Buenos Aires		Edit - All signatures invalidated

Affidavit:

N/A

(b) (6)	Approved	Mar-24-2021 16:58:53 (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.

090177e196ae2e43\Final\Final On: 01-Apr-2021 03:09 (GMT)

Header Text: C4591001

Visit: Investigator Signature -
Unscheduled

Form: CASEBOOK SIGNATURE FORM - Signature
History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Verified

Site No: 1231

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

Subject No: 12314197

Subject Initials: ---

Generated By:

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

(b) (4)

(b) (6)	N/A	Mar-05-2021 13:59:04 (UTC-03:00) City of Buenos Aires		Edit - All signatures invalidated
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Affidavit:

N/A

(b) (6)	Approved	Feb-04-2021 18:40:25 (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	Feb-01-2021 13:37:06 (UTC-03:00) City of Buenos Aires		Edit - All signatures invalidated
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Affidavit:

N/A

(b) (6)	Approved	Jan-29-2021 14:56:42 (UTC-03:00) City of Buenos Aires	BOOK	Signed
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090177e196ae2e43\Final\Final On: 01-Apr-2021 03:09 (GMT)

Header Text: C4591001

Visit: Investigator Signature -
Unscheduled

Form: CASEBOOK SIGNATURE FORM - Signature
History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Verified

Site No: 1231

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

Subject No: 12314197

Subject Initials: ---

Generated By:

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

(b) (4)

Affidavit:

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

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

(b) (6)	N/A	Jan-27-2021 12:29:38 (UTC-03:00) City of Buenos Aires		Edit - All signatures invalidated
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Affidavit:

N/A

(b) (6)	Approved	Nov-27-2020 19:46:16 (UTC-03:00) City of Buenos Aires	BOOK	Signed
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090177e196ae2e43\Final\Final On: 01-Apr-2021 03:09 (GMT)

Header Text: C4591001

Visit: Investigator Signature -
Unscheduled

Form: CASEBOOK SIGNATURE FORM - Signature
History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Verified

Site No: 1231

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

Subject No: 12314197

Subject Initials: ---

Generated By:

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

(b) (4)

Affidavit:

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

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

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

(b) (6)	N/A	Nov-26-2020 16:31:51 (UTC-03:00) City of Buenos Aires		Edit - All signatures invalidated
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Affidavit:

N/A

(b) (6)	Approved	Nov-26-2020 15:49:08 (UTC-03:00) City of Buenos Aires	BOOK	Signed
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090177e196ae2e43\Final\Final On: 01-Apr-2021 03:09 (GMT)

Header Text: C4591001

Visit: Investigator Signature -
Unscheduled

Form: CASEBOOK SIGNATURE FORM - Signature
History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Verified

Site No: 1231

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

Subject No: 12314197

Subject Initials: ---

Generated By:

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

(b) (4)

Affidavit:

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

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

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

(b) (6)	N/A	Nov-26-2020 09:36:30 (UTC-03:00) City of Buenos Aires		Edit - All signatures invalidated
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Affidavit:

N/A

(b) (6)	Approved	Nov-13-2020 18:55:37 (UTC-03:00) City of Buenos Aires	BOOK	Signed
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090177e196ae2e43\Final\Final On: 01-Apr-2021 03:09 (GMT)

Header Text: C4591001

Visit: Investigator Signature -
Unscheduled

Form: CASEBOOK SIGNATURE FORM - Signature
History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Verified

Site No: 1231

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

Subject No: 12314197

Subject Initials: ---

Generated By:

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

(b) (4)

Affidavit:

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

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

(b) (6)	N/A	Nov-13-2020 09:06:14 (UTC-03:00) City of Buenos Aires		Edit - All signatures invalidated
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Affidavit:

N/A

(b) (6)	Approved	Oct-30-2020 15:31:44 (UTC-03:00) City of Buenos Aires	BOOK	Signed
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090177e196ae2e43\Final\Final On: 01-Apr-2021 03:09 (GMT)

Header Text: C4591001

Visit: Investigator Signature -
Unscheduled

Form: CASEBOOK SIGNATURE FORM - Signature
History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Verified

Site No: 1231

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

Subject No: 12314197

Subject Initials: ---

Generated By:

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

(b) (4)

Affidavit:

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

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

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

(b) (6)	N/A	Oct-30-2020 09:22:37 (UTC-03:00) City of Buenos Aires		Edit - All signatures invalidated
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Affidavit:

N/A

(b) (6)	Approved	Oct-29-2020 18:30:45 (UTC-03:00) City of Buenos Aires	BOOK	Signed
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090177e196ae2e43\Final\Final On: 01-Apr-2021 03:09 (GMT)

Header Text: C4591001

Visit: Investigator Signature -
Unscheduled

Form: CASEBOOK SIGNATURE FORM - Signature
History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Verified

Site No: 1231

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

Subject No: 12314197

Subject Initials: ---

Generated By:

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

(b) (4)

Affidavit:

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

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

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

(b) (6)	N/A	Oct-29-2020 08:31:30 (UTC-03:00) City of Buenos Aires		Edit - All signatures invalidated
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Affidavit:

N/A

(b) (6)	Approved	Oct-21-2020 17:23:44 (UTC-03:00) City of Buenos Aires	BOOK	Signed
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090177e196ae2e43\Final\Final On: 01-Apr-2021 03:09 (GMT)

Header Text: C4591001

Visit: Investigator Signature -
Unscheduled

Form Version: 22-Apr-2020 21:04

Site No: 1231

Subject No: 12314197

Generated By:

(b) (4)

Form: CASEBOOK SIGNATURE FORM - Signature
History

Form Status: Data Complete, Verified

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

Subject Initials: ---

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

Affidavit:

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

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

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

Header Text: C4591001

Visit: COHORT_SELECTION

Form: COHORT SELECTION - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:29

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1231

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

Subject No: 12314197

Subject Initials: ---

Generated By:

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

(b) (4)

[Back to Form](#)

1. Select appropriate response - Protocol version

Date	Location	User	Value	Reason
Aug-26-2020 15:13:53 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 24 JUL 2020	Initial Entry

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

Date	Location	User	Value	Reason
Aug-26-2020 15:13:53 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: STAGE 3 COHOR TS	Initial Entry

090177e196ae2e43\Final\Final On: 01-Apr-2021 03:09 (GMT)

Header Text: C4591001

Visit: COHORT_SELECTION

Form Version: 22-Apr-2020 21:02

Site No: 1231

Subject No: 12314197

Generated By:

(b) (4)

Form: MAIN INFORMED CONSENT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

[Back to Form](#)

1. Consent Was:

Date	Location	User	Value	Reason
Aug-26-2020 15:14:37 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: OBTAINED Date Written Co nsent Obtained Aug/26/2020	Initial Entry

090177e196ae2e43\Final\Final On: 01-Apr-2021 03:09 (GMT)

Header Text: C4591001

Visit: COHORT_SELECTION

Form Version: 06-Jul-2020 21:55

Site No: 1231

Subject No: 12314197

Generated By:

(b) (4)

Form: DEMOGRAPHY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

[Back to Form](#)

1. Subject ID

Date	Location	User	Value	Reason
Aug-26-2020 12:35:47 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 12314197	Item copied from previous form

2. Birth Date:

Date	Location	User	Value	Reason
Aug-26-2020 12:35:43 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: (b) (6)/1943	Enrollment Entry

3. Sex:

Date	Location	User	Value	Reason
Aug-26-2020 15:16:05 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: MALE	Initial Entry

4. Ethnicity:

Date	Location	User	Value	Reason
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090177e196ae2e43\Final\Final On: 01-Apr-2021 03:09 (GMT)

Header Text: C4591001

Visit: COHORT_SELECTION

Form: DEMOGRAPHY - eCRF Audit Trail History

Form Version: 06-Jul-2020 21:55

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1231

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

Subject No: 12314197

Subject Initials: ---

Generated By:

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

(b) (4)

Aug-26-2020 15:16:05 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: HISPANIC OR LA TINO(A) OR OF SPANISH ORIGI N	Initial Entry
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5. Race: (Check X all that apply):

Date	Location	User	Value	Reason
Aug-26-2020 15:16:05 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: WHITE	Initial Entry

090177e196ae2e43\Final\Final On: 01-Apr-2021 03:09 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:02

Site No: 1231

Subject No: 12314197

Generated By:

(b) (4)

Form: DATE OF VISIT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

[Back to Form](#)

1. Date of Visit

Date	Location	User	Value	Reason
Aug-26-2020 15:16:22 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Aug/26/2020	Initial Entry

090177e196ae2e43\Final\Final On: 01-Apr-2021 03:09 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form: DISPOSITION - SCREENING - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1231

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

Subject No: 12314197

Subject Initials: ---

Generated By:

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

(b) (4)

[Back to Form](#)

1. Date of Completion/Discontinuation/Death

Date	Location	User	Value	Reason
Aug-26-2020 15:18:24 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Aug/26/2020	Initial Entry

2. Phase of Disposition:

Date	Location	User	Value	Reason
Aug-26-2020 15:18:24 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SCREENING	Initial Entry

3. Status:

Date	Location	User	Value	Reason
Aug-26-2020 15:18:24 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: COMPLETED	Initial Entry

090177e196ae2e43\Final\Final On: 01-Apr-2021 03:09 (GMT)

Header Text: C4591001**Visit:** V1_DAY1_VAX1_L**Form Version:** 22-Apr-2020 21:03**Site No:** 1231**Subject No:** 12314197**Generated By:**

(b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History**Form Status:** Data Complete, Locked, Frozen, Verified**Site Name:** (1231) Hospital Militar Central Cirujano Mayor Dr. Cosme Argerich**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 20:34[Back to Form](#)*1.a*

Date	Location	User	Value	Reason
Aug-26-2020 15:23:36 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH 1 Number: Medical Hi prostatic story Term hyperplas : ia Start Date: Aug/31/2 018 Ongoing: YES	Initial Entry

1.a Line/MH Number:

Date	Location	User	Value	Reason
Aug-26-2020 15:23:36 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 1	Initial Entry

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

Date	Location	User	Value	Reason
Aug-26-2020 15:23:36 (UTC-03:00)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: prostatic hyperplas ia	Initial Entry

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1231

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

Subject No: 12314197

Subject Initials: ---

Generated By:

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

(b) (4)

City of Buenos Aires

1.a Start Date:

Date	Location	User	Value	Reason
Aug-26-2020 15:23:36 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Aug/31/2018	Initial Entry

1.a Ongoing:

Date	Location	User	Value	Reason
Aug-26-2020 15:23:36 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

1.b

Date	Location	User	Value	Reason
Aug-26-2020 15:24:33 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH 2 Number: Medical History Term arterial hypertension : on	Initial Entry

090177e196ae2e43\Final\Final On: 01-Apr-2021 03:09 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1231

Subject No: 12314197

Generated By:

(b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

			Start Date: Aug/25/2018	
			Ongoing: YES	

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1231

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

Subject No: 12314197

Subject Initials: ---

Generated By:

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

(b) (4)

1.b Line/MH Number:

Date	Location	User	Value	Reason
Aug-26-2020 15:24:33 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 2	Initial Entry

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

Date	Location	User	Value	Reason
Aug-26-2020 15:24:33 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: arterial hypertension	Initial Entry

1.b Start Date:

Date	Location	User	Value	Reason
Aug-26-2020 15:24:33 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Aug/25/2018	Initial Entry

1.b Ongoing:

Date	Location	User	Value	Reason
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090177e196ae2e43\Final\Final On: 01-Apr-2021 03:09 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1231

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

Subject No: 12314197

Subject Initials: ---

Generated By:

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

(b) (4)

Aug-26-2020 15:24:33 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry
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Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 21-Aug-2020 02:51

Site No: 1231

Subject No: 12314197

Generated By:

(b) (4)

Form: VITAL SIGNS - BASELINE - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

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1. Date:

Date	Location	User	Value	Reason
Aug-26-2020 15:25:59 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Aug/26/2020	Initial Entry

2. Weight:

Date	Location	User	Value	Reason
Aug-26-2020 15:25:59 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 89.0	Initial Entry

3. Unit:

Date	Location	User	Value	Reason
Aug-26-2020 15:25:59 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: kg	Initial Entry

4. Height:

090177e196ae2e43\Final\Final On: 01-Apr-2021 03:09 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form: VITAL SIGNS - BASELINE - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:51

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1231

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

Subject No: 12314197

Subject Initials: ---

Generated By:

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

(b) (4)

Date	Location	User	Value	Reason
Aug-26-2020 15:25:59 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 169.0	Initial Entry

5. Unit:

Date	Location	User	Value	Reason
Aug-26-2020 15:25:59 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: cm	Initial Entry

6. Body Mass Index:

Date	Location	User	Value	Reason
Aug-26-2020 15:25:59 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 31.2	Initial Entry

7.a

Date	Location	User	Value	Reason
Aug-26-2020 15:25:59 (UTC-03:00)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Record I 1	Initial Entry

090177e196ae2e43\Final\Final On: 01-Apr-2021 03:09 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form: VITAL SIGNS - BASELINE - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:51

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1231

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

Subject No: 12314197

Subject Initials: ---

Generated By:

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

(b) (4)

City of Buenos Aires			dentifier: : Temperat 36.3 ure: Temperat C ure Unit: Temperat ORAL ure Locat CAVI ion:: TY	
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7.a Record Identifier:

Date	Location	User	Value	Reason
Aug-26-2020 15:25:59 (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-26-2020 15:25:59 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 36.3	Initial Entry

7.a Unit:

090177e196ae2e43\Final\Final On: 01-Apr-2021 03:09 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form: VITAL SIGNS - BASELINE - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:51

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1231

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

Subject No: 12314197

Subject Initials: ---

Generated By:

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

(b) (4)

Date	Location	User	Value	Reason
Aug-26-2020 15:25:59 (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-26-2020 15:25:59 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: ORAL CAVITY	Initial Entry

090177e196ae2e43\Final\Final On: 01-Apr-2021 03:09 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1231

Subject No: 12314197

Generated By:

(b) (4)

Form: RANDOMIZATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

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1. Randomization Date :

Date	Location	User	Value	Reason
Aug-26-2020 15:26:30 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Aug/26/2020	Initial Entry

2. Randomization Number:

Date	Location	User	Value	Reason
Aug-26-2020 15:26:30 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 241376	Initial Entry

090177e196ae2e43\Final\Final On: 01-Apr-2021 03:09 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1231

Subject No: 12314197

Generated By:

(b) (4)

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

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

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1. Data Origin

Date	Location	User	Value	Reason
Aug-26-2020 15:26:40 (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-26-2020 15:26:40 (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-27-2020 12:48:48 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Closed	Close Auto Query
Aug-27-2020 12:47:45 (UTC-03:00)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Opened	'Sample Collected?' is Yes, however

090177e196ae2e43\Final\Final On: 01-Apr-2021 03:09 (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: 12314197

Subject Initials: ---

Generated By:

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

(b) (4)

City of Buenos Aires		(b) (4), (b) (6)		no barcodes are entered. Please review and correct as appropriate.
Aug-27-2020 12:42:59 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Aug-27-2020 12:39:53 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Aug-27-2020 02:19:34 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Aug-26-2020 15:26:40 (UTC-03:00)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however

090177e196ae2e43\Final\Final On: 01-Apr-2021 03:09 (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: 12314197

Subject Initials: ---

Generated By:

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

(b) (4)

City of Buenos Aires				no barcodes are entered. Please review and correct as appropriate.
Aug-26-2020 15:26:40 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Date of Collection: Aug/26/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Aug-27-2020 12:42:31 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID:	Transcription Error (DELETED)
Aug-27-2020 12:41:14 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID:	Transcription Error
Aug-27-2020 12:39:53 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID BPT98 : G	Initial Entry

5.a Sample ID

090177e196ae2e43\Final\Final On: 01-Apr-2021 03:09 (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: 12314197

Subject Initials: ---

Generated By:

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

(b) (4)

Date	Location	User	Value	Reason
Aug-27-2020 12:42:31 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Transcription Error (DELETED)
Aug-27-2020 12:41:14 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Transcription Error
Aug-27-2020 12:39:53 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BPT98G	Initial Entry

5.b

Date	Location	User	Value	Reason
Aug-27-2020 12:42:47 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID BPT98 : H	Transcription Error (DELETED)
Aug-27-2020 12:40:04 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID BPT98 : H	Initial Entry

090177e196ae2e43\Final\Final On: 01-Apr-2021 03:09 (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: 12314197

Subject Initials: ---

Generated By:

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

(b) (4)

5.b Sample ID

Date	Location	User	Value	Reason
Aug-27-2020 12:42:47 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BPT98H	Transcription Error (DELETED)
Aug-27-2020 12:40:04 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BPT98H	Initial Entry

5.c

Date	Location	User	Value	Reason
Aug-27-2020 12:42:59 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID BPT98 : J	Transcription Error (DELETED)
Aug-27-2020 12:40:26 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID BPT98 : J	Initial Entry

090177e196ae2e43\Final\Final On: 01-Apr-2021 03:09 (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: 12314197

Subject Initials: ---

Generated By:

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

(b) (4)

5.c Sample ID

Date	Location	User	Value	Reason
Aug-27-2020 12:42:59 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BPT98J	Transcription Error (DELETED)
Aug-27-2020 12:40:26 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BPT98J	Initial Entry

5.d

Date	Location	User	Value	Reason
Aug-27-2020 12:48:48 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample I BNTYD D: R	Initial Entry

5.d Sample ID

Date	Location	User	Value	Reason
Aug-27-2020 12:48:48 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BNTYDR	Initial Entry

5.e

090177e196ae2e43\Final\Final On: 01-Apr-2021 03:09 (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: 12314197

Subject Initials: ---

Generated By:

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

(b) (4)

Date	Location	User	Value	Reason
Aug-27-2020 12:48:57 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample I BNTYD D: S	Initial Entry

5.e Sample ID

Date	Location	User	Value	Reason
Aug-27-2020 12:48:57 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BNTYDS	Initial Entry

5.f

Date	Location	User	Value	Reason
Aug-27-2020 17:53:26 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	Alan Colombo (b) (4)	Data Entry: Sample I BPTF9 D: 0	Initial Entry

5.f Sample ID

Date	Location	User	Value	Reason
Aug-27-2020 17:53:26 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	Alan Colombo (b) (4)	Data Entry: BPTF90	Initial Entry

090177e196ae2e43\Final\Final On: 01-Apr-2021 03:09 (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: 12314197

Subject Initials: ---

Generated By:

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

(b) (4)

5.g

Date	Location	User	Value	Reason
Aug-27-2020 17:53:32 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	Alan Colombo (b) (4)	Data Entry: Sample I BPTF9 D: 1	Initial Entry

5.g Sample ID

Date	Location	User	Value	Reason
Aug-27-2020 17:53:32 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	Alan Colombo (b) (4)	Data Entry: BPTF91	Initial Entry

5.h

Date	Location	User	Value	Reason
Aug-27-2020 17:53:37 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	Alan Colombo (b) (4)	Data Entry: Sample I BPTF9 D: 2	Initial Entry

090177e196ae2e43\Final\Final On: 01-Apr-2021 03:09 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1231

Subject No: 12314197

Generated By:

(b) (4)

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

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

5.h Sample ID

Date	Location	User	Value	Reason
Aug-27-2020 17:53:37 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	Alan Colombo (b) (4)	Data Entry: BPTF92	Initial Entry

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1231

Subject No: 12314197

Generated By:

(b) (4)

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

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

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1. Data Origin

Date	Location	User	Value	Reason
Aug-26-2020 15:26:48 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Aug-26-2020 15:26:48 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: NASAL_SWAB	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Aug-27-2020 16:23:32 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Aug-27-2020 02:19:34 (UTC-03:00)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	'Sample Collected?' is Yes, however

090177e196ae2e43\Final\Final On: 01-Apr-2021 03:09 (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: 12314197

Subject Initials: ---

Generated By:

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

(b) (4)

City of Buenos Aires				no barcodes are entered. Please review and correct as appropriate.
Aug-26-2020 15:26:48 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Aug-26-2020 15:26:48 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Date of Collection: Aug/26/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Aug-27-2020 16:23:32 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	Alan Colombo (b) (4)	Data Entry: Sample I BPT9P D: S	Initial Entry

5.a Sample ID

090177e196ae2e43\Final\Final On: 01-Apr-2021 03:09 (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: 12314197

Subject Initials: ---

Generated By:

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

(b) (4)

Date	Location	User	Value	Reason
Aug-27-2020 16:23:32 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	Alan Colombo (b) (4)	Data Entry: BPT9PS	Initial Entry

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:04

Site No: 1231

Subject No: 12314197

Generated By:

(b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

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1. Was there a temporary delay of vaccination?

Date	Location	User	Value	Reason
Aug-26-2020 15:27:28 (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-26-2020 15:27:28 (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-26-2020 15:27:28 (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
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090177e196ae2e43\Final\Final On: 01-Apr-2021 03:09 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:04

Site No: 1231

Subject No: 12314197

Generated By:

(b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

Aug-26-2020 15:27:28 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Aug/26/2020 13:38	Initial Entry
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5. Anatomical Location:

Date	Location	User	Value	Reason
Aug-26-2020 15:27:28 (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-26-2020 15:27:28 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: LEFT	Initial Entry

7. Route:

Date	Location	User	Value	Reason
Aug-26-2020 15:27:28 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: INTRAMUSCULAR	Initial Entry

090177e196ae2e43\Final\Final On: 01-Apr-2021 03:09 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:04

Site No: 1231

Subject No: 12314197

Generated By:

(b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

10. Timeframe Subject Was Observed

Date	Location	User	Value	Reason
Aug-26-2020 15:27:28 (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-26-2020 15:27:28 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

090177e196ae2e43\Final\Final On: 01-Apr-2021 03:09 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 06-Jul-2020 21:53

Site No: 1231

Subject No: 12314197

Generated By:

(b) (4)

Form: REACTOGENICITY DIARY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

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1. Select appropriate response - Reactogenicity diary collection

Date	Location	User	Value	Reason
Aug-26-2020 15:27:35 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO - REACTOGENICITY E-DIARY NOT COLLECTED FOR THIS SUBJECT	Initial Entry

Header Text: C4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:02

Site No: 1231

Subject No: 12314197

Generated By:

(b) (4)

Form: DATE OF VISIT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

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1. Date of Visit

Date	Location	User	Value	Reason
Oct-05-2020 03:59:22 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Per site confirmation
Oct-04-2020 15:54:01 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	For the subject in question, the symptom referred to by the investigator in charge is not interpreted as a possible covid disease. Thank you.
Oct-02-2020 06:49:17 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	Balaji Prabu R (b) (4)	Query 1: Opened	As per Illness diary records, subject reported "Yes" for the question "Have you experienced any of the following?"

090177e196ae2e43\Final\Final On: 01-Apr-2021 03:09 (GMT)

Header Text: C4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:02

Site No: 1231

Subject No: 12314197

Generated By:

(b) (4)

Form: DATE OF VISIT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

				for the COVID-19 symptoms or diagnosis on 23Sep2020. But there is no COVID Illness visit reported in the database. Please clarify.
Sep-18-2020 09:38:54 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sep/14/2020	Initial Entry

090177e196ae2e43\Final\Final On: 01-Apr-2021 03:09 (GMT)

Header Text: C4591001

Visit: V2_VAX2_L

Form Version: 15-Sep-2020 21:54

Site No: 1231

Subject No: 12314197

Generated By:

(b) (4)

Form: VITAL SIGNS - TEMP - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

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1. Date:

Date	Location	User	Value	Reason
Sep-18-2020 09:39:05 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sep/14/2020	Initial Entry

2.a

Date	Location	User	Value	Reason
Sep-18-2020 09:39:05 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Record Identifier:: Temperature: 36.1 Temperature Unit: C Temperature Location: ORAL CAVITY : Y	Initial Entry

2.a Record Identifier:

Date	Location	User	Value	Reason
Sep-18-2020 09:39:05 (UTC-03:00) City	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 1	Initial Entry

090177e196ae2e43\Final\Final On: 01-Apr-2021 03:09 (GMT)

Header Text: C4591001

Visit: V2_VAX2_L

Form: VITAL SIGNS - TEMP - eCRF Audit Trail History

Form Version: 15-Sep-2020 21:54

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1231

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

Subject No: 12314197

Subject Initials: ---

Generated By:

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

(b) (4)

of Buenos Aires

2.a Temperature:

Date	Location	User	Value	Reason
Sep-18-2020 09:39:05 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 36.1	Initial Entry

2.a Unit:

Date	Location	User	Value	Reason
Sep-18-2020 09:39:05 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: C	Initial Entry

2.a Temperature Location:

Date	Location	User	Value	Reason
Sep-18-2020 09:39:05 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: ORAL CAVITY	Initial Entry

090177e196ae2e43\Final\Final On: 01-Apr-2021 03:09 (GMT)

Header Text: C4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:03

Site No: 1231

Subject No: 12314197

Generated By:

(b) (4)

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

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

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1. Data Origin

Date	Location	User	Value	Reason
Sep-14-2020 16:25:22 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Sep-14-2020 16:25:22 (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-14-2020 16:25:33 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Sep-14-2020 16:25:22 (UTC-03:00)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidat e	'Sample Collected?' is Yes, however

090177e196ae2e43\Final\Final On: 01-Apr-2021 03:09 (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: 12314197

Subject Initials: ---

Generated By:

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

(b) (4)

City of Buenos Aires				no barcodes are entered. Please review and correct as appropriate.
Sep-14-2020 16:25:22 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	Alan Colombo (b) (4)	Data Entry: YES Date of Collection: Sep/14/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Sep-14-2020 16:25:33 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	Alan Colombo (b) (4)	Data Entry: Sample I BP2FH D: Z	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Sep-14-2020 16:25:33 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	Alan Colombo (b) (4)	Data Entry: BP2FHZ	Initial Entry

090177e196ae2e43\Final\Final On: 01-Apr-2021 03:09 (GMT)

Header Text: C4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:04

Site No: 1231

Subject No: 12314197

Generated By:

(b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

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1. Was there a temporary delay of vaccination?

Date	Location	User	Value	Reason
Sep-18-2020 09:39:30 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2. Treatment Name

Date	Location	User	Value	Reason
Sep-18-2020 09:39:30 (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-18-2020 09:39:30 (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-18-2020	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Initial Entry

090177e196ae2e43\Final\Final On: 01-Apr-2021 03:09 (GMT)

Header Text: C4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:04

Site No: 1231

Subject No: 12314197

Generated By:

(b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

09:39:30
(UTC-03:00) City
of Buenos Aires

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

Sep/14/2020 09:00

5. Anatomical Location:

Date	Location	User	Value	Reason
Sep-18-2020 09:39:30 (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-18-2020 09:39:30 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: LEFT	Initial Entry

7. Route:

Date	Location	User	Value	Reason
Sep-18-2020 09:39:30 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: INTRAMUSCULAR	Initial Entry

10. Timeframe Subject Was Observed

Date	Location	User	Value	Reason
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090177e196ae2e43\Final\Final On: 01-Apr-2021 03:09 (GMT)

Header Text: C4591001

Visit: V2_VAX2_L

Form: VACCINATION - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1231

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

Subject No: 12314197

Subject Initials: ---

Generated By:

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

(b) (4)

Sep-18-2020 09:39:30 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: THE PROTOCOL SPE CIFIED OBSERVATIO N PERIOD	Initial Entry
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11. Was the subject observed for at least the protocol specified observation period after investigational product administration?

Date	Location	User	Value	Reason
Sep-18-2020 09:39:30 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

090177e196ae2e43\Final\Final On: 01-Apr-2021 03:09 (GMT)

Header Text: C4591001

Visit: V3_MONTH1_POSTVAX2_L

Form: DATE OF VISIT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1231

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

Subject No: 12314197

Subject Initials: ---

Generated By:

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

(b) (4)

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1. Date of Visit

Date	Location	User	Value	Reason
Oct-16-2020 09:44:33 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Oct/16/2020	Initial Entry

090177e196ae2e43\Final\Final On: 01-Apr-2021 03:09 (GMT)

Header Text: C4591001

Visit: V3_MONTH1_POSTVAX2_L **Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - eCRF Audit Trail History

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

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

Subject No: 12314197 **Subject Initials:** ---

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

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1. Data Origin

Date	Location	User	Value	Reason
Oct-16-2020 09:44:39 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Oct-16-2020 09:44:39 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SERUM	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Oct-16-2020 12:45:18 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Oct-16-2020 09:49:13 (UTC-03:00)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	'Sample Collected?' is Yes, however

090177e196ae2e43\Final\Final On: 01-Apr-2021 03:09 (GMT)

Header Text: C4591001

Visit: V3_MONTH1_POSTVAX2_L Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - eCRF Audit Trail History

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

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

Subject No: 12314197 Subject Initials: ---

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

City of Buenos Aires				no barcodes are entered. Please review and correct as appropriate.
Oct-16-2020 09:44:39 (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-16-2020 09:44:39 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Date of Collection: Oct/16/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Oct-16-2020 12:45:18 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	Agustin Morato Cabral (b) (4)	Data Entry: Sample I BLBX7 D: F	Initial Entry

5.a Sample ID

090177e196ae2e43\Final\Final On: 01-Apr-2021 03:09 (GMT)

Header Text: C4591001

Visit: V3_MONTH1_POSTVAX2_L Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - eCRF Audit Trail History

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

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

Subject No: 12314197 Subject Initials: ---

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

Date	Location	User	Value	Reason
Oct-16-2020 12:45:18 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	Agustin Morato Cabral (b) (4)	Data Entry: BLBX7F	Initial Entry

5.b

Date	Location	User	Value	Reason
Oct-16-2020 14:48:48 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	Alan Colombo (b) (4)	Data Entry: Sample I BPW65 D: 4	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Oct-16-2020 14:48:48 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	Alan Colombo (b) (4)	Data Entry: BPW654	Initial Entry

5.c

Date	Location	User	Value	Reason
Oct-16-2020 15:57:53 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample I BLBX6 D: K	Initial Entry

090177e196ae2e43\Final\Final On: 01-Apr-2021 03:09 (GMT)

Header Text: C4591001

Visit: V3_MONTH1_POSTVAX2_L **Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - eCRF Audit Trail History

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

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

Subject No: 12314197 **Subject Initials:** ---

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

(b) (4)

5.c Sample ID

Date	Location	User	Value	Reason
Oct-16-2020 15:57:53 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BLBX6K	Initial Entry

Header Text: C4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Oct/26/2020

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: 12314197

Subject Initials: ---

Generated By:

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

(b) (4)

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1. Date of Visit

Date	Location	User	Value	Reason
Mar-05-2021 06:47:02 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Closed	updated
Mar-04-2021 15:29:11 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	Adolfo Gonzalez (b) (4)	Query 3: Answered	the subject is currently going through an AE, the subject will be cited as soon as the AE is resolved, thank you
Mar-04-2021 08:52:08 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Opened	PDQ: Convalescent visit is missing and 35+ days (36) have passed since COVID Illness Visit. If visit occurred record data as a matching CONVA visit;

090177e196ae2e43\Final\Final On: 01-Apr-2021 03:09 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Oct/26/2020

Form Version: 22-Apr-2020 21:03

Site No: 1231

Subject No: 12314197

Generated By:

(b) (4)

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

Form Status: Data Complete, Frozen, Verified

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

Subject Initials: ---

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

				if visit did not occur attempt to schedule visit even if OOW and obtain the CONVA sample else clarify.
Oct-29-2020 08:34:01 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Oct-29-2020 08:32:40 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Deleted	Close Auto Query
Oct-29-2020 08:31:28 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Candid ate	Date of Visit is completed but Date of Assessment in the Signs and Symptoms form is missing. Please review and update as appropriate.

090177e196ae2e43\Final\Final On: 01-Apr-2021 03:09 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Oct/26/2020

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: 12314197

Subject Initials: ---

Generated By:

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

(b) (4)

Oct-29-2020 08:31:28 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candid ate	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-29-2020 08:31:28 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Oct/26/2020	Initial Entry

3. COVID-19 Illness Visit:

Date	Location	User	Value	Reason
Oct-29-2020 08:31:28 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: COVID_A	Initial Entry

090177e196ae2e43\Final\Final On: 01-Apr-2021 03:09 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Oct/26/2020

Form Version: 10-Oct-2020 16:02

Site No: 1231

Subject No: 12314197

Generated By:

(b) (4)

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

Form Status: Data Complete, Frozen, Not Complete

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

Subject Initials: ---

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

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1. Date of Assessment:

Date	Location	User	Value	Reason
Oct-29-2020 08:32:40 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Oct/26/2020	Initial Entry

2. Date of First Symptom Started:

Date	Location	User	Value	Reason
Oct-29-2020 08:32:40 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Oct/26/2020	Initial Entry

3. Symptoms Ongoing?

Date	Location	User	Value	Reason
Feb-02-2021 06:50:08 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Feb-01-2021 16:19:24 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	New Information

090177e196ae2e43\Final\Final On: 01-Apr-2021 03:09 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Oct/26/2020

Form Version: 10-Oct-2020 16:02

Site No: 1231

Subject No: 12314197

Generated By:

(b) (4)

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

Form Status: Data Complete, Frozen, Not Complete

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

Subject Initials: ---

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

Feb-01-2021 16:19:24 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO Date of Last Sym ptom Resolved: Nov/1/2020	New Information
Feb-01-2021 04:34:46 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	DM: Next visit should be entered only if all the symptoms at this visit resolved. If resolved, please review and update the date of last symptom resolved as appropriate. If not, please move details from next visit into this visit. Thank you.
Oct-29-2020 08:32:40 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

4.a

090177e196ae2e43\Final\Final On: 01-Apr-2021 03:09 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Oct/26/2020

Form Version: 10-Oct-2020 16:02

Site No: 1231

Subject No: 12314197

Generated By:

(b) (4)

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

Form Status: Data Complete, Frozen, Not Complete

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

Subject Initials: ---

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

Date	Location	User	Value	Reason
Oct-29-2020 08:32:40 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptoms: FEVE R Symptom Present: NO	Initial Entry

4.a Symptoms:

Date	Location	User	Value	Reason
Oct-29-2020 08:32:40 (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-29-2020 08:32:40 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

4.b

Date	Location	User	Value	Reason
Oct-29-2020 08:32:40 (UTC-03:00) City	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptoms: NEW OR IN CREASED C	Initial Entry

090177e196ae2e43\Final\Final On: 01-Apr-2021 03:09 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Oct/26/2020

Form Version: 10-Oct-2020 16:02

Site No: 1231

Subject No: 12314197

Generated By:

(b) (4)

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

Form Status: Data Complete, Frozen, Not Complete

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

Subject Initials: ---

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

of Buenos Aires			OUGH Sympto NO m Pres ent:	
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4.b Symptoms:

Date	Location	User	Value	Reason
Oct-29-2020 08:32:40 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NEW OR INCREASE D COUGH	Initial Entry

4.b Was symptom present?

Date	Location	User	Value	Reason
Oct-29-2020 08:32:40 (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-29-2020 08:32:40 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symp NEW OR INC toms: REASED SHO RTNESS OF B REATH	Initial Entry

090177e196ae2e43\Final\Final On: 01-Apr-2021 03:09 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Oct/26/2020

Form Version: 10-Oct-2020 16:02

Site No: 1231

Subject No: 12314197

Generated By:

(b) (4)

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

Form Status: Data Complete, Frozen, Not Complete

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

Subject Initials: ---

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

			Symp tom P resent :	
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4.c Symptoms:

Date	Location	User	Value	Reason
Oct-29-2020 08:32:40 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NEW OR INCREASE D SHORTNESS OF B REATH	Initial Entry

4.c Was symptom present?

Date	Location	User	Value	Reason
Oct-29-2020 08:32:40 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

4.d

Date	Location	User	Value	Reason
Oct-29-2020 08:32:40 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptoms: CHIL LS Symptom Pre sent: NO	Initial Entry

090177e196ae2e43\Final\Final On: 01-Apr-2021 03:09 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Oct/26/2020

Form Version: 10-Oct-2020 16:02

Site No: 1231

Subject No: 12314197

Generated By:

(b) (4)

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

Form Status: Data Complete, Frozen, Not Complete

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

Subject Initials: ---

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

4.d Symptoms:

Date	Location	User	Value	Reason
Oct-29-2020 08:32:40 (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-29-2020 08:32:40 (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-29-2020 08:32:40 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sympt NEW OR IN oms: CREASED M USCLE PAIN Sympt YES om Pr esent:	Initial Entry

090177e196ae2e43\Final\Final On: 01-Apr-2021 03:09 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Oct/26/2020

Form Version: 10-Oct-2020 16:02

Site No: 1231

Subject No: 12314197

Generated By:

(b) (4)

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

Form Status: Data Complete, Frozen, Not Complete

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

Subject Initials: ---

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

4.e Symptoms:

Date	Location	User	Value	Reason
Oct-29-2020 08:32:40 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NEW OR INCREASE D MUSCLE PAIN	Initial Entry

4.e Was symptom present?

Date	Location	User	Value	Reason
Oct-30-2020 14:11:07 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Oct-30-2020 09:23:47 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Rhinitis was add. Thank you.
Oct-29-2020 20:45:55 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	Per source, subject also presented rhinitis. Please add Rhinitis as OTHER symptom.
Oct-29-2020 08:32:40	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

090177e196ae2e43\Final\Final On: 01-Apr-2021 03:09 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Oct/26/2020

Form Version: 10-Oct-2020 16:02

Site No: 1231

Subject No: 12314197

Generated By:

(b) (4)

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

Form Status: Data Complete, Frozen, Not Complete

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

Subject Initials: ---

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

(UTC-03:00) City of Buenos Aires	(b) (4), (b) (6)
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4.f

Date	Location	User	Value	Reason
Oct-29-2020 08:32:40 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom: NEW LOSS OF TASTE OR SMELL Symptom Present: NO	Initial Entry

4.f Symptoms:

Date	Location	User	Value	Reason
Oct-29-2020 08:32:40 (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-29-2020 08:32:40 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

090177e196ae2e43\Final\Final On: 01-Apr-2021 03:09 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Oct/26/2020

Form Version: 10-Oct-2020 16:02

Site No: 1231

Subject No: 12314197

Generated By:

(b) (4)

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

Form Status: Data Complete, Frozen, Not Complete

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

Subject Initials: ---

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

4.g

Date	Location	User	Value	Reason
Oct-29-2020 08:32:40 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom Present: NEW OR INCREASED SORE THROAT Symptom Present: NO	Initial Entry

4.g Symptoms:

Date	Location	User	Value	Reason
Oct-29-2020 08:32:40 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NEW OR INCREASED SORE THROAT	Initial Entry

4.g Was symptom present?

Date	Location	User	Value	Reason
Oct-29-2020 08:32:40 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

4.h

090177e196ae2e43\Final\Final On: 01-Apr-2021 03:09 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Oct/26/2020

Form Version: 10-Oct-2020 16:02

Site No: 1231

Subject No: 12314197

Generated By:

(b) (4)

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

Form Status: Data Complete, Frozen, Not Complete

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

Subject Initials: ---

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

Date	Location	User	Value	Reason
Oct-29-2020 08:32:40 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptoms: DIARR HEA Symptom P NO resent:	Initial Entry

4.h Symptoms:

Date	Location	User	Value	Reason
Oct-29-2020 08:32:40 (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-29-2020 08:32:40 (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-29-2020 08:32:40 (UTC-03:00) City	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptoms: VOMIT ING	Initial Entry

090177e196ae2e43\Final\Final On: 01-Apr-2021 03:09 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Oct/26/2020

Form Version: 10-Oct-2020 16:02

Site No: 1231

Subject No: 12314197

Generated By:

(b) (4)

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

Form Status: Data Complete, Frozen, Not Complete

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

Subject Initials: ---

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

of Buenos Aires			Symptom P NO resent:	
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4.i Symptoms:

Date	Location	User	Value	Reason
Oct-29-2020 08:32:40 (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-29-2020 08:32:40 (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-30-2020 09:22:37 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptoms - Rhini Other: tis.	Initial Entry

5.a Symptoms - Other Text:

Date	Location	User	Value	Reason
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090177e196ae2e43\Final\Final On: 01-Apr-2021 03:09 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Oct/26/2020

Form Version: 10-Oct-2020 16:02

Site No: 1231

Subject No: 12314197

Generated By:

(b) (4)

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

Form Status: Data Complete, Frozen, Not Complete

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

Subject Initials: ---

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

Oct-30-2020 09:22:37 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Rhinitis.	Initial Entry
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Header Text: C4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Oct/26/2020

Form Version: 06-Jul-2020 21:54

Site No: 1231

Subject No: 12314197

Generated By:

(b) (4)

Form: MICROBIOLOGY SPECIMEN - Audit Trail

Form Status:

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

Subject Initials: ---

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

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Date	Location	User	Value	Reason
Oct-29-2020 08:33:20 (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 Oct/26/2020

Form: MICROBIOLOGY SPECIMEN - eCRF Audit
Trail History

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen, Verified

Site No: 1231

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

Subject No: 12314197

Subject Initials: ---

Generated By:

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

(b) (4)

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1. Actual Date of Collection:

Date	Location	User	Value	Reason
Oct-29-2020 08:33:20 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Oct/26/2020	Initial Entry

2. Specimen Type:

Date	Location	User	Value	Reason
Oct-29-2020 08:33:20 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: SWABBED MATERIA L	Initial Entry

3. Specimen Collection Location:

Date	Location	User	Value	Reason
Oct-29-2020 08:33:20 (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-29-2020	ACV0PFEINFP6000	auto calc	Data Entry:	Initial Entry

090177e196ae2e43\Final\Final On: 01-Apr-2021 03:09 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Oct/26/2020

Form Version: 06-Jul-2020 21:54

Site No: 1231

Subject No: 12314197

Generated By:

(b) (4)

Form: MICROBIOLOGY SPECIMEN - eCRF Audit
Trail History

Form Status: Data Complete, Frozen, Verified

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

Subject Initials: ---

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

08:33:20
(UTC-03:00) City
of Buenos Aires

(autocalc)

SEVERE ACUTE RES
P SYNDROME CORO
NAVIRUS 2

5. Device Type:

Date	Location	User	Value	Reason
Oct-29-2020 08:33:20 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SARS-COV-2 DIAGN OSTIC TEST	Initial Entry

6. Trade Name:

Date	Location	User	Value	Reason
Oct-29-2020 08:33:20 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: ATILA BIOSYSTEMS IAMP COVID-19 DET ECTION KIT	Initial Entry

7. Test Result:

Date	Location	User	Value	Reason
Oct-29-2020 08:33:20 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NEGATIVE	Initial Entry

090177e196ae2e43\Final\Final On: 01-Apr-2021 03:09 (GMT)

Header Text: C4591001**Visit:** POT_COVID_ILL 1 -
Unscheduled Visit on Oct/26/2020**Form Version:** 22-Apr-2020 21:03**Site No:** 1231**Subject No:** 12314197**Generated By:**

(b) (4)

Form: ELECTRONIC SAMPLE TRACKING - NASAL
SWAB SELF - eCRF Audit Trail History**Form Status:** Data Complete, Frozen, Verified**Site Name:** (1231) Hospital Militar Central Cirujano
Mayor Dr. Cosme Argerich**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 20:34[Back to Form](#)**1. Data Origin**

Date	Location	User	Value	Reason
Oct-29-2020 08:33:50 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Oct-29-2020 08:33:50 (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-29-2020 08:33:50 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

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

Date	Location	User	Value	Reason
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Header Text: C4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Oct/26/2020

Form Version: 22-Apr-2020 21:03

Site No: 1231

Subject No: 12314197

Generated By:

(b) (4)

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

Form Status: Data Complete, Frozen, Verified

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

Subject Initials: ---

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

Oct-29-2020 08:33:50 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample collected by th e physician team	Initial Entry
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Header Text: C4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Oct/26/2020

Form Version: 22-Apr-2020 21:03

Site No: 1231

Subject No: 12314197

Generated By:

(b) (4)

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

Form Status: Data Complete, Frozen, Verified

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

Subject Initials: ---

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

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1. Data Origin

Date	Location	User	Value	Reason
Oct-29-2020 08:34:01 (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 08:34:01 (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-29-2020 09:20:36 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Oct-29-2020 08:39:07 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	'Sample Collected?' is Yes, however no barcodes

090177e196ae2e43\Final\Final On: 01-Apr-2021 03:09 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Oct/26/2020

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: 12314197

Subject Initials: ---

Generated By:

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

(b) (4)

				are entered. Please review and correct as appropriate.
Oct-29-2020 08:34:01 (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-29-2020 08:34:01 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Date of Collection: Oct/26/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Oct-29-2020 09:20:36 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID BPT7Z : B	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
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090177e196ae2e43\Final\Final On: 01-Apr-2021 03:09 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Oct/26/2020

Form Version: 22-Apr-2020 21:03

Site No: 1231

Subject No: 12314197

Generated By:

(b) (4)

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

Form Status: Data Complete, Frozen, Verified

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

Subject Initials: ---

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

Oct-29-2020 09:20:36 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BPT7ZB	Initial Entry
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Header Text: C4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Oct/26/2020

Form Version: 10-Oct-2020 15:59

Site No: 1231

Subject No: 12314197

Generated By:

(b) (4)

Form: HEALTH CARE UTILIZATION - eCRF Audit
Trail History

Form Status: Data Complete, Frozen, Verified

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

Subject Initials: ---

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1.a

Date	Location	User	Value	Reason
Oct-29-2020 08:34:34 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Type of Practitioner: SPECIALIST T Occurrence of Visits or Contacts: NO	Initial Entry

1.a Physician or Healthcare Professional:

Date	Location	User	Value	Reason
Oct-29-2020 08:34:34 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: SPECIALIST	Initial Entry

1.a Occurrence of Visits or Contacts:

Date	Location	User	Value	Reason
Oct-29-2020 08:34:34 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

090177e196ae2e43\Final\Final On: 01-Apr-2021 03:09 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Oct/26/2020

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: 12314197

Subject Initials: ---

Generated By:

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

(b) (4)

1.b

Date	Location	User	Value	Reason
Oct-29-2020 08:34:34 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Type of Pra EMERG ctitioner: ENCY R OOM Occurrence NO of Visits or Contacts:	Initial Entry

1.b Physician or Healthcare Professional:

Date	Location	User	Value	Reason
Oct-29-2020 08:34:34 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: EMERGENCY ROOM	Initial Entry

1.b Occurrence of Visits or Contacts:

Date	Location	User	Value	Reason
Oct-29-2020 08:34:34 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

1.c

Date	Location	User	Value	Reason
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090177e196ae2e43\Final\Final On: 01-Apr-2021 03:09 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Oct/26/2020

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: 12314197

Subject Initials: ---

Generated By:

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

(b) (4)

Oct-29-2020 08:34:34 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Type of Pr PRIMAR actitioner: Y CARE PHYSICI AN Occurrenc NO e of Visits or Contac ts:	Initial Entry
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1.c Physician or Healthcare Professional:

Date	Location	User	Value	Reason
Oct-29-2020 08:34:34 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: PRIMARY CARE PH YSICIAN	Initial Entry

1.c Occurrence of Visits or Contacts:

Date	Location	User	Value	Reason
Oct-29-2020 08:34:34 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

1.d

Date	Location	User	Value	Reason
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090177e196ae2e43\Final\Final On: 01-Apr-2021 03:09 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Oct/26/2020

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: 12314197

Subject Initials: ---

Generated By:

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

(b) (4)

Oct-29-2020 08:34:34 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Type of Practitioner: URGE NT CA RE Occurrence of Visits or Contacts: NO	Initial Entry
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1.d Physician or Healthcare Professional:

Date	Location	User	Value	Reason
Oct-29-2020 08:34:34 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: URGENT CARE	Initial Entry

1.d Occurrence of Visits or Contacts:

Date	Location	User	Value	Reason
Oct-29-2020 08:34:34 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

1.e

Date	Location	User	Value	Reason
Oct-29-2020 08:34:34 (UTC-03:00) City	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Type of Practitioner: TELEPH ONE CO	Initial Entry

090177e196ae2e43\Final\Final On: 01-Apr-2021 03:09 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Oct/26/2020

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: 12314197

Subject Initials: ---

Generated By:

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

(b) (4)

of Buenos Aires			NSULTAT ION	
			Occurrence of Visits or Contacts:	

I.e Physician or Healthcare Professional:

Date	Location	User	Value	Reason
Oct-29-2020 08:34:34 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: TELEPHONE CONSU LTATION	Initial Entry

I.e Occurrence of Visits or Contacts:

Date	Location	User	Value	Reason
Oct-29-2020 08:34:34 (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-29-2020 08:34:34 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Type of Practitioner: OT HE R	Initial Entry

090177e196ae2e43\Final\Final On: 01-Apr-2021 03:09 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Oct/26/2020

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: 12314197

Subject Initials: ---

Generated By:

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

(b) (4)

			Occurrence of NO Visits or Contac ts:	
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1.f Physician or Healthcare Professional:

Date	Location	User	Value	Reason
Oct-29-2020 08:34:34 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: OTHER	Initial Entry

1.f Occurrence of Visits or Contacts:

Date	Location	User	Value	Reason
Oct-29-2020 08:34:34 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

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

Date	Location	User	Value	Reason
Oct-29-2020 08:34:34 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

090177e196ae2e43\Final\Final On: 01-Apr-2021 03:09 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Oct/26/2020

Form Version: 06-Jul-2020 21:52

Site No: 1231

Subject No: 12314197

Generated By:

(b) (4)

Form: ILLNESS DETAILS - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

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

Subject Initials: ---

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

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1. Category of Clinical Event:

Date	Location	User	Value	Reason
Oct-29-2020 08:34:54 (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-29-2020 08:34:54 (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-29-2020 08:34:54 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 1	Initial Entry

090177e196ae2e43\Final\Final On: 01-Apr-2021 03:09 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 2 -
Unscheduled Visit on Jan/27/2021

Form Version: 22-Apr-2020 21:03

Site No: 1231

Subject No: 12314197

Generated By:

(b) (4)

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

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

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1. Date of Visit

Date	Location	User	Value	Reason
Mar-25-2021 03:21:43 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Closed	Query to be raised post BLA. PD tracker will be updated accordingly.
Mar-22-2021 02:54:21 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Reissued: Candidate	PDQ RQ1: As per Query response, CONVA visit will be checked after V101.
Mar-20-2021 18:01:24 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Answered	the volunteer could not perform his convalescence visit due to having undergone a hip replacement operation. It will coordinate with V101. Thanks

090177e196ae2e43\Final\Final On: 01-Apr-2021 03:09 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 2 -
Unscheduled Visit on Jan/27/2021

Form Version: 22-Apr-2020 21:03

Site No: 1231

Subject No: 12314197

Generated By:

(b) (4)

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

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

Mar-19-2021 09:17:56 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Opened	PDQ: Convalescent visit is missing and 35+ days (51) have passed since COVID Illness Visit. If visit occurred record data as a matching CONVA visit; if visit did not occur attempt to schedule visit even if OOW and obtain the CONVA sample else clarify.
Jan-29-2021 12:47:48 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Jan-29-2021 12:46:21 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Deleted	Close Auto Query

090177e196ae2e43\Final\Final On: 01-Apr-2021 03:09 (GMT)

Header Text: C4591001
Visit: POT_COVID_ILL 2 -
 Unscheduled Visit on Jan/27/2021
Form Version: 22-Apr-2020 21:03
Site No: 1231
Subject No: 12314197
Generated By:
 (b) (4)
Form: DATE OF VISIT - ILLNESS ONSET - eCRF
 Audit Trail History
Form Status: Data Complete, Locked, Frozen, Verified
Site Name: (1231) Hospital Militar Central Cirujano
 Mayor Dr. Cosme Argerich
Subject Initials: ---
Generated Time (GMT): 29-Mar-2021 20:34

Jan-29-2021 12:45:54 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Candidat e	Date of Visit is completed but Date of Assessment in the Signs and Symptoms form is missing. Please review and update as appropriate.
Jan-29-2021 12:45:54 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidat e	Date of Visit is completed but Date of Collection in both Nasal Swab Self and Nasal Swab are missing. Please review and update as appropriate.
Jan-29-2021 12:45:54 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6) [Redacted]	Data Entry: Jan/27/2021	Initial Entry

3. COVID-19 Illness Visit:				
Date	Location	User	Value	Reason

Header Text: C4591001

Visit: POT_COVID_ILL 2 -
Unscheduled Visit on Jan/27/2021

Form Version: 22-Apr-2020 21:03

Site No: 1231

Subject No: 12314197

Generated By:

(b) (4)

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

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

Jan-29-2021 12:45:54 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: COVID_B	Initial Entry
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Header Text: C4591001

Visit: POT_COVID_ILL 2 -
Unscheduled Visit on Jan/27/2021

Form Version: 14-Jan-2021 02:23

Site No: 1231

Subject No: 12314197

Generated By:

(b) (4)

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

Form Status: Data Complete, Locked, Frozen

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

Subject Initials: ---

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

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1. Date of Assessment:

Date	Location	User	Value	Reason
Jan-29-2021 12:46:21 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Jan/27/2021	Initial Entry

2. Date of First Symptom Started:

Date	Location	User	Value	Reason
Jan-29-2021 12:46:21 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Jan/25/2021	Initial Entry

3. Symptoms Ongoing?

Date	Location	User	Value	Reason
Jan-29-2021 12:46:56 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO Date of Last Symptom Resolved: Jan/27/2021	Transcription Error
Jan-29-2021 12:46:21	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

090177e196ae2e43\Final\Final On: 01-Apr-2021 03:09 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 2 -
Unscheduled Visit on Jan/27/2021

Form Version: 14-Jan-2021 02:23

Site No: 1231

Subject No: 12314197

Generated By:

(b) (4)

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

Form Status: Data Complete, Locked, Frozen

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

Subject Initials: ---

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

(UTC-03:00) City
of Buenos Aires

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

4.a

Date	Location	User	Value	Reason
Jan-29-2021 12:46:21 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptoms: FEV ER Symptom Present: YES	Initial Entry

4.a Symptoms:

Date	Location	User	Value	Reason
Jan-29-2021 12:46:21 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: FEVER	Initial Entry

4.a Was symptom present?

Date	Location	User	Value	Reason
Jan-29-2021 12:46:21 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

4.b

090177e196ae2e43\Final\Final On: 01-Apr-2021 03:09 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 2 -
Unscheduled Visit on Jan/27/2021

Form Version: 14-Jan-2021 02:23

Site No: 1231

Subject No: 12314197

Generated By:

(b) (4)

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

Form Status: Data Complete, Locked, Frozen

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

Subject Initials: ---

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

Date	Location	User	Value	Reason
Jan-29-2021 12:46:21 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sympt NEW OR I oms: NCREASE D COUGH Sympt NO om Pre sent:	Initial Entry

4.b Symptoms:

Date	Location	User	Value	Reason
Jan-29-2021 12:46:21 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NEW OR INCREAS ED COUGH	Initial Entry

4.b Was symptom present?

Date	Location	User	Value	Reason
Jan-29-2021 12:46:21 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

4.c

Date	Location	User	Value	Reason
Jan-29-2021	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Initial Entry

090177e196ae2e43\Final\Final On: 01-Apr-2021 03:09 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 2 -
Unscheduled Visit on Jan/27/2021

Form Version: 14-Jan-2021 02:23

Site No: 1231

Subject No: 12314197

Generated By:

(b) (4)

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

Form Status: Data Complete, Locked, Frozen

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

Subject Initials: ---

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

12:46:21 (UTC-03:00) City of Buenos Aires		(b) (4), (b) (6)	Symp NEW OR IN toms: CREAS S HORTNESS OF BREATH Symp NO tom Prese nt:	
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4.c Symptoms:

Date	Location	User	Value	Reason
Jan-29-2021 12:46:21 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NEW OR INCREAS ED SHORTNESS O F BREATH	Initial Entry

4.c Was symptom present?

Date	Location	User	Value	Reason
Jan-29-2021 12:46:21 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

4.d

Date	Location	User	Value	Reason
Jan-29-2021 12:46:21	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptoms: CHIL	Initial Entry

090177e196ae2e43\Final\Final On: 01-Apr-2021 03:09 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 2 -
Unscheduled Visit on Jan/27/2021

Form Version: 14-Jan-2021 02:23

Site No: 1231

Subject No: 12314197

Generated By:

(b) (4)

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

Form Status: Data Complete, Locked, Frozen

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

Subject Initials: ---

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

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

Date	Location	User	Value	Reason
Jan-29-2021 12:46:21 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: CHILLS	Initial Entry

4.d Was symptom present?

Date	Location	User	Value	Reason
Jan-29-2021 12:46:21 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

4.e

Date	Location	User	Value	Reason
Jan-29-2021 12:46:21 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom: NEW OR INCREASED MUSCLE PAIN	Initial Entry

090177e196ae2e43\Final\Final On: 01-Apr-2021 03:09 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 2 -
Unscheduled Visit on Jan/27/2021

Form Version: 14-Jan-2021 02:23

Site No: 1231

Subject No: 12314197

Generated By:

(b) (4)

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

Form Status: Data Complete, Locked, Frozen

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

Subject Initials: ---

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

			Sympt NO om Pr esent:	
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4.e Symptoms:

Date	Location	User	Value	Reason
Jan-29-2021 12:46:21 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NEW OR INCREAS ED MUSCLE PAIN	Initial Entry

4.e Was symptom present?

Date	Location	User	Value	Reason
Jan-29-2021 12:46:21 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

4.f

Date	Location	User	Value	Reason
Jan-29-2021 12:46:21 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sympt NEW LOSS oms: OF TASTE OR SMELL Sympt NO om Pr esent:	Initial Entry

090177e196ae2e43\Final\Final On: 01-Apr-2021 03:09 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 2 -
Unscheduled Visit on Jan/27/2021

Form Version: 14-Jan-2021 02:23

Site No: 1231

Subject No: 12314197

Generated By:

(b) (4)

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

Form Status: Data Complete, Locked, Frozen

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

Subject Initials: ---

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

4.f Symptoms:

Date	Location	User	Value	Reason
Jan-29-2021 12:46:21 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NEW LOSS OF TAS TE OR SMELL	Initial Entry

4.f Was symptom present?

Date	Location	User	Value	Reason
Jan-29-2021 12:46:21 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

4.g

Date	Location	User	Value	Reason
Jan-29-2021 12:46:21 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sympt NEW OR IN oms: CREASED SORE THR OAT Sympt NO om Pr esent:	Initial Entry

090177e196ae2e43\Final\Final On: 01-Apr-2021 03:09 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 2 -
Unscheduled Visit on Jan/27/2021

Form Version: 14-Jan-2021 02:23

Site No: 1231

Subject No: 12314197

Generated By:

(b) (4)

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

Form Status: Data Complete, Locked, Frozen

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

Subject Initials: ---

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

4.g Symptoms:

Date	Location	User	Value	Reason
Jan-29-2021 12:46:21 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NEW OR INCREASED SORE THROAT	Initial Entry

4.g Was symptom present?

Date	Location	User	Value	Reason
Jan-29-2021 12:46:21 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

4.h

Date	Location	User	Value	Reason
Jan-29-2021 12:46:21 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptoms: DIARR HEA Symptom NO Present:	Initial Entry

090177e196ae2e43\Final\Final On: 01-Apr-2021 03:09 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 2 -
Unscheduled Visit on Jan/27/2021

Form Version: 14-Jan-2021 02:23

Site No: 1231

Subject No: 12314197

Generated By:

(b) (4)

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

Form Status: Data Complete, Locked, Frozen

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

Subject Initials: ---

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

4.h Symptoms:

Date	Location	User	Value	Reason
Jan-29-2021 12:46:21 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: DIARRHEA	Initial Entry

4.h Was symptom present?

Date	Location	User	Value	Reason
Jan-29-2021 12:46:21 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

4.i

Date	Location	User	Value	Reason
Jan-29-2021 12:46:21 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptoms: VOMI TING Symptom NO Present:	Initial Entry

090177e196ae2e43\Final\Final On: 01-Apr-2021 03:09 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 2 -
Unscheduled Visit on Jan/27/2021

Form Version: 14-Jan-2021 02:23

Site No: 1231

Subject No: 12314197

Generated By:

(b) (4)

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

Form Status: Data Complete, Locked, Frozen

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

Subject Initials: ---

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

4.i Symptoms:

Date	Location	User	Value	Reason
Jan-29-2021 12:46:21 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: VOMITING	Initial Entry

4.i Was symptom present?

Date	Location	User	Value	Reason
Jan-29-2021 12:46:21 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

Header Text: C4591001

Visit: POT_COVID_ILL 2 -
Unscheduled Visit on Jan/27/2021

Form Version: 06-Jul-2020 21:54

Site No: 1231

Subject No: 12314197

Generated By:

(b) (4)

Form: MICROBIOLOGY SPECIMEN - Audit Trail

Form Status:

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

Subject Initials: ---

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

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Date	Location	User	Value	Reason
Jan-29-2021 12:46:37 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Created	

Header Text: C4591001

Visit: POT_COVID_ILL 2 -
Unscheduled Visit on Jan/27/2021

Form Version: 06-Jul-2020 21:54

Site No: 1231

Subject No: 12314197

Generated By:

(b) (4)

Form: MICROBIOLOGY SPECIMEN - eCRF Audit
Trail History

Form Status: Data Complete, Locked, Frozen

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

Subject Initials: ---

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

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1. Actual Date of Collection:

Date	Location	User	Value	Reason
Jan-29-2021 12:46:37 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Jan/27/2021	Initial Entry

2. Specimen Type:

Date	Location	User	Value	Reason
Jan-29-2021 12:46:37 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: SWABBED MATERI AL	Initial Entry

3. Specimen Collection Location:

Date	Location	User	Value	Reason
Jan-29-2021 12:46:37 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NASOPHARYNX	Initial Entry

4. Assay Code and Description:

Date	Location	User	Value	Reason
Jan-29-2021	ACV0PFEINFP6000	auto calc	Data Entry:	Initial Entry

090177e196ae2e43\Final\Final On: 01-Apr-2021 03:09 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 2 -
Unscheduled Visit on Jan/27/2021

Form Version: 06-Jul-2020 21:54

Site No: 1231

Subject No: 12314197

Generated By:

(b) (4)

Form: MICROBIOLOGY SPECIMEN - eCRF Audit
Trail History

Form Status: Data Complete, Locked, Frozen

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

Subject Initials: ---

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

12:46:37
(UTC-03:00) City
of Buenos Aires

(autocalc)

SEVERE ACUTE RES
P SYNDROME CORO
NAVIRUS 2

5. Device Type:

Date	Location	User	Value	Reason
Jan-29-2021 12:46:37 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SARS-COV-2 DIAGN OSTIC TEST	Initial Entry

6. Trade Name:

Date	Location	User	Value	Reason
Jan-29-2021 12:46:37 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: ATILA BIOSYSTE MS IAMP COVID-1 9 DETECTION KIT	Initial Entry

7. Test Result:

Date	Location	User	Value	Reason
Jan-29-2021 12:46:37 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NEGATIVE	Initial Entry

090177e196ae2e43\Final\Final On: 01-Apr-2021 03:09 (GMT)

Header Text: C4591001**Visit:** POT_COVID_ILL 2 -
Unscheduled Visit on Jan/27/2021**Form Version:** 22-Apr-2020 21:03**Site No:** 1231**Subject No:** 12314197**Generated By:**

(b) (4)

Form: ELECTRONIC SAMPLE TRACKING - NASAL
SWAB SELF - eCRF Audit Trail History**Form Status:** Data Complete, Locked, Frozen, Verified**Site Name:** (1231) Hospital Militar Central Cirujano
Mayor Dr. Cosme Argerich**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 20:34[Back to Form](#)**1. Data Origin**

Date	Location	User	Value	Reason
Jan-29-2021 12:47:38 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Jan-29-2021 12:47:38 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: NASAL_SWAB_SELF	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Jan-29-2021 12:47:38 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

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

Date	Location	User	Value	Reason
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Header Text: C4591001

Visit: POT_COVID_ILL 2 -
Unscheduled Visit on Jan/27/2021

Form Version: 22-Apr-2020 21:03

Site No: 1231

Subject No: 12314197

Generated By:

(b) (4)

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

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

Jan-29-2021 12:47:38 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample collected by t eam physician.	Initial Entry
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Header Text: C4591001

Visit: POT_COVID_ILL 2 -
Unscheduled Visit on Jan/27/2021

Form Version: 22-Apr-2020 21:03

Site No: 1231

Subject No: 12314197

Generated By:

(b) (4)

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

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

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1. Data Origin

Date	Location	User	Value	Reason
Jan-29-2021 12:47:48 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Jan-29-2021 12:47:48 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: NASAL_SWAB	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Feb-01-2021 13:37:06 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Jan-31-2021 23:59:52 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	'Sample Collected?' is Yes, however no barcodes

090177e196ae2e43\Final\Final On: 01-Apr-2021 03:09 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 2 -
Unscheduled Visit on Jan/27/2021

Form Version: 22-Apr-2020 21:03
Site No: 1231

Subject No: 12314197

Generated By:

(b) (4)

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

Form Status: Data Complete, Locked, Frozen, Verified
Site Name: (1231) Hospital Militar Central Cirujano
Mayor Dr. Cosme Argerich

Subject Initials: ---

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

				are entered. Please review and correct as appropriate.
Jan-29-2021 12:47:48 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Jan-29-2021 12:47:48 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Date of Collectio n: Jan/27/2021	Initial Entry

5.a

Date	Location	User	Value	Reason
Feb-01-2021 13:37:06 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample I BPW6J D: 8	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
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090177e196ae2e43\Final\Final On: 01-Apr-2021 03:09 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 2 -
Unscheduled Visit on Jan/27/2021

Form Version: 22-Apr-2020 21:03

Site No: 1231

Subject No: 12314197

Generated By:

(b) (4)

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

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

Feb-01-2021 13:37:06 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BPW6J8	Initial Entry
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Header Text: C4591001**Visit:** POT_COVID_ILL 2 -
Unscheduled Visit on Jan/27/2021**Form Version:** 14-Jan-2021 02:24**Site No:** 1231**Subject No:** 12314197**Generated By:**

(b) (4)

Form: HEALTH CARE UTILIZATION - eCRF Audit
Trail History**Form Status:** Data Complete, Locked, Frozen**Site Name:** (1231) Hospital Militar Central Cirujano
Mayor Dr. Cosme Argerich**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 20:34[Back to Form](#)*I.a*

Date	Location	User	Value	Reason
Jan-29-2021 12:47:19 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Type of Prac SPEC titioner: IALI ST Occurrence NO of Visits or C ontacts:	Initial Entry

I.a Physician or Healthcare Professional:

Date	Location	User	Value	Reason
Jan-29-2021 12:47:19 (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
Jan-29-2021 12:47:19 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

Header Text: C4591001

Visit: POT_COVID_ILL 2 -
Unscheduled Visit on Jan/27/2021

Form Version: 14-Jan-2021 02:24

Site No: 1231

Subject No: 12314197

Generated By:

(b) (4)

Form: HEALTH CARE UTILIZATION - eCRF Audit
Trail History

Form Status: Data Complete, Locked, Frozen

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

Subject Initials: ---

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

1.b

Date	Location	User	Value	Reason
Jan-29-2021 12:47:19 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Type of Pr EMER actitioner: GENC Y ROO M Occurrence NO of Visits or Contact s:	Initial Entry

1.b Physician or Healthcare Professional:

Date	Location	User	Value	Reason
Jan-29-2021 12:47:19 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: EMERGENCY ROO M	Initial Entry

1.b Occurrence of Visits or Contacts:

Date	Location	User	Value	Reason
Jan-29-2021 12:47:19 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

1.c

090177e196ae2e43\Final\Final On: 01-Apr-2021 03:09 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 2 -
Unscheduled Visit on Jan/27/2021

Form Version: 14-Jan-2021 02:24

Site No: 1231

Subject No: 12314197

Generated By:

(b) (4)

Form: HEALTH CARE UTILIZATION - eCRF Audit
Trail History

Form Status: Data Complete, Locked, Frozen

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

Subject Initials: ---

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

Date	Location	User	Value	Reason
Jan-29-2021 12:47:19 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Type of P PRIMAR ractitione Y CARE r: PHYSICI AN Occurren NO ce of Visi ts or Con tacts:	Initial Entry

1.c Physician or Healthcare Professional:

Date	Location	User	Value	Reason
Jan-29-2021 12:47:19 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: PRIMARY CARE P HYSICIAN	Initial Entry

1.c Occurrence of Visits or Contacts:

Date	Location	User	Value	Reason
Jan-29-2021 12:47:19 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

1.d

Date	Location	User	Value	Reason
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090177e196ae2e43\Final\Final On: 01-Apr-2021 03:09 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 2 -
Unscheduled Visit on Jan/27/2021

Form: HEALTH CARE UTILIZATION - eCRF Audit
Trail History

Form Version: 14-Jan-2021 02:24

Form Status: Data Complete, Locked, Frozen

Site No: 1231

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

Subject No: 12314197

Subject Initials: ---

Generated By:

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

(b) (4)

Jan-29-2021 12:47:19 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Type of Practitioner: URGE NT C ARE Occurrence of Visits or Contacts: NO	Initial Entry
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1.d Physician or Healthcare Professional:

Date	Location	User	Value	Reason
Jan-29-2021 12:47:19 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: URGENT CARE	Initial Entry

1.d Occurrence of Visits or Contacts:

Date	Location	User	Value	Reason
Jan-29-2021 12:47:19 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

1.e

Date	Location	User	Value	Reason
Jan-29-2021 12:47:19 (UTC-03:00) City	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Type of Practitioner: TELEPH ONE CO	Initial Entry

090177e196ae2e43\Final\Final On: 01-Apr-2021 03:09 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 2 -
Unscheduled Visit on Jan/27/2021

Form Version: 14-Jan-2021 02:24

Site No: 1231

Subject No: 12314197

Generated By:

(b) (4)

Form: HEALTH CARE UTILIZATION - eCRF Audit
Trail History

Form Status: Data Complete, Locked, Frozen

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

Subject Initials: ---

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

of Buenos Aires			r: NSULTA TION	
			Occurren NO ce of Visi ts or Con tacts:	

I.e Physician or Healthcare Professional:

Date	Location	User	Value	Reason
Jan-29-2021 12:47:19 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: TELEPHONE CONS ULTATION	Initial Entry

I.e Occurrence of Visits or Contacts:

Date	Location	User	Value	Reason
Jan-29-2021 12:47:19 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

I.f

Date	Location	User	Value	Reason
Jan-29-2021 12:47:19 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Type of Practi OT tioner: HE R	Initial Entry

090177e196ae2e43\Final\Final On: 01-Apr-2021 03:09 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 2 -
Unscheduled Visit on Jan/27/2021

Form: HEALTH CARE UTILIZATION - eCRF Audit
Trail History

Form Version: 14-Jan-2021 02:24

Form Status: Data Complete, Locked, Frozen

Site No: 1231

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

Subject No: 12314197

Subject Initials: ---

Generated By:

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

(b) (4)

			Occurrence of NO Visits or Cont acts:	
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1.f Physician or Healthcare Professional:

Date	Location	User	Value	Reason
Jan-29-2021 12:47:19 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: OTHER	Initial Entry

1.f Occurrence of Visits or Contacts:

Date	Location	User	Value	Reason
Jan-29-2021 12:47:19 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

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

Date	Location	User	Value	Reason
Jan-29-2021 12:47:19 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

090177e196ae2e43\Final\Final On: 01-Apr-2021 03:09 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 2 -
Unscheduled Visit on Jan/27/2021

Form Version: 06-Jul-2020 21:52

Site No: 1231

Subject No: 12314197

Generated By:

(b) (4)

Form: ILLNESS DETAILS - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen

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

Subject Initials: ---

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

[Back to Form](#)

1. Category of Clinical Event:

Date	Location	User	Value	Reason
Jan-29-2021 12:47:08 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: POTENTIAL COVID- 19 ILLNESS	Initial Entry

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

Date	Location	User	Value	Reason
Jan-29-2021 12:47:08 (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
Jan-29-2021 12:47:08 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 1	Initial Entry

090177e196ae2e43\Final\Final On: 01-Apr-2021 03:09 (GMT)

Header Text: C4591001

Visit: POT_COVID_CONVA 1 -
Unscheduled Visit on Nov/26/2020

Form Version: 22-Apr-2020 21:04

Site No: 1231

Subject No: 12314197

Generated By:

(b) (4)

Form: DATE OF VISIT - ILLNESS CONVALESCENT -
eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

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

Subject Initials: ---

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

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1. Date of Visit

Date	Location	User	Value	Reason
Nov-26-2020 09:36:29 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Nov/26/2020	Initial Entry

3. COVID-19 Illness Visit:

Date	Location	User	Value	Reason
Nov-26-2020 09:36:29 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: COVID_A1	Initial Entry

Header Text: C4591001

Visit: POT_COVID_CONVA 1 -
Unscheduled Visit on Nov/26/2020

Form Version: 22-Apr-2020 21:03

Site No: 1231

Subject No: 12314197

Generated By:

(b) (4)

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

Form Status: Data Complete, Frozen, Verified

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

Subject Initials: ---

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

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1. Data Origin

Date	Location	User	Value	Reason
Nov-26-2020 09:36:37 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Nov-26-2020 09:36:37 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SERUM	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Nov-26-2020 11:14:21 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Nov-26-2020 09:36:37 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes

090177e196ae2e43\Final\Final On: 01-Apr-2021 03:09 (GMT)

Header Text: C4591001

Visit: POT_COVID_CONVA 1 -
Unscheduled Visit on Nov/26/2020

Form Version: 22-Apr-2020 21:03

Site No: 1231

Subject No: 12314197

Generated By:

(b) (4)

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

Form Status: Data Complete, Frozen, Verified

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

Subject Initials: ---

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

				are entered. Please review and correct as appropriate.
Nov-26-2020 09:36:37 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Date of Collection: Nov/26/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Nov-26-2020 11:14:21 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample I BRVMH D: H	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Nov-26-2020 11:14:21 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BRVMHH	Initial Entry

5.b

Date	Location	User	Value	Reason
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090177e196ae2e43\Final\Final On: 01-Apr-2021 03:09 (GMT)

Header Text: C4591001

Visit: POT_COVID_CONVA 1 -
Unscheduled Visit on Nov/26/2020

Form Version: 22-Apr-2020 21:03
Site No: 1231

Subject No: 12314197

Generated By:

(b) (4)

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

Form Status: Data Complete, Frozen, Verified

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

Subject Initials: ---

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

Nov-26-2020 15:40:40 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample I BRVMH D: 5	Initial Entry
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5.b Sample ID

Date	Location	User	Value	Reason
Nov-26-2020 15:40:40 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BRVMH5	Initial Entry

5.c

Date	Location	User	Value	Reason
Nov-26-2020 16:31:51 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID BPWSP : Z	Initial Entry

5.c Sample ID

Date	Location	User	Value	Reason
Nov-26-2020 16:31:51 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BPWSPZ	Initial Entry

090177e196ae2e43\Final\Final On: 01-Apr-2021 03:09 (GMT)

Header Text: C4591001

Visit: POT_COVID_CONVA 2 -
Unscheduled Visit on Mar/26/2021

Form: DATE OF VISIT - ILLNESS CONVALESCENT -
eCRF Audit Trail History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Verified

Site No: 1231

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

Subject No: 12314197

Subject Initials: ---

Generated By:

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

(b) (4)

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1. Date of Visit

Date	Location	User	Value	Reason
Mar-26-2021 12:35:18 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Mar/26/2021	Initial Entry

3. COVID-19 Illness Visit:

Date	Location	User	Value	Reason
Mar-26-2021 12:35:18 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: COVID_B1	Initial Entry

Header Text: C4591001

Visit: POT_COVID_CONVA 2 -
Unscheduled Visit on Mar/26/2021

Form Version: 22-Apr-2020 21:03

Site No: 1231

Subject No: 12314197

Generated By:

(b) (4)

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

Form Status: Data Complete, Verified

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

Subject Initials: ---

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

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1. Data Origin

Date	Location	User	Value	Reason
Mar-26-2021 12:35:28 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Mar-26-2021 12:35:28 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SERUM	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Mar-26-2021 13:32:17 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Mar-26-2021 12:35:28 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes

090177e196ae2e43\Final\Final On: 01-Apr-2021 03:09 (GMT)

Header Text: C4591001

Visit: POT_COVID_CONVA 2 -
Unscheduled Visit on Mar/26/2021

Form Version: 22-Apr-2020 21:03

Site No: 1231

Subject No: 12314197

Generated By:

(b) (4)

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

Form Status: Data Complete, Verified

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

Subject Initials: ---

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

				are entered. Please review and correct as appropriate.
Mar-26-2021 12:35:28 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Date of Collection: Mar/26/2021	Initial Entry

5.a

Date	Location	User	Value	Reason
Mar-26-2021 13:32:17 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample I BS1RF D: B	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Mar-26-2021 13:32:17 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BS1RFB	Initial Entry

5.b

Date	Location	User	Value	Reason
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090177e196ae2e43\Final\Final On: 01-Apr-2021 03:09 (GMT)

Header Text: C4591001

Visit: POT_COVID_CONVA 2 -
Unscheduled Visit on Mar/26/2021

Form Version: 22-Apr-2020 21:03

Site No: 1231

Subject No: 12314197

Generated By:

(b) (4)

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

Form Status: Data Complete, Verified

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

Subject Initials: ---

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

Mar-26-2021 14:00:37 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	Alan Colombo (b) (4)	Data Entry: Sample I BS1RD D: Z	Initial Entry
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5.b Sample ID

Date	Location	User	Value	Reason
Mar-26-2021 14:00:37 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	Alan Colombo (b) (4)	Data Entry: BS1RDZ	Initial Entry

5.c

Date	Location	User	Value	Reason
Mar-29-2021 09:43:19 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	Alan Colombo (b) (4)	Data Entry: Sample I BPW7T D: Z	Initial Entry

5.c Sample ID

Date	Location	User	Value	Reason
Mar-29-2021 09:43:19 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	Alan Colombo (b) (4)	Data Entry: BPW7TZ	Initial Entry

090177e196ae2e43\Final\Final On: 01-Apr-2021 03:09 (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: 12314197 **Subject Initials:** ---

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

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1. Date of Completion/Discontinuation/Death :

Date	Location	User	Value	Reason
Oct-16-2020 10:04:38 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Oct/16/2020	Initial Entry

2. Phase of Disposition:

Date	Location	User	Value	Reason
Oct-16-2020 10:04:38 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: VACCINATION	Initial Entry

3. Status:

Date	Location	User	Value	Reason
Oct-16-2020 10:04:38 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: COMPLETED	Initial Entry

090177e196ae2e43\Final\Final On: 01-Apr-2021 03:09 (GMT)

Header Text: C4591001

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

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1231

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

Subject No: 12314197

Subject Initials: ---

Generated By:

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

(b) (4)

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1. Date of Visit

Date	Location	User	Value	Reason
Jan-27-2021 12:29:38 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Jan/26/2021	Initial Entry

090177e196ae2e43\Final\Final On: 01-Apr-2021 03:09 (GMT)

Header Text: C4591001

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

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

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

Subject No: 12314197 **Subject Initials:** ---

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

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

Date	Location	User	Value	Reason
Mar-26-2021 08:54:13 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Closed	Query opened at subject status
Mar-17-2021 10:41:10 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	Rivkah Rosen (b) (4)	Query 2: Reissu ed:Candidate	Check for V101 update 24-Mar-21.
Mar-16-2021 13:59:52 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	Adolfo Gonzalez (b) (4)	Query 2: Answer red	the v101 has not happen yet, the information required will be completed as soon as the subject comes, the visit will be scheduled as soon as possible, thank you
Mar-15-2021 12:03:47	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Reissu ed:Opened	DM1: Date Written

090177e196ae2e43\Final\Final On: 01-Apr-2021 03:09 (GMT)

Header Text: C4591001

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

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

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

Subject No: 12314197 **Subject Initials:** ---

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

(b) (4)

(UTC-03:00) City of Buenos Aires				Consent Obtained is missing in Informed Consent - Further Vaccination CRF. Kindly review and update, else clarify.
Mar-04-2021 17:28:28 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Reissu ed:Candidate	pending patient REVAX visit
Mar-04-2021 13:07:03 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	Adolfo Gonzalez (b) (4)	Query 2: Answe red	the v101 has not happen yet, the information required will be completed as soon as the subject comes, the visit will be scheduled as soon as possible, thank you
Mar-04-2021 00:19:02	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Opene d	DM: Participant is

090177e196ae2e43\Final\Final On: 01-Apr-2021 03:09 (GMT)

Header Text: C4591001

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

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

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

Subject No: 12314197 **Subject Initials:** ---

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

(b) (4)

(UTC-03:00) City of Buenos Aires		(b) (4), (b) (6)		eligible and confirmed to have received Placebo, but Date Written Consent Obtained is missing in Informed Consent - Further Vaccination CRF. Please review and update as appropriate.
Jan-27-2021 12:29:58 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Jan-27-2021 12:29:46 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	The response indicates participant was unblinded, however the TREATMENT UNBLINDED date is missing in the DISP visit. Please

090177e196ae2e43\Final\Final On: 01-Apr-2021 03:09 (GMT)

Header Text: C4591001

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

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

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

Subject No: 12314197 **Subject Initials:** ---

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

(b) (4)

				complete this date.
Jan-27-2021 12:29:46 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Participant is willing to return for Vaccination 3 Participant is: eligible per local/national recommendations and confirmed to have received only placebo at Vaccination 1/2	Initial Entry

090177e196ae2e43\Final\Final On: 01-Apr-2021 03:09 (GMT)

Header Text: C4591001

Visit: V101_VAX3

Form Version: 22-Apr-2020 21:02

Site No: 1231

Subject No: 12314197

Generated By:

(b) (4)

Form: DATE OF VISIT - eCRF Audit Trail History

Form Status: Data Complete, Verified

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

Subject Initials: ---

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

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1. Date of Visit

Date	Location	User	Value	Reason
Mar-26-2021 12:56:38 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Mar/26/2021	Initial Entry

090177e196ae2e43\Final\Final On: 01-Apr-2021 03:09 (GMT)

Header Text: C4591001

Visit: V101_VAX3

Form: INFORMED CONSENT - FURTHER
VACCINATION - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:31

Form Status: Data Complete, Verified

Site No: 1231

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

Subject No: 12314197

Subject Initials: ---

Generated By:

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

(b) (4)

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1. Consent Was:

Date	Location	User	Value	Reason
Mar-26-2021 12:56:49 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: OBTAINED Date Written Conse nt Obtained Mar/26/2021	Initial Entry

090177e196ae2e43\Final\Final On: 01-Apr-2021 03:09 (GMT)

Header Text: C4591001

Visit: V101_VAX3

Form: DISPOSITION - SCREENING FOR FURTHER VACCINATION - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:31

Form Status: Data Complete, Verified

Site No: 1231

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

Subject No: 12314197

Subject Initials: ---

Generated By:

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

(b) (4)

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1. Date of Completion/Discontinuation/Death :

Date	Location	User	Value	Reason
Mar-26-2021 12:57:19 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Mar/26/2021	Initial Entry

2. Phase of Disposition:

Date	Location	User	Value	Reason
Mar-26-2021 12:57:19 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: REPEAT SCREENING 1	Initial Entry

3. Status:

Date	Location	User	Value	Reason
Mar-26-2021 12:57:19 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: COMPLETED	Initial Entry

Header Text: C4591001**Visit:** V101_VAX3**Form:** ELECTRONIC SAMPLE TRACKING -
IMMUNOGENICITY - eCRF Audit Trail History**Form Version:** 22-Apr-2020 21:03**Form Status:** Data Complete, Verified**Site No:** 1231**Site Name:** (1231) Hospital Militar Central Cirujano
Mayor Dr. Cosme Argerich**Subject No:** 12314197**Subject Initials:** ---**Generated By:****Generated Time (GMT):** 29-Mar-2021 20:34

(b) (4)

[Back to Form](#)**1. Data Origin**

Date	Location	User	Value	Reason
Mar-26-2021 12:57:38 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Mar-26-2021 12:57:38 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SERUM	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Mar-26-2021 12:57:38 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

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

Date	Location	User	Value	Reason
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Header Text: C4591001

Visit: V101_VAX3

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Verified

Site No: 1231

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

Subject No: 12314197

Subject Initials: ---

Generated By:

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

(b) (4)

Mar-26-2021 12:57:38 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample was captured in the convalescent vi sit which was carried out the same day	Initial Entry
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Header Text: C4591001

Visit: V101_VAX3

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Verified

Site No: 1231

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

Subject No: 12314197

Subject Initials: ---

Generated By:

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

(b) (4)

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1. Data Origin

Date	Location	User	Value	Reason
Mar-26-2021 12:57:50 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Mar-26-2021 12:57:50 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: NASAL_SWAB	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Mar-26-2021 14:27:15 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Mar-26-2021 12:57:50 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes

090177e196ae2e43\Final\Final On: 01-Apr-2021 03:09 (GMT)

Header Text: C4591001

Visit: V101_VAX3

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Verified

Site No: 1231

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

Subject No: 12314197

Subject Initials: ---

Generated By:

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

(b) (4)

				are entered. Please review and correct as appropriate.
Mar-26-2021 12:57:50 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Date of Collection: Mar/26/2021	Initial Entry

5.a

Date	Location	User	Value	Reason
Mar-26-2021 14:27:15 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample I BPT8W D: 5	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Mar-26-2021 14:27:15 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BPT8W5	Initial Entry

090177e196ae2e43\Final\Final On: 01-Apr-2021 03:09 (GMT)

Header Text: C4591001

Visit: V101_VAX3

Form Version: 10-Dec-2020 02:26

Site No: 1231

Subject No: 12314197

Generated By:

(b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Verified

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

Subject Initials: ---

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

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1. Was there a temporary delay of vaccination?

Date	Location	User	Value	Reason
Mar-26-2021 12:58:08 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2. Treatment Name

Date	Location	User	Value	Reason
Mar-26-2021 12:58:08 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: BNT162b2	Initial Entry

3. Formulation:

Date	Location	User	Value	Reason
Mar-26-2021 12:58:08 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: INJECTION	Initial Entry

4. Dose Date Time:

Date	Location	User	Value	Reason
Mar-26-2021	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Initial Entry

090177e196ae2e43\Final\Final On: 01-Apr-2021 03:09 (GMT)

Header Text: C4591001

Visit: V101_VAX3

Form: VACCINATION - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:26

Form Status: Data Complete, Verified

Site No: 1231

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

Subject No: 12314197

Subject Initials: ---

Generated By:

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

(b) (4)

12:58:08 (UTC-03:00) City of Buenos Aires		(b) (4), (b) (6)	Mar/26/2021 11:09	
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5. Anatomical Location:

Date	Location	User	Value	Reason
Mar-26-2021 12:58:08 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: DELTOID MUSCLE	Initial Entry

6. Body Side:

Date	Location	User	Value	Reason
Mar-26-2021 12:58:08 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: RIGHT	Initial Entry

7. Route:

Date	Location	User	Value	Reason
Mar-26-2021 12:58:08 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: INTRAMUSCULAR	Initial Entry

8. Actual Dose:

Date	Location	User	Value	Reason
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090177e196ae2e43\Final\Final On: 01-Apr-2021 03:09 (GMT)

Header Text: C4591001

Visit: V101_VAX3

Form: VACCINATION - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:26

Form Status: Data Complete, Verified

Site No: 1231

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

Subject No: 12314197

Subject Initials: ---

Generated By:

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

(b) (4)

Mar-26-2021 12:58:08 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 30.0	Initial Entry
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9. Unit:

Date	Location	User	Value	Reason
Mar-26-2021 12:58:08 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: ug	Initial Entry

10. Timeframe Subject Was Observed

Date	Location	User	Value	Reason
Mar-26-2021 12:58:08 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 30 MINUTES	Initial Entry

11. Was the subject observed for at least the protocol specified observation period after investigational product administration?

Date	Location	User	Value	Reason
Mar-26-2021 12:58:08 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

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

Subject Initials: ---

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Date	Location	User	Value	Reason
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Form Status:

Site No: 1231

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

Subject No: 12314197

Subject Initials: ---

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Date	Location	User	Value	Reason
Mar-05-2021 13:59:04 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Created	

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

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Date	Location	User	Value	Reason
Mar-08-2021 16:25:49 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Deleted	SAE loaded by mistake, duplicated with #EA 2
Mar-08-2021 16:21:01 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Created	

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Form Status:

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Site Name: (1231) Hospital Militar Central Cirujano
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Subject No: 12314197

Subject Initials: ---

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Date	Location	User	Value	Reason
Mar-29-2021 10:42:33 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Created	

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Form Status: Data Complete, Locked, Frozen

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

Subject No: 12314197

Subject Initials: ---

Generated By:

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1. Category:

Date	Location	User	Value	Reason
Nov-13-2020 09:06:14 (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
Nov-13-2020 09:06:14 (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
Nov-26-2020 18:01:38 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: hip osteoarthritis	New Information
Nov-19-2020 15:40:52 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query

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Subject No: 12314197

Subject Initials: ---

Generated By:

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(b) (4)

Nov-19-2020 13:51:34 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Original value is correct. The subject has no medical history of arthritis or hip pain
Nov-19-2020 12:24:37 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	clinical: pls advise if pt has prior hx of hip pain or arthritis. Thanks
Nov-13-2020 09:06:14 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Hip joint pain	Initial Entry

4. Start Date Time:

Date	Location	User	Value	Reason
Nov-13-2020 12:03:17 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Nov/11/2020 20:30	New Information
Nov-13-2020 09:09:50 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Nov/12/2020 20:30	Transcription Error

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(b) (4)

Nov-13-2020 09:06:14 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Nov/11/2020 20:30	Initial Entry
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5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Nov-26-2020 18:02:07 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO End Date Time: Nov/26/2020 17:47	New Information
Nov-13-2020 09:06:14 (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
Nov-13-2020 09:06:14 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 1	Initial Entry

7. Is the adverse event serious?

If Yes, NOTIFY PFIZER IMMEDIATELY.

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Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).

Date	Location	User	Value	Reason
Nov-13-2020 09:06:14 (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
Nov-13-2020 09:06:14 (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
Nov-13-2020 09:06:14 (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	Initial Entry

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(b) (4)

			<i>If Other, specify:</i>	
			Unknown	

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Nov-13-2020 09:06:14 (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
Nov-13-2020 09:06:14 (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
Nov-13-2020 09:06:14 (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?:

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Date	Location	User	Value	Reason
Nov-26-2020 18:02:20 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Nov-26-2020 18:02:20 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: RECOVERED/RESOLVED	New Information
Nov-26-2020 18:02:07 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	For AE hip osteoarthritis: Response to "What was the outcome of this adverse event?" is 'Not Recovered/Not Resolved' but AE End Date/Time is present.
Nov-13-2020 09:06:14 (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
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Nov-13-2020 09:06:14 (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
Mar-05-2021 13:59:04 (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
Mar-05-2021 13:59:04 (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
Mar-12-2021 00:28:57 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Mar-10-2021 16:20:46	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	The subject was diagnosed

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Subject No: 12314197

Subject Initials: ---

Generated By:

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(UTC-03:00) City of Buenos Aires				with hip OA on January 13, 2021, however the condition worsened on January 23, 2021 and surgery was performed.
Mar-09-2021 10:07:57 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	CLINICAL - subject had no prior diagnosis of Hip OA (prior to 13Nov20, in study). Please consider if 'worsening' therefore is appropriate for this case, and update event term in AE/SAE as appropriate
Mar-08-2021 16:21:54 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Worsening of left hip osteoarthritis	Transcription Error

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

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Mar-08-2021 16:19:16 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Left hip osteoarthritis	Transcription Error
Mar-05-2021 13:59:04 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Worsening of left c oxofemoral arthrosis	Initial Entry

4. Start Date Time:

Date	Location	User	Value	Reason
Mar-12-2021 00:28:47 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Mar-10-2021 16:20:58 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	The subject was diagnosed with hip OA on January 13, 2021, however the condition worsened on January 23, 2021 and surgery was performed.

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Mar-09-2021 10:06:32 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	Clinical - Start date is 23Jan21 (hospitalization date); however, SAE report diagnosis made on 13Nov20. In Vaccine study, SAE start date is day event starts; not day it meets serious criteria (item 11 in vaccine SAE instruct); please update in AE/SAE
Mar-05-2021 13:59:04 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Jan/23/2021 08:00	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Mar-16-2021 10:36:36 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO End Date Time: Mar/15/2021 10:0	New Information

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

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			0	
Mar-05-2021 13:59:04 (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
Mar-05-2021 13:59:04 (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
Mar-09-2021 07:33:35 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Closed	Response satisfies query
Mar-09-2021 07:32:28	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query

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Subject No: 12314197

Subject Initials: ---

Generated By:

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(UTC-03:00) City of Buenos Aires				
Mar-08-2021 16:27:25 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Answered	On 3/5 the SAE initial reporting form was sent via mail. Thank you
Mar-08-2021 16:21:54 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	For AE Worsening of left hip osteoarthritis: Response to "Is the adverse event serious?" is 'Yes' but "Serious Adverse Event Number" is blank.
Mar-08-2021 16:19:16 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	For AE Left hip osteoarthritis: Response to "Is the adverse event serious?" is 'Yes' but "Serious Adverse Event Number" is blank.

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Mar-08-2021 07:50:44 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Opened	SAE RECON: Worsening of left coxofemoral arthrosis is not reported to Safety database but marked serious on AE CRF. Confirm seriousness and report to Pfizer immediately. If this event is not serious, downgrade the event on AE CRF
Mar-05-2021 13:59:04 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	For AE Worsening of left coxofemoral arthrosis: Response to "Is the adverse event serious?" is 'Yes' but "Serious Adverse Event Number" is blank.

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<p>Mar-05-2021 13:59:04 (UTC-03:00) City of Buenos Aires</p>	<p>ACV0PFEINFP6000</p>	<p>(b) (4), (b) (6)</p>	<p>Data Entry: YES Is this serious event associated with congenital anomaly or birth defect? NO Did this serious event result in death? NO Did this serious event require or prolong hospitalization? YES Did this serious event result in persistent or significant disability/incapacity? NO Is this serious event life threatening? NO</p>	<p>Initial Entry</p>
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			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
Mar-05-2021 13:59:04 (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
Mar-05-2021 13:59:04 (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:

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(b) (4)

Date	Location	User	Value	Reason
Mar-05-2021 13:59:04 (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
Mar-05-2021 13:59:04 (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
Mar-05-2021 13:59:04 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

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

Date	Location	User	Value	Reason
Mar-29-2021 03:50:02 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Closed	Response satisfies query

090177e196ae2e43\Final\Final On: 01-Apr-2021 03:09 (GMT)

Header Text: C4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete

Site No: 1231

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

Subject No: 12314197

Subject Initials: ---

Generated By:

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

(b) (4)

Mar-26-2021 11:19:38 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 3: Answered	New Information
Mar-26-2021 11:19:38 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry : RECOVERED/RESOLVED WITH SEQUELAE	New Information
Mar-26-2021 06:54:45 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Opened	SAE RECON:AER#2021251319, outcome was updated to RECOVERED/RESOLVED WITH SEQUELAE in Safety database.while reported as RECOVERED/RESOLVED in AE CRF.Please confirm correct outcome. If safety update is required, please submit a follow-up form.
Mar-19-2021 06:20:22 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Closed	outcome updated in SDB. issue resolved

090177e196ae2e43\Final\Final On: 01-Apr-2021 03:09 (GMT)

Header Text: C4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete

Site No: 1231

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

Subject No: 12314197

Subject Initials: ---

Generated By:

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

(b) (4)

Mar-18-2021 08:26:10 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Re issued:Candidate	Pending SDB update
Mar-17-2021 10:44:56 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Answered	FU was sent on 15MAR with this information.
Mar-17-2021 06:45:07 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Opened	SAE RECON:AER#2021251319, outcome was updated to RECOVERED/RESOLVED on AE CRF while reported as Recovering/resolving in Safety database. Please confirm correct outcome. If safety update is required, please submit a follow-up form.
Mar-16-2021 10:36:50 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Mar-16-2021 10:36:50 (UTC-03:00)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry : RECOVER	New Information

090177e196ae2e43\Final\Final On: 01-Apr-2021 03:09 (GMT)

Header Text: C4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete

Site No: 1231

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

Subject No: 12314197

Subject Initials: ---

Generated By:

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

(b) (4)

City of Buenos Aires			ED/RESOLVED	
Mar-16-2021 10:36:36 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	For AE Worsening of left hip osteoarthritis: Response to "What was the outcome of this adverse event?" is 'Recovering/Resolving' but AE End Date/Time is present.
Mar-05-2021 13:59:04 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry : RECOVERING/RESOLVING	Initial Entry

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

Date	Location	User	Value	Reason
Mar-05-2021 13:59:04 (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
Mar-09-2021 07:32:28 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 2021251319	Initial Entry

090177e196ae2e43\Final\Final On: 01-Apr-2021 03:09 (GMT)

Header Text: C4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1231

Subject No: 12314197

Generated By:

(b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Deleted, Locked, Frozen

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

Subject Initials: ---

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

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

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1. Category:

Date	Location	User	Value	Reason
Mar-08-2021 16:21:01 (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
Mar-08-2021 16:21:01 (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
Mar-08-2021 16:21:01 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Worsening of left hip osteoarthritis	Initial Entry

4. Start Date Time:

090177e196ae2e43\Final\Final On: 01-Apr-2021 03:09 (GMT)

Date	Location	User	Value	Reason
Mar-08-2021 16:21:01 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Jan/23/2021 08:00	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Mar-08-2021 16:21:01 (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
Mar-08-2021 16:21:01 (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
Mar-08-2021 16:25:49 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Mar-08-2021 16:21:01 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	For AE Worsening of left hip osteoarthritis:

				Response to "Is the adverse event serious?" is 'Yes' but "Serious Adverse Event Number" is blank.
Mar-08-2021 16:21:01 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<p>Data Entry: YES</p> <p>Is this serious event associated with congenital anomaly or birth defect?</p> <p>NO</p> <p>Did this serious event result in death?</p> <p>NO</p> <p>Did this serious event require or prolong hospitalization?</p> <p>YES</p> <p>Did this serious event result in persistent or significant disability/incapacity?</p> <p>NO</p> <p>Is this serious event life threatening?</p> <p>NO</p> <p>Other medically important serious event</p>	Initial Entry

			NO	
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8. Is this adverse event the result of a study Medication Error?

If Yes, record the type of medication error on the Medication Error Log.

Date	Location	User	Value	Reason
Mar-08-2021 16:21:01 (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
Mar-08-2021 16:21:01 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NOT RELATED If Not Related to stu dy 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
Mar-08-2021 16:21:01 (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
Mar-08-2021 16:21:01 (UTC-03:00) City	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

of Buenos Aires				
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12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Mar-08-2021 16:21:01 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

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

Date	Location	User	Value	Reason
Mar-08-2021 16:21:01 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: RECOVERING/RES OLVING	Initial Entry

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

Date	Location	User	Value	Reason
Mar-08-2021 16:21:01 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

Header Text: C4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete

Site No: 1231

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

Subject No: 12314197

Subject Initials: ---

Generated By:

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

(b) (4)

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1. Category:

Date	Location	User	Value	Reason
Mar-29-2021 10:42:33 (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
Mar-29-2021 10:42:33 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 4	Initial Entry

3. Adverse Event:

(If possible specify diagnosis, not individual symptoms)

Date	Location	User	Value	Reason
Mar-29-2021 10:42:33 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Left hip osteoarthritis	Initial Entry

4. Start Date Time:

090177e196ae2e43\Final\Final On: 01-Apr-2021 03:09 (GMT)

Header Text: C4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete

Site No: 1231

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

Subject No: 12314197

Subject Initials: ---

Generated By:

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

(b) (4)

Date	Location	User	Value	Reason
Mar-29-2021 10:42:33 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Nov/13/2020 09:00	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Mar-29-2021 10:42:33 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO End Date Time: Mar/26/2021 10:00	Initial Entry

6. Toxicity Grade:

Date	Location	User	Value	Reason
Mar-29-2021 10:42:33 (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.

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Header Text: C4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete

Site No: 1231

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

Subject No: 12314197

Subject Initials: ---

Generated By:

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

(b) (4)

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
Mar-29-2021 10:42:33 (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
Mar-29-2021 10:42:33 (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
Mar-29-2021 10:42:33 (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:	Initial Entry

090177e196ae2e43\Final\Final On: 01-Apr-2021 03:09 (GMT)

Header Text: C4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete

Site No: 1231

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

Subject No: 12314197

Subject Initials: ---

Generated By:

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

(b) (4)

			OTHER	
			<i>If Other, specify:</i>	
			unknown	

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Mar-29-2021 10:42:33 (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
Mar-29-2021 10:42:33 (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
Mar-29-2021	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Initial Entry

090177e196ae2e43\Final\Final On: 01-Apr-2021 03:09 (GMT)

Header Text: C4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete

Site No: 1231

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

Subject No: 12314197

Subject Initials: ---

Generated By:

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

(b) (4)

10:42:33 (UTC-03:00) City of Buenos Aires		(b) (4), (b) (6)	YES	
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13. What was the outcome of this adverse event?:

Date	Location	User	Value	Reason
Mar-29-2021 10:42:33 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: RECOVERED/RESOLVED WITH SEQUELAE	Initial Entry

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

Date	Location	User	Value	Reason
Mar-29-2021 10:42:33 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

090177e196ae2e43\Final\Final On: 01-Apr-2021 03:09 (GMT)

Header Text: C4591001

Visit: Disposition - Unscheduled

Form: TREATMENT UNBLINDED - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1231

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

Subject No: 12314197

Subject Initials: ---

Generated By:

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

(b) (4)

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1. Date Treatment Unblinded :

Date	Location	User	Value	Reason
Jan-27-2021 12:29:58 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Jan/26/2021	Initial Entry

2. Primary Reason for Unblinding:

Date	Location	User	Value	Reason
Jan-27-2021 12:29:58 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: ASSESS ELIGIBILITY FOR ADDITIONAL VACCINATION	Initial Entry

090177e196ae2e43\Final\Final On: 01-Apr-2021 03:09 (GMT)

Header Text: C4591001

Visit: Subject Status - Unscheduled

Form: SUBJECT STATUS - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Verified

Site No: 1231

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

Subject No: 12314197

Subject Initials: ---

Generated By:

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

(b) (4)

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1. Subject Status

Date	Location	User	Value	Reason
Mar-29-2021 09:26:53 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Mar-26-2021 11:47:36 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Visit 101 has not yet taken place due to participant medical reasons. It will be done as soon as possible and the data will be updated. Thank you
Mar-26-2021 08:53:35 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	DM: Participant is eligible and confirmed to have received Placebo, however Date Written Consent Obtained is

090177e196ae2e43\Final\Final On: 01-Apr-2021 03:09 (GMT)

Header Text: C4591001**Visit:** Subject Status - Unscheduled**Form:** SUBJECT STATUS - eCRF Audit Trail History**Form Version:** 22-Apr-2020 21:03**Form Status:** Data Complete, Verified**Site No:** 1231**Site Name:** (1231) Hospital Militar Central Cirujano
Mayor Dr. Cosme Argerich**Subject No:** 12314197**Subject Initials:** ---**Generated By:****Generated Time (GMT):** 29-Mar-2021 20:34

(b) (4)

				missing in V101 Informed Consent - Further Vaccination CRF. Please review and update as appropriate.
Oct-16-2020 10:04:38 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: FOLLOW-UP	Initial Entry
Aug-26-2020 15:26:30 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: ENROLLED/RAN DOMIZED	Initial Entry
Aug-26-2020 15:18:24 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SCREENED	Initial Entry

2. Subject Status Date

Date	Location	User	Value	Reason
Oct-16-2020 10:04:38 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Oct/16/2020	Initial Entry

Header Text: C4591001

Visit: Subject Status - Unscheduled

Form: SUBJECT STATUS - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Verified

Site No: 1231

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

Subject No: 12314197

Subject Initials: ---

Generated By:

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

(b) (4)

Aug-26-2020 15:26:30 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Aug/26/2020	Initial Entry
Aug-26-2020 15:18:24 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Aug/26/2020	Initial Entry

090177e196ae2e43\Final\Final On: 01-Apr-2021 03:09 (GMT)

Header Text: C4591001

Visit: Investigator Signature -
Unscheduled

Form Version: 22-Apr-2020 21:04

Site No: 1231

Subject No: 12314197

Generated By:

(b) (4)

Form: CASEBOOK SIGNATURE FORM - eCRF Audit
Trail History

Form Status: Data Complete, Verified

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

Subject Initials: ---

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

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1. Casebook Signature

Date	Location	User	Value	Reason
Oct-21-2020 17:23:31 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Click Here to Enable	Initial Entry

090177e196ae2e43\Final\Final On: 01-Apr-2021 03:09 (GMT)