

Header Text: C4591001

Visit: COHORT_SELECTION

Form Version: 30-Jul-2020 21:29

Site No: 1231

Subject No: 12314583

Generated By: (b) (4)

Form: COHORT_SELECTION

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Cohort Selection

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

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

Header Text: C4591001

Visit: COHORT_SELECTION

Form Version: 22-Apr-2020 21:02

Site No: 1231

Subject No: 12314583

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/27/2020
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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: 12314583

Subject Initials: ---

Generated By: (b) (4)

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

[eCRF Audit Trail History](#)

Demography

1.	Subject ID	[12314583]
2.	Birth Date:	(b) (6) /1999
3.	Sex:	FEMALE
4.	Ethnicity:	HISPANIC OR LATINO(A) OR OF SPANISH ORIGIN
5.	Race: (Check X all that apply):	WHITE
6.	Racial Designation:	

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:02

Site No: 1231

Subject No: 12314583

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/27/2020
2.	Erroneous Visit	

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 30-Jul-2020 21:29

Site No: 1231

Subject No: 12314583

Generated By: (b) (4)

Form: INCLUSION/EXCLUSION CRITERIA

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

Form Comments

Inclusion Criteria Not Met

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

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

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1231

Subject No: 12314583

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/27/2020
2.	Phase of Disposition:	SCREENING
3.	Status:	COMPLETED
4.	Specify Status:	[]

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1231

Subject No: 12314583

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

Form Comments

Medical History Details

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

090177e196ae2ead\Final\Final On: 01-Apr-2021 03:20 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 21-Aug-2020 02:51

Site No: 1231

Subject No: 12314583

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/27/2020
2.	Weight:	[52.0]
3.	Unit:	kg
4.	Height:	[153.0]
5.	Unit:	cm
6.	Body Mass Index:	[22.2]

Vital Signs Details

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

090177e196ae2ead\Final\Final On: 01-Apr-2021 03:20 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 21-Aug-2020 02:49

Site No: 1231

Subject No: 12314583

Generated By: (b) (4)

Form: LAB URINALYSIS - PREGNANCY TEST

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Lab Urinalysis

1.	Lab Panel:	URINALYSIS
2.	Lab Sub-Panel:	PREGNANCY
3.	Collection Date:	Aug/27/2020
4.	Laboratory Name and Address (Derived)	[STUDY SITE]
5.	Specimen Type:	URINE

Lab Result

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

090177e196ae2ead\Final\Final On: 01-Apr-2021 03:20 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1231

Subject No: 12314583

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/27/2020
2.	Randomization Number:	[70872]
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: 12314583

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: Aug/27/2020
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[]

Aliquot

Please enter barcode for each aliquot.

5.a	Sample ID	[BPTG57]
5.b	Sample ID	[BPTG58]
5.c	Sample ID	[BPTG59]
5.d	Sample ID	[BLBJJ3]
5.e	Sample ID	[BLBJJ4]

090177e196ae2ead\Final\Final On: 01-Apr-2021 03:20 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1231

Subject No: 12314583

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Electronic Sample Tracking

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB
3.	Sample Collected?	YES Date of Collection: Aug/27/2020
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[]

Aliquot

Please enter barcode for each aliquot.

5.a	Sample ID	[BPT9YT]
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090177e196ae2ead\Final\Final On: 01-Apr-2021 03:20 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:04

Site No: 1231

Subject No: 12314583

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/27/2020 17:10
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

090177e196ae2ead\Final\Final On: 01-Apr-2021 03:20 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 06-Jul-2020 21:53

Site No: 1231

Subject No: 12314583

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: 12314583

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/15/2020
2.	Erroneous Visit	

Header Text: C4591001

Visit: V2_VAX2_L

Form Version: 15-Sep-2020 21:54

Site No: 1231

Subject No: 12314583

Generated By: (b) (4)

Form: VITAL SIGNS - TEMP

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Vital Signs

1.	Date:	Sep/15/2020
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Vital Signs Details

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

Header Text: C4591001

Visit: V2_VAX2_L

Form Version: 21-Aug-2020 02:49

Site No: 1231

Subject No: 12314583

Generated By: (b) (4)

Form: LAB URINALYSIS - PREGNANCY TEST

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Lab Urinalysis

1.	Lab Panel:	URINALYSIS
2.	Lab Sub-Panel:	PREGNANCY
3.	Collection Date:	Sep/15/2020
4.	Laboratory Name and Address (Derived)	[STUDY SITE]
5.	Specimen Type:	URINE

Lab Result

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

090177e196ae2ead\Final\Final On: 01-Apr-2021 03:20 (GMT)

Header Text: C4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:03

Site No: 1231

Subject No: 12314583

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Electronic Sample Tracking

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB
3.	Sample Collected?	YES Date of Collection: Sep/15/2020
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	[BP1RJ3]
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090177e196ae2ead\Final\Final On: 01-Apr-2021 03:20 (GMT)

Header Text: C4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:04

Site No: 1231

Subject No: 12314583

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/15/2020 18:00
5.	Anatomical Location:	DELTOID MUSCLE
6.	Body Side:	RIGHT
7.	Route:	INTRAMUSCULAR
8.	Actual Dose:	[]
9.	Unit:	
10.	Timeframe Subject Was Observed	THE PROTOCOL SPECIFIED OBSERVATION PERIOD
11.	Was the subject observed for at least the protocol specified observation period after investigational product administration?	YES

090177e196ae2ead\Final\Final On: 01-Apr-2021 03:20 (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: 12314583

Subject Initials: ---

Generated By: (b) (4)

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

[eCRF Audit Trail History](#)

Date of Visit

1.	Date of Visit	Oct/19/2020
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: 12314583

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/19/2020
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	[BLBKR7]
5.b	Sample ID	[BLBGYB]
5.c	Sample ID	[BP1PM1]

090177e196ae2ead\Final\Final On: 01-Apr-2021 03:20 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled
Visit on Oct/20/2020

Form: DATE OF VISIT - ILLNESS ONSET

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1231

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

Subject No: 12314583

Subject Initials: ---

Generated By: (b) (4)

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

[eCRF Audit Trail History](#)

Date of Visit

1.	Date of Visit	Oct/20/2020
2.	Erroneous Visit	

COVID-19 Illness Visit

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

Visit: POT_COVID_ILL 1 - Unscheduled
Visit on Oct/20/2020

Form: SIGNS AND SYMPTOMS OF POTENTIAL COVID-19

Form Version: 10-Oct-2020 16:02

Form Status: Data Complete, Frozen, Verified

Site No: 1231

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

Subject No: 12314583

Subject Initials: ---

Generated By: (b) (4)

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

[eCRF Audit Trail History](#)

Signs and Symptoms

1.	Date of Assessment:	Oct/20/2020
2.	Date of First Symptom Started:	Oct/18/2020
3.	Symptoms Ongoing?	NO
	Date of Last Symptom Resolved:	Oct/19/2020

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?	NO
4.f	Symptoms:	NEW LOSS OF TASTE OR SMELL
	Was symptom present?	NO
4.g	Symptoms:	NEW OR INCREASED SORE THROAT
	Was symptom present?	NO

090177e196ae2ead\Final\Final On: 01-Apr-2021 03:20 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled
Visit on Oct/20/2020

Form: SIGNS AND SYMPTOMS OF POTENTIAL COVID-19

Form Version: 10-Oct-2020 16:02

Form Status: Data Complete, Frozen, Verified

Site No: 1231

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

Subject No: 12314583

Subject Initials: ---

Generated By: (b) (4)

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

4.h	Symptoms:	DIARRHEA
	Was symptom present?	YES
4.i	Symptoms:	VOMITING
	Was symptom present?	NO
Symptoms - Other		
5.	Symptoms - Other Text:	[]

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: 12314583

Subject Initials: ---

Generated By: (b) (4)

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

#	Date of Collection	Specimen Type	Specimen Collection Location	Assay Code and Description	Device Type	Form Instance
1.	Oct/20/2020	RESPIRATORY SECRETIONS	NASOPHARYNX	SEVERE ACUTE RESPIRATORY SYNDROME CORONAVIRUS 2	SARS-COV-2 DIAGNOSTIC TEST	Repeating Pages

090177e196ae2ead\Final\Final On: 01-Apr-2021 03:20 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled **Form:** MICROBIOLOGY SPECIMEN

Visit on Oct/20/2020

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen, Verified

Site No: 1231

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

Subject No: 12314583

Subject Initials: ---

Generated By: (b) (4)

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

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

Microbiology Specimen

1.	Actual Date of Collection:	Oct/20/2020
2.	Specimen Type:	RESPIRATORY SECRETIONS
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:	[]

090177e196ae2ead\Final\Final On: 01-Apr-2021 03:20 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled
Visit on Oct/20/2020

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: 12314583

Subject Initials: ---

Generated By: (b) (4)

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

[eCRF Audit Trail History](#)

Electronic Sample Tracking

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

Aliquot

Please enter barcode for each aliquot.

5.	Sample ID	[]
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090177e196ae2ead\Final\Final On: 01-Apr-2021 03:20 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled
Visit on Oct/20/2020

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1231

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

Subject No: 12314583

Subject Initials: ---

Generated By: (b) (4)

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

[eCRF Audit Trail History](#)

Electronic Sample Tracking

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB
3.	Sample Collected?	YES Date of Collection: Oct/20/2020
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	[BPT7WP]
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090177e196ae2ead\Final\Final On: 01-Apr-2021 03:20 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled **Form:** HEALTH CARE UTILIZATION

Visit on Oct/20/2020

Form Version: 10-Oct-2020 15:59

Form Status: Data Complete, Frozen, Verified

Site No: 1231

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

Subject No: 12314583

Subject Initials: ---

Generated By: (b) (4)

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

[eCRF Audit Trail History](#)

Health Care Utilization

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

090177e196ae2ead\Final\Final On: 01-Apr-2021 03:20 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled
Visit on Oct/20/2020

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: 12314583

Subject Initials: ---

Generated By: (b) (4)

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

Health Care Utilization Other

2.	Other Type of Practitioner Specify:	[]
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Health Care Utilization

3.	Has the subject been hospitalized due to potential COVID-19 illness?	NO
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Header Text: C4591001

Visit: POT_COVID_ILL 1

Form: RESPIRATORY TREATMENT

Form Version: 06-Jul-2020 21:53

Site No: 1231

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

Subject No: 12314583

Subject Initials: ---

Generated By: (b) (4)

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

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

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled **Form:** RESPIRATORY TREATMENT

Visit on Oct/20/2020

Form Version: 06-Jul-2020 21:53

Form Status: Not Started

Site No: 1231

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

Subject No: 12314583

Subject Initials: ---

Generated By: (b) (4)

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

[Back to Form](#)

Respiratory Treatment

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

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled **Form:** ILLNESS DETAILS

Visit on Oct/20/2020

Form Version: 06-Jul-2020 21:52

Form Status: Data Complete, Frozen, Verified

Site No: 1231

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

Subject No: 12314583

Subject Initials: ---

Generated By: (b) (4)

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

[eCRF Audit Trail History](#)

Illness Details

1.	Category of Clinical Event:	POTENTIAL COVID-19 ILLNESS
2.	Was a diagnosis obtained for Potential COVID-19 Illness?	YES Respiratory Illness Diagnosis: [Gastroenteritis] Date of Diagnosis: Oct/21/2020
3.	Toxicity Grade:	1

090177e196ae2ead\Final\Final On: 01-Apr-2021 03:20 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1

Form: ILLNESS DETAILS - SEVERE

Form Version: 17-Jul-2020 21:55

Site No: 1231

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

Subject No: 12314583

Subject Initials: ---

Generated By: (b) (4)

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

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

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled **Form:** ILLNESS DETAILS - SEVERE

Visit on Oct/20/2020

Form Version: 17-Jul-2020 21:55

Form Status: Not Started

Site No: 1231

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

Subject No: 12314583

Subject Initials: ---

Generated By: (b) (4)

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

[Back to Form](#)

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: 12314583

Subject Initials: ---

Generated By: (b) (4)

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

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

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled
Visit on Oct/20/2020

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: 12314583

Subject Initials: ---

Generated By: (b) (4)

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

[Back to Form](#)

Lab Chemistry Details

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

Lab Result

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

090177e196ae2ead\Final\Final On: 01-Apr-2021 03:20 (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: 12314583

Subject Initials: ---

Generated By: (b) (4)

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

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

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled
Visit on Oct/20/2020

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: 12314583

Subject Initials: ---

Generated By: (b) (4)

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

[Back to Form](#)

Laboratory Data Hematology

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

Lab Result

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

090177e196ae2ead\Final\Final On: 01-Apr-2021 03:20 (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: 12314583

Subject Initials: ---

Generated By: (b) (4)

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

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

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled **Form:** VITAL SIGNS - COVID

Visit on Oct/20/2020

Form Version: 21-Aug-2020 02:50

Form Status: Not Started

Site No: 1231

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

Subject No: 12314583

Subject Initials: ---

Generated By: (b) (4)

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

[Back to Form](#)

Vital Signs

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

Vital Signs Details

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

090177e196ae2ead\Final\Final On: 01-Apr-2021 03:20 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1

Form: VITAL SIGNS - PULSE OX ROOM AIR

Form Version: 21-Aug-2020 02:51

Site No: 1231

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

Subject No: 12314583

Subject Initials: ---

Generated By: (b) (4)

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

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

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled
Visit on Oct/20/2020

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: 12314583

Subject Initials: ---

Generated By: (b) (4)

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

[Back to Form](#)

Vital Signs

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

Vital Signs Details

2.	Record Identifier:	
	SPO2 Pulse Oximetry %	[]

Header Text: C4591001

Visit: POT_COVID_ILL 1

Form: OXYGENATION PARAMETERS

Form Version: 06-Jul-2020 21:52

Site No: 1231

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

Subject No: 12314583

Subject Initials: ---

Generated By: (b) (4)

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

#	Date Time of Assessment	Arterial Blood Gases PaO ₂	FiO ₂ (Fraction of Inhaled Oxygen)	Form Instance
1.				Repeating Pages

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled
Visit on Oct/20/2020

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: 12314583

Subject Initials: ---

Generated By: (b) (4)

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

[Back to Form](#)

Oxygenation Parameters

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

Header Text: C4591001

Visit: POT_COVID_ILL 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: 12314583

Subject Initials: ---

Generated By: (b) (4)

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

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

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled
Visit on Oct/20/2020

Form: CONCOMITANT MEDICATIONS - VASOPRESSORS

Form Version: 06-Jul-2020 21:55

Form Status: Not Started

Site No: 1231

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

Subject No: 12314583

Subject Initials: ---

Generated By: (b) (4)

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?	

090177e196ae2ead\Final\Final On: 01-Apr-2021 03:20 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1

Form: IMAGING

Form Version: 06-Jul-2020 21:53

Site No: 1231

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

Subject No: 12314583

Subject Initials: ---

Generated By: (b) (4)

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

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

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled **Form:** IMAGING

Visit on Oct/20/2020

Form Version: 06-Jul-2020 21:53

Form Status: Not Started

Site No: 1231

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

Subject No: 12314583

Subject Initials: ---

Generated By: (b) (4)

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

[Back to Form](#)

Imaging

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

Header Text: C4591001

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

Form: DATE OF VISIT - ILLNESS ONSET

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1231

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

Subject No: 12314583

Subject Initials: ---

Generated By: (b) (4)

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

[eCRF Audit Trail History](#)

Date of Visit

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

COVID-19 Illness Visit

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

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

Form: SIGNS AND SYMPTOMS OF POTENTIAL COVID-19

Form Version: 14-Jan-2021 02:23

Form Status: Data Complete

Site No: 1231

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

Subject No: 12314583

Subject Initials: ---

Generated By: (b) (4)

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

[eCRF Audit Trail History](#)

Signs and Symptoms

1.	Date of Assessment:	Jan/27/2021
2.	Date of First Symptom Started:	Jan/26/2021
3.	Symptoms Ongoing?	NO Date of Last Symptom Resolved: Feb/3/2021

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
4.f	Symptoms:	NEW LOSS OF TASTE OR SMELL
	Was symptom present?	YES
4.g	Symptoms:	NEW OR INCREASED SORE THROAT
	Was symptom present?	NO

090177e196ae2ead\Final\Final On: 01-Apr-2021 03:20 (GMT)

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

Site No: 1231

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

Subject No: 12314583

Subject Initials: ---

Generated By: (b) (4)

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

4.h	Symptoms:	DIARRHEA
	Was symptom present?	NO
4.i	Symptoms:	VOMITING
	Was symptom present?	NO
Symptoms - Other		
5.a	Symptoms - Other Text:	[Headache]

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: 12314583

Subject Initials: ---

Generated By: (b) (4)

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

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

090177e196ae2ead\Final\Final On: 01-Apr-2021 03:20 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 2 - Unscheduled **Form:** MICROBIOLOGY SPECIMEN

Visit on Jan/27/2021

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete

Site No: 1231

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

Subject No: 12314583

Subject Initials: ---

Generated By: (b) (4)

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

[Back to Form](#)
[eCRF Audit Trail History](#)
[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:	POSITIVE
8.	Comments/Findings/Details:	[]
9.	Trade Name Other, Specify:	[]

090177e196ae2ead\Final\Final On: 01-Apr-2021 03:20 (GMT)

Header Text: C4591001

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

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB
SELF

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1231

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

Subject No: 12314583

Subject Initials: ---

Generated By: (b) (4)

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

[eCRF Audit Trail History](#)

Electronic Sample Tracking

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

Aliquot

Please enter barcode for each aliquot.

5.	Sample ID	[]
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090177e196ae2ead\Final\Final On: 01-Apr-2021 03:20 (GMT)

Header Text: C4591001

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

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1231

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

Subject No: 12314583

Subject Initials: ---

Generated By: (b) (4)

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

[eCRF Audit Trail History](#)

Electronic Sample Tracking

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB
3.	Sample Collected?	YES Date of Collection: Jan/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	[BPW6JB]
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090177e196ae2ead\Final\Final On: 01-Apr-2021 03:20 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 2 - Unscheduled **Form:** HEALTH CARE UTILIZATION

Visit on Jan/27/2021

Form Version: 14-Jan-2021 02:24

Form Status: Data Complete

Site No: 1231

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

Subject No: 12314583

Subject Initials: ---

Generated By: (b) (4)

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

[eCRF Audit Trail History](#)

Health Care Utilization

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

Health Care Utilization Other

090177e196ae2ead\Final\Final On: 01-Apr-2021 03:20 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 2 - Unscheduled **Form:** HEALTH CARE UTILIZATION

Visit on Jan/27/2021

Form Version: 14-Jan-2021 02:24

Form Status: Data Complete

Site No: 1231

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

Subject No: 12314583

Subject Initials: ---

Generated By: (b) (4)

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

2.	Other Type of Practitioner Specify:	[]
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Health Care Utilization

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

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: 12314583

Subject Initials: ---

Generated By: (b) (4)

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

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

Header Text: C4591001

Visit: POT_COVID_ILL 2 - Unscheduled **Form:** RESPIRATORY TREATMENT

Visit on Jan/27/2021

Form Version: 06-Jul-2020 21:53

Form Status: Not Started

Site No: 1231

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

Subject No: 12314583

Subject Initials: ---

Generated By: (b) (4)

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

[Back to Form](#)

Respiratory Treatment

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

090177e196ae2ead\Final\Final On: 01-Apr-2021 03:20 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 2 - Unscheduled **Form:** ILLNESS DETAILS

Visit on Jan/27/2021

Form Version: 06-Jul-2020 21:52

Form Status: Data Complete

Site No: 1231

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

Subject No: 12314583

Subject Initials: ---

Generated By: (b) (4)

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

[eCRF Audit Trail History](#)

Illness Details

1.	Category of Clinical Event:	POTENTIAL COVID-19 ILLNESS
2.	Was a diagnosis obtained for Potential COVID-19 Illness?	YES Respiratory Illness Diagnosis: [Mild COVID-19 illness] Date of Diagnosis: Jan/27/2021
3.	Toxicity Grade:	1

090177e196ae2ead\Final\Final On: 01-Apr-2021 03:20 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 2

Form: ILLNESS DETAILS - SEVERE

Form Version: 17-Jul-2020 21:55

Site No: 1231

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

Subject No: 12314583

Subject Initials: ---

Generated By: (b) (4)

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

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

Header Text: C4591001

Visit: POT_COVID_ILL 2 - Unscheduled **Form:** ILLNESS DETAILS - SEVERE

Visit on Jan/27/2021

Form Version: 17-Jul-2020 21:55

Form Status: Not Started

Site No: 1231

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

Subject No: 12314583

Subject Initials: ---

Generated By: (b) (4)

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

[Back to Form](#)

Illness Details

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

Header Text: C4591001

Visit: POT_COVID_ILL 2

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY

Form Version: 21-Aug-2020 02:49

Site No: 1231

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

Subject No: 12314583

Subject Initials: ---

Generated By: (b) (4)

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

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

090177e196ae2ead\Final\Final On: 01-Apr-2021 03:20 (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: 12314583

Subject Initials: ---

Generated By: (b) (4)

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

[Back to Form](#)

Lab Chemistry Details

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

Lab Result

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

090177e196ae2ead\Final\Final On: 01-Apr-2021 03:20 (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: 12314583

Subject Initials: ---

Generated By: (b) (4)

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

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

090177e196ae2ead\Final\Final On: 01-Apr-2021 03:20 (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: 12314583

Subject Initials: ---

Generated By: (b) (4)

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

[Back to Form](#)

Laboratory Data Hematology

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

Lab Result

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

090177e196ae2ead\Final\Final On: 01-Apr-2021 03:20 (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: 12314583

Subject Initials: ---

Generated By: (b) (4)

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

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

Header Text: C4591001

Visit: POT_COVID_ILL 2 - Unscheduled **Form:** VITAL SIGNS - COVID

Visit on Jan/27/2021

Form Version: 21-Aug-2020 02:50

Form Status: Not Started

Site No: 1231

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

Subject No: 12314583

Subject Initials: ---

Generated By: (b) (4)

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

[Back to Form](#)

Vital Signs

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

Vital Signs Details

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

090177e196ae2ead\Final\Final On: 01-Apr-2021 03:20 (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: 12314583

Subject Initials: ---

Generated By: (b) (4)

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

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

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: 12314583

Subject Initials: ---

Generated By: (b) (4)

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

[Back to Form](#)

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: 12314583

Subject Initials: ---

Generated By: (b) (4)

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

#	Date Time of Assessment	Arterial Blood Gases PaO ₂	FiO ₂ (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: 12314583

Subject Initials: ---

Generated By: (b) (4)

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

[Back to Form](#)

Oxygenation Parameters

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

090177e196ae2ead\Final\Final On: 01-Apr-2021 03:20 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 2

Form: CONCOMITANT MEDICATIONS - VASOPRESSORS

Form Version: 06-Jul-2020 21:55

Site No: 1231

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

Subject No: 12314583

Subject Initials: ---

Generated By: (b) (4)

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

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

Header Text: C4591001

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

Form: CONCOMITANT MEDICATIONS - VASOPRESSORS

Form Version: 06-Jul-2020 21:55

Form Status: Not Started

Site No: 1231

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

Subject No: 12314583

Subject Initials: ---

Generated By: (b) (4)

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?	

090177e196ae2ead\Final\Final On: 01-Apr-2021 03:20 (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: 12314583

Subject Initials: ---

Generated By: (b) (4)

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

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

Header Text: C4591001

Visit: POT_COVID_ILL 2 - Unscheduled **Form:** IMAGING

Visit on Jan/27/2021

Form Version: 06-Jul-2020 21:53

Form Status: Not Started

Site No: 1231

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

Subject No: 12314583

Subject Initials: ---

Generated By: (b) (4)

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

[Back to Form](#)

Imaging

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

Header Text: C4591001

Visit: POT_COVID_CONVA 1 -
Unscheduled Visit on Jan/19/2021

Form Version: 22-Apr-2020 21:04

Site No: 1231

Subject No: 12314583

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	Jan/19/2021
2.	Erroneous Visit	

COVID-19 Illness Visit

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

Header Text: C4591001

Visit: POT_COVID_CONVA 1 -
Unscheduled Visit on Jan/19/2021

Form: ELECTRONIC SAMPLE TRACKING -
IMMUNOGENICITY

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1231

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

Subject No: 12314583

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: Jan/19/2021
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	[BRYTCF]
5.b	Sample ID	[BRYTCG]
5.c	Sample ID	[BRYT9J]
5.d	Sample ID	[BPWBF6]

090177e196ae2ead\Final\Final On: 01-Apr-2021 03:20 (GMT)

Header Text: C4591001

Visit: POT_COVID_CONVA 2 -
Unscheduled Visit on Mar/05/2021

Form Version: 22-Apr-2020 21:04

Site No: 1231

Subject No: 12314583

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	Mar/5/2021
2.	Erroneous Visit	

COVID-19 Illness Visit

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

Header Text: C4591001

Visit: POT_COVID_CONVA 2 -
Unscheduled Visit on Mar/05/2021

Form Version: 22-Apr-2020 21:03

Site No: 1231

Subject No: 12314583

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: Mar/5/2021
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	[BR22Z6]
5.b	Sample ID	[BLBHC7]
5.c	Sample ID	[BLBHDG]

090177e196ae2ead\Final\Final On: 01-Apr-2021 03:20 (GMT)

Header Text: C4591001

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

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

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

Subject No: 12314583 **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: 12314583 **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: 12314583

Subject Initials: ---

Generated By: (b) (4)

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

[eCRF Audit Trail History](#)

Disposition - Treatment

1.	Date of Completion/Discontinuation /Death :	Oct/19/2020
2.	Phase of Disposition:	VACCINATION
3.	Status:	COMPLETED
4.	Specify Status:	[]

Header Text: C4591001

Visit: Follow-Up - Unscheduled

Form Version: 15-Sep-2020 21:53

Site No: 1231

Subject No: 12314583

Generated By: (b) (4)

Form: DISPOSITION - FOLLOW-UP

Form Status: Not Started

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

Subject Initials: ---

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

Disposition - Follow-Up

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

Header Text: C4591001

Visit: POT_COVID_REPEAT_SWAB -
New Unscheduled Visit

Form: DATE OF VISIT - REPEAT SWAB

Form Version: 10-Oct-2020 15:57

Form Status: Not Started

Site No: 1231

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

Subject No: 12314583

Subject Initials: ---

Generated By: (b) (4)

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

Date of Visit

1.	Date of Visit	//
2.	Erroneous Visit	

COVID-19 Repeat Swab

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

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: 12314583

Subject Initials: ---

Generated By: (b) (4)

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

Electronic Sample Tracking

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

Aliquot

Please enter barcode for each aliquot.

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

090177e196ae2ead\Final\Final On: 01-Apr-2021 03:20 (GMT)

Header Text: C4591001

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

Form Version: 22-Apr-2020 21:02

Form Status: Not Started

Site No: 1231

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

Subject No: 12314583

Subject Initials: ---

Generated By: (b) (4)

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

Date of Visit

1.	Date of Visit	//
2.	Erroneous Visit	

Header Text: C4591001

Visit: Unplanned Vaccination - Unscheduled **Form:** VITAL SIGNS - TEMP

Form Version: 28-Mar-2021 02:28

Form Status: Not Started

Site No: 1231

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

Subject No: 12314583

Subject Initials: ---

Generated By: (b) (4)

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

Vital Signs

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

Vital Signs Details

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

Header Text: C4591001

Visit: Unplanned Vaccination - Unscheduled **Form:** LAB URINALYSIS - PREGNANCY TEST

Form Version: 20-Feb-2021 02:14

Form Status: Not Started

Site No: 1231

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

Subject No: 12314583

Subject Initials: ---

Generated By: (b) (4)

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

Lab Urinalysis

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

Lab Result

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

090177e196ae2ead\Final\Final On: 01-Apr-2021 03:20 (GMT)

Header Text: C4591001

Visit: Unplanned Vaccination - Unscheduled **Form:** VACCINATION

Form Version: 10-Dec-2020 02:26

Form Status: Not Started

Site No: 1231

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

Subject No: 12314583

Subject Initials: ---

Generated By: (b) (4)

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

Vaccination

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

090177e196ae2ead\Final\Final On: 01-Apr-2021 03:20 (GMT)

Header Text: C4591001

Visit: Unplanned Vaccination - Unscheduled **Form:** CONTACT OUTCOME - MONTH 1

Form Version: 10-Oct-2020 15:57

Form Status: Not Started

Site No: 1231

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

Subject No: 12314583

Subject Initials: ---

Generated By: (b) (4)

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

Contact Outcome

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

Header Text: C4591001

Visit: Unplanned Vaccination - Unscheduled **Form:** CONTACT OUTCOME - MONTH 6

Form Version: 10-Oct-2020 16:01

Form Status: Not Started

Site No: 1231

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

Subject No: 12314583

Subject Initials: ---

Generated By: (b) (4)

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

Contact Outcome

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

Header Text: C4591001

Visit: Potential ReVax Initial Contact -
Unscheduled

Form: DATE OF VISIT

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1231

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

Subject No: 12314583

Subject Initials: ---

Generated By: (b) (4)

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

[eCRF Audit Trail History](#)

Date of Visit

1.	Date of Visit	Mar/10/2021
2.	Erroneous Visit	

Header Text: C4591001

Visit: Potential ReVax Initial Contact -
Unscheduled

Form: FURTHER VACCINATION CONFIRMATION

Form Version: 10-Dec-2020 02:25

Form Status: Data Complete, Locked, Frozen

Site No: 1231

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

Subject No: 12314583

Subject Initials: ---

Generated By: (b) (4)

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

[eCRF Audit Trail History](#)

Further Vaccination Confirmation

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

Header Text: C4591001

Visit: V101_VAX3

Form Version: 22-Apr-2020 21:02

Site No: 1231

Subject No: 12314583

Generated By: (b) (4)

Form: DATE OF VISIT

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

[eCRF Audit Trail History](#)

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

Header Text: C4591001

Visit: V101_VAX3

Form Version: 10-Dec-2020 02:31

Site No: 1231

Subject No: 12314583

Generated By: (b) (4)

Form: INFORMED CONSENT - FURTHER 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](#)

Informed Consent - Further Vaccination

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

Header Text: C4591001

Visit: V101_VAX3

Form: INCLUSION/EXCLUSION CRITERIA - FURTHER VACCINATION

Form Version: 10-Dec-2020 02:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1231

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

Subject No: 12314583

Subject Initials: ---

Generated By: (b) (4)

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

Header Text: C4591001

Visit: V101_VAX3

Form: DISPOSITION - SCREENING FOR FURTHER VACCINATION

Form Version: 10-Dec-2020 02:31

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1231

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

Subject No: 12314583

Subject Initials: ---

Generated By: (b) (4)

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

[eCRF Audit Trail History](#)

Disposition - Screening for Further Vaccination

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

Header Text: C4591001

Visit: V101_VAX3

Form Version: 20-Feb-2021 02:14

Site No: 1231

Subject No: 12314583

Generated By: (b) (4)

Form: LAB URINALYSIS - PREGNANCY TEST

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Lab Urinalysis

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

Lab Result

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

090177e196ae2ead\Final\Final On: 01-Apr-2021 03:20 (GMT)

Header Text: C4591001

Visit: V101_VAX3

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1231

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

Subject No: 12314583

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: Mar/13/2021
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[]

Aliquot

Please enter barcode for each aliquot.

5.a	Sample ID	[BPT659]
5.b	Sample ID	[BRYH4B]
5.c	Sample ID	[BRYH2V]

090177e196ae2ead\Final\Final On: 01-Apr-2021 03:20 (GMT)

Header Text: C4591001

Visit: V101_VAX3

Form Version: 22-Apr-2020 21:03

Site No: 1231

Subject No: 12314583

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: Mar/13/2021
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[]

Aliquot

Please enter barcode for each aliquot.

5.a	Sample ID	[BR1LKT]
-----	-----------	----------

090177e196ae2ead\Final\Final On: 01-Apr-2021 03:20 (GMT)

Header Text: C4591001

Visit: V101_VAX3

Form Version: 10-Dec-2020 02:26

Site No: 1231

Subject No: 12314583

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	[BNT162b2]
3.	Formulation:	INJECTION
4.	Dose Date Time:	Mar/13/2021 16:17
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

090177e196ae2ead\Final\Final On: 01-Apr-2021 03:20 (GMT)

Header Text: C4591001

Visit: V102_VAX4

Form Version: 22-Apr-2020 21:02

Site No: 1231

Subject No: 12314583

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 Version: 20-Feb-2021 02:14

Site No: 1231

Subject No: 12314583

Generated By: (b) (4)

Form: LAB URINALYSIS - PREGNANCY TEST

Form Status: Not Started

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

Subject Initials: ---

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

Lab Urinalysis

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

Lab Result

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

090177e196ae2ead\Final\Final On: 01-Apr-2021 03:20 (GMT)

Header Text: C4591001

Visit: V102_VAX4

Form Version: 22-Apr-2020 21:03

Site No: 1231

Subject No: 12314583

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB

Form Status: Not Started

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

Subject Initials: ---

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

Electronic Sample Tracking

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

Aliquot

Please enter barcode for each aliquot.

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

090177e196ae2ead\Final\Final On: 01-Apr-2021 03:20 (GMT)

Header Text: C4591001

Visit: V102_VAX4

Form Version: 10-Dec-2020 02:26

Site No: 1231

Subject No: 12314583

Generated By: (b) (4)

Form: VACCINATION

Form Status: Not Started

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

Subject Initials: ---

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

Vaccination

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

090177e196ae2ead\Final\Final On: 01-Apr-2021 03:20 (GMT)

Header Text: C4591001

Visit: V103_MONTH1

Form Version: 22-Apr-2020 21:02

Site No: 1231

Subject No: 12314583

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: 12314583

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: 12314583

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: 12314583

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: 12314583

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: 12314583

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 - **Form:** DISPOSITION - TREATMENT

Unscheduled

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: 12314583

Subject Initials: ---

Generated By: (b) (4)

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

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: 12314583

Subject Initials: ---

Generated By: (b) (4)

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

#	Category	AE Identifier	Adverse Event	Start Date	Is the Adverse Event Still Ongoing	Form Instance
1.	ADVERSE EVENT	1	Epigastralgia	Oct/15/2020 06:30	NO End Date Time: Oct/19/2020 17:00	Repeating Pages
2.	ADVERSE EVENT	2	acute pancreatitis	Nov/30/2020 22:00	NO End Date Time: Dec/14/2020 18:00	Repeating Pages

090177e196ae2ead\Final\Final On: 01-Apr-2021 03:20 (GMT)

Header Text: C4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1231

Subject No: 12314583

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

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

Adverse Event Report

1.	Category:	ADVERSE EVENT
2.	AE ID:	[1]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[Epigastralgia]
4.	Start Date Time:	Oct/15/2020 06:30
5.	Is the adverse event still ongoing?	NO End Date Time: Oct/19/2020 17:00
6.	Toxicity Grade:	1
7.	Is the adverse event serious? If Yes, NOTIFY PFIZER IMMEDIATELY. Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).	NO
8.	Is this adverse event the result of a study Medication Error? If Yes, record the type of medication error on the Medication Error Log.	NO

090177e196ae2ead\Final\Final On: 01-Apr-2021 03:20 (GMT)

Header Text: C4591001**Visit:** Logs - Unscheduled**Form Version:** 22-Apr-2020 21:02**Site No:** 1231**Subject No:** 12314583**Generated By:** (b) (4)**Form:** ADVERSE EVENT REPORT**Form Status:** Data Complete, Locked, Frozen, Verified**Site Name:** (1231) Hospital Militar Central Cirujano Mayor Dr. Cosme Argerich**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 20:34

9.	Is this event related to study treatment:	NOT RELATED If Not Related to study treatment(s), this event is due to: OTHER If Other, specify: [unknown]
10.	Latest Action Taken with Study Treatment:	NOT APPLICABLE
11.	Was a Concomitant Medication given?	NO
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	[]

Header Text: C4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1231

Subject No: 12314583

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

[Back to Form](#)

[eCRF Audit Trail History](#)

[Form Audit Trail](#)

Adverse Event Report

1.	Category:	ADVERSE EVENT
2.	AE ID:	[2]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[acute pancreatitis]
4.	Start Date Time:	Nov/30/2020 22:00
5.	Is the adverse event still ongoing?	NO End Date Time: Dec/14/2020 18:00
6.	Toxicity Grade:	2
7.	Is the adverse event serious? If Yes, NOTIFY PFIZER IMMEDIATELY. Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).	YES Is this serious event associated with congenital anomaly or birth defect? NO Did this serious event result in death? NO Did this serious event require or prolong hospitalization? YES Did this serious event result in persistent or significant disability/incapacity? NO Is this serious event life threatening? NO Other medically important serious event YES

090177e196ae2ead\Final\Final On: 01-Apr-2021 03:20 (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: 12314583		Subject Initials: ---
Generated By: (b) (4)		Generated Time (GMT): 29-Mar-2021 20:34
8.	Is this adverse event the result of a study Medication Error? If Yes, record the type of medication error on the Medication Error Log.	NO
9.	Is this event related to study treatment:	NOT RELATED If Not Related to study treatment(s), this event is due to: OTHER If Other, specify: [unknown]
10.	Latest Action Taken with Study Treatment:	NOT APPLICABLE
11.	Was a Concomitant Medication given?	YES
12.	Was a Non-Drug Treatment given?	NO
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	[2020478859]

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: 12314583

Subject Initials: ---

Generated By: (b) (4)

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

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

Header Text: C4591001

Visit: Logs - Unscheduled

Form Version: 17-Jul-2020 21:54

Site No: 1231

Subject No: 12314583

Generated By: (b) (4)

Form: MEDICATION ERROR

Form Status: Not Started

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

Subject Initials: ---

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

[Back to Form](#)

Medication Error

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

090177e196ae2ead\Final\Final On: 01-Apr-2021 03:20 (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: 12314583

Subject Initials: ---

Generated By: (b) (4)

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

#	Sponsor-Defined Identifier	Category for Medication	Concomitant Medications Pre-specified	Name of Medication	Start Date	Form Instance
1.						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: 12314583

Subject Initials: ---

Generated By: (b) (4)

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.	Date:	//

090177e196ae2ead\Final\Final On: 01-Apr-2021 03:20 (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: 12314583

Subject Initials: ---

Generated By: (b) (4)

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

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

Header Text: C4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1231

Subject No: 12314583

Generated By: (b) (4)

Form: CONCOMITANT MEDICATIONS - PROHIBITED

Form Status: Not Started

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

Subject Initials: ---

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

[Back to Form](#)

Concomitant Medications

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

090177e196ae2ead\Final\Final On: 01-Apr-2021 03:20 (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: 12314583

Subject Initials: ---

Generated By: (b) (4)

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

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

Header Text: C4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1231

Subject No: 12314583

Generated By: (b) (4)

Form: RADIATION TREATMENT

Form Status: Not Started

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

Subject Initials: ---

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

[Back to Form](#)

Radiation Treatment

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

090177e196ae2ead\Final\Final On: 01-Apr-2021 03:20 (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: 12314583

Subject Initials: ---

Generated By: (b) (4)

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

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

Header Text: C4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1231

Subject No: 12314583

Generated By: (b) (4)

Form: TRANSFUSIONS

Form Status: Not Started

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

Subject Initials: ---

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

[Back to Form](#)

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

Header Text: C4591001

Visit: Disposition - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1231

Subject No: 12314583

Generated By: (b) (4)

Form: TREATMENT UNBLINDED

Form Status: Data Complete, Frozen, Verified

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

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Treatment Unblinded

1.	Date Treatment Unblinded :	Mar/10/2021
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: 12314583

Generated By: (b) (4)

Form: WITHDRAWAL OF CONSENT

Form Status: Not Started

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

Subject Initials: ---

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

Withdrawal Of Consent

1.	Withdrawal of Consent Date :	//
----	------------------------------	----

Header Text: C4591001

Visit: Disposition - Unscheduled

Form: DEATH DETAILS CODED

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: 12314583

Subject Initials: ---

Generated By: (b) (4)

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

Death Details

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

Cause of Death

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

Header Text: C4591001

Visit: Subject Status - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1231

Subject No: 12314583

Generated By: (b) (4)

Form: SUBJECT STATUS

Form Status: Data Complete, Verified

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

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Subject Status

1.	Subject Status	FOLLOW-UP
2.	Subject Status Date	Oct/19/2020

Header Text: C4591001

Visit: Investigator Signature - Unscheduled **Form:** CASEBOOK SIGNATURE FORM

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Signed, Verified

Site No: 1231

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

Subject No: 12314583

Subject Initials: ---

Generated By: (b) (4)

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

[eCRF Audit Trail History](#)

Casebook Signature Form

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

Header Text: C4591001

Visit: Investigator Signature - Unscheduled

Form: CASEBOOK SIGNATURE FORM

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Signed, Verified

Site No: 1231

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

Subject No: 12314583

Subject Initials: ---

Generated By: (b) (4)

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

[Audit Trail](#)

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

- CRF_Sign

Name	Signature Meaning	Date	Type	Action
Yanina Rivera	Approved	Mar-16-2021 18:02:07 (UTC-03:00) City of Buenos Aires	BOOK	Signed

Affidavit:

By my dated signature below, I, YaninaRivera, 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.

090177e196ae2ead\Final\Final On: 01-Apr-2021 03:20 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 30-Jul-2020 21:29

Site No: 1231

Subject No: 12314583

Generated By: (b) (4)

Form: INCLUSION/EXCLUSION CRITERIA - Comments

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

[Back to Form](#)

Item	Date	User	Comment
Form	Aug-27-2020 18:22:16 (UTC-03:00) City of Buenos Aires	(b) (4), (b) (6)	Not Applicable

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1231

Subject No: 12314583

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - Comments

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

[Back to Form](#)

Item	Date	User	Comment
Form	Aug-27-2020 18:22:48 (UTC-03:00) City of Buenos Aires	(b) (4), (b) (6)	Not Applicable

Header Text: C4591001

Visit: V101_VAX3

Form: INCLUSION/EXCLUSION CRITERIA - FURTHER VACCINATION - Comments

Form Version: 10-Dec-2020 02:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1231

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

Subject No: 12314583

Subject Initials: ---

Generated By: (b) (4)

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

[Back to Form](#)

Item	Date	User	Comment
Form	Mar-14-2021 10:31:26 (UTC-03:00) City of Buenos Aires	(b) (4), (b) (6)	Not Applicable

Header Text: C4591001

Visit: Investigator Signature - Unscheduled **Form:** CASEBOOK SIGNATURE FORM - Signature History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Signed, Verified

Site No: 1231

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

Subject No: 12314583

Subject Initials: ---

Generated By: (b) (4)

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

[Back to Form](#)

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

- CRF_Sign

Name	Signature Meaning	Date	Type	Action
Yanina Rivera	Approved	Mar-16-2021 18:02:07 (UTC-03:00) City of Buenos Aires	BOOK	Signed

Affidavit:

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

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

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

(b) (6)	N/A	Mar-10-2021 12:48:23 (UTC-03:00) City of Buenos Aires		Edit - All signatures invalidated
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Affidavit:

N/A

Maria Beretta	Approved	Mar-09-2021 19:31:13 (UTC-03:00) City of Buenos Aires	BOOK	Signed
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Affidavit:

By my dated signature below, I, MariaBeretta, 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.

090177e196ae2ead\Final\Final On: 01-Apr-2021 03:20 (GMT)

Header Text: C4591001**Visit:** Investigator Signature - Unscheduled **Form:** CASEBOOK SIGNATURE FORM - Signature History**Form Version:** 22-Apr-2020 21:04**Form Status:** Data Complete, Signed, Verified**Site No:** 1231**Site Name:** (1231) Hospital Militar Central Cirujano Mayor Dr. Cosme Argerich**Subject No:** 12314583**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 20:34

Martina Davalli	N/A	Mar-05-2021 10:43:51 (UTC-03:00) City of Buenos Aires		Edit - All signatures invalidated
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Affidavit:

N/A

(b) (6)	Approved	Feb-09-2021 17:41:56 (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-05-2021 11:16:11 (UTC-03:00) City of Buenos Aires		Edit - All signatures invalidated
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Affidavit:

N/A

Tatiana Estrada	Approved	Jan-29-2021 15:13:22 (UTC-03:00) City of Buenos Aires	BOOK	Signed
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Affidavit:

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

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

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

Header Text: C4591001

Visit: Investigator Signature - Unscheduled **Form:** CASEBOOK SIGNATURE FORM - Signature History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Signed, Verified

Site No: 1231

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

Subject No: 12314583

Subject Initials: ---

Generated By: (b) (4)

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

(b) (6)	N/A	Jan-28-2021 13:20:45 (UTC-03:00) City of Buenos Aires		Edit - All signatures invalidated
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Affidavit:

N/A

(b) (6)	Approved	Jan-21-2021 08:42:17 (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	Dec-03-2020 12:23:24 (UTC-03:00) City of Buenos Aires		Edit - All signatures invalidated
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Affidavit:

N/A

Fernando Polack	Approved	Oct-28-2020 19:28:08 (UTC-03:00) City of Buenos Aires	BOOK	Signed
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Affidavit:

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

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

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

090177e196ae2ead\Final\Final On: 01-Apr-2021 03:20 (GMT)

Header Text: C4591001

Visit: Investigator Signature - Unscheduled **Form:** CASEBOOK SIGNATURE FORM - Signature History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Signed, Verified

Site No: 1231

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

Subject No: 12314583

Subject Initials: ---

Generated By: (b) (4)

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

(b) (6)	N/A	Oct-27-2020 10:04:36 (UTC-03:00) City of Buenos Aires		Edit - All signatures invalidated
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Affidavit:

N/A

(b) (6)	Approved	Oct-23-2020 18:52:01 (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.

090177e196ae2ead\Final\Final On: 01-Apr-2021 03:20 (GMT)

Header Text: C4591001

Visit: COHORT_SELECTION

Form Version: 30-Jul-2020 21:29

Site No: 1231

Subject No: 12314583

Generated By: (b) (4)

Form: COHORT SELECTION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

[Back to Form](#)

1. Select appropriate response - Protocol version

Date	Location	User	Value	Reason
Aug-27-2020 18:20:52 (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-27-2020 18:20:52 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: STAGE 3 COHORTS	Initial Entry

090177e196ae2ead\Final\Final On: 01-Apr-2021 03:20 (GMT)

Header Text: C4591001

Visit: COHORT_SELECTION

Form Version: 22-Apr-2020 21:02

Site No: 1231

Subject No: 12314583

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](#)

I. Consent Was:

Date	Location	User	Value	Reason
Aug-27-2020 18:21:04 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: OBTAINED Date Written Consent Obtained Aug/27/2020	Initial Entry

Header Text: C4591001**Visit:** COHORT_SELECTION**Form Version:** 06-Jul-2020 21:55**Site No:** 1231**Subject No:** 12314583**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-27-2020 16:14:23 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 12314583	Item copied from previous form

2. Birth Date:

Date	Location	User	Value	Reason
Aug-27-2020 16:14:10 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: (b) (6) /1999	Enrollment Entry

3. Sex:

Date	Location	User	Value	Reason
Aug-27-2020 18:21:34 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: FEMALE	Initial Entry

4. Ethnicity:

Date	Location	User	Value	Reason
Aug-27-2020 18:21:34 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: HISPANIC OR LATINO(A) OR OF SPANISH ORIGIN	Initial Entry

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

Date	Location	User	Value	Reason
Aug-27-2020 18:21:34 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: WHITE	Initial Entry

Header Text: C4591001

Visit: COHORT_SELECTION

Form Version: 06-Jul-2020 21:55

Site No: 1231

Subject No: 12314583

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

Buenos Aires

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

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:02

Site No: 1231

Subject No: 12314583

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-27-2020 18:21:57 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Aug/27/2020	Initial Entry

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1231

Subject No: 12314583

Generated By: (b) (4)

Form: DISPOSITION - SCREENING - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

[Back to Form](#)

1. Date of Completion/Discontinuation/Death

Date	Location	User	Value	Reason
Aug-27-2020 18:22:32 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Aug/27/2020	Initial Entry

2. Phase of Disposition:

Date	Location	User	Value	Reason
Aug-27-2020 18:22:32 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SCREENING	Initial Entry

3. Status:

Date	Location	User	Value	Reason
Aug-27-2020 18:22:32 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: COMPLETED	Initial Entry

090177e196ae2ead\Final\Final On: 01-Apr-2021 03:20 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 21-Aug-2020 02:51

Site No: 1231

Subject No: 12314583

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

[Back to Form](#)

1. Date:

Date	Location	User	Value	Reason
Aug-27-2020 18:23:29 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Aug/27/2020	Initial Entry

2. Weight:

Date	Location	User	Value	Reason
Aug-27-2020 18:23:29 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 52.0	Initial Entry

3. Unit:

Date	Location	User	Value	Reason
Aug-27-2020 18:23:29 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: kg	Initial Entry

4. Height:

Date	Location	User	Value	Reason
Aug-27-2020 18:23:29 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 153.0	Initial Entry

5. Unit:

Date	Location	User	Value	Reason
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090177e196ae2ead\Final\Final On: 01-Apr-2021 03:20 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 21-Aug-2020 02:51

Site No: 1231

Subject No: 12314583

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

Aug-27-2020 18:23:29 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: cm	Initial Entry
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6. Body Mass Index:

Date	Location	User	Value	Reason
Aug-27-2020 18:23:29 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 22.2	Initial Entry

7.a

Date	Location	User	Value	Reason
Aug-27-2020 18:23:29 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Record Identifier: Temperature: 36.7 Temperature Unit: Temperature Location: ORAL CAVITY	Initial Entry

7.a Record Identifier:

Date	Location	User	Value	Reason
Aug-27-2020 18:23:29 (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-27-2020 18:23:29 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 36.7	Initial Entry

090177e196ae2ead\Final\Final On: 01-Apr-2021 03:20 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 21-Aug-2020 02:51

Site No: 1231

Subject No: 12314583

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

Buenos Aires		(b) (4), (b) (6)	
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7.a Unit:

Date	Location	User	Value	Reason
Aug-27-2020 18:23:29 (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-27-2020 18:23:29 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: ORAL CAVITY	Initial Entry

090177e196ae2ead\Final\Final On: 01-Apr-2021 03:20 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

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

Form Version: 21-Aug-2020 02:49

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1231

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

Subject No: 12314583

Subject Initials: ---

Generated By: (b) (4)

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

[Back to Form](#)

1. Lab Panel:

Date	Location	User	Value	Reason
Aug-27-2020 18:23:40 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: URINALYSIS	Initial Entry

2. Lab Sub-Panel:

Date	Location	User	Value	Reason
Aug-27-2020 18:23:40 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: PREGNANCY	Initial Entry

3. Collection Date:

Date	Location	User	Value	Reason
Aug-27-2020 18:23:40 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Aug/27/2020	Initial Entry

4. Laboratory Name and Address (Derived)

Date	Location	User	Value	Reason
Aug-27-2020 18:23:40 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: STUDY SITE	Initial Entry

5. Specimen Type:

Date	Location	User	Value	Reason
Aug-27-2020 18:23:40 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: URINE	Initial Entry

090177e196ae2ead\Final\Final On: 01-Apr-2021 03:20 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

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

Form Version: 21-Aug-2020 02:49

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1231

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

Subject No: 12314583

Subject Initials: ---

Generated By: (b) (4)

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

Buenos Aires				
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6.a

Date	Location	User	Value	Reason
Aug-27-2020 18:23:40 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sponsor-Defined Identifier: Test:: Choriogonadotropin Beta_PX 113 Result:: NEGATIVE Not Done::	Initial Entry

6.a Sponsor ID:

Date	Location	User	Value	Reason
Aug-27-2020 18:23:40 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 113	Initial Entry

6.a Test:

Date	Location	User	Value	Reason
Aug-27-2020 18:23:40 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Choriogonadotropin Beta_PX113	Initial Entry

6.a Result:

Date	Location	User	Value	Reason
Aug-27-2020 18:23:40 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NEGATIVE	Initial Entry

090177e196ae2ead\Final\Final On: 01-Apr-2021 03:20 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 21-Aug-2020 02:49

Site No: 1231

Subject No: 12314583

Generated By: (b) (4)

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

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

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

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1231

Subject No: 12314583

Generated By: (b) (4)

Form: RANDOMIZATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

[Back to Form](#)

1. Randomization Date :

Date	Location	User	Value	Reason
Aug-27-2020 18:23:57 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Aug/27/2020	Initial Entry

2. Randomization Number:

Date	Location	User	Value	Reason
Aug-27-2020 18:23:57 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 70872	Initial Entry

090177e196ae2ead\Final\Final On: 01-Apr-2021 03:20 (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: 12314583

Subject Initials: ---

Generated By: (b) (4)

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

[Back to Form](#)

1. Data Origin

Date	Location	User	Value	Reason
Aug-27-2020 18:24:06 (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-27-2020 18:24:06 (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-28-2020 16:02:36 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Aug-28-2020 02:25:34 (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-27-2020 18:24:06 (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

090177e196ae2ead\Final\Final On: 01-Apr-2021 03:20 (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: 12314583

Subject Initials: ---

Generated By: (b) (4)

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

				correct as appropriate.
Aug-27-2020 18:24:06 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Date of Collection: Aug/27/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Aug-28-2020 16:02:36 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	Alan Colombo (b) (4)	Data Entry: Sample ID: BPTG57	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Aug-28-2020 16:02:36 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	Alan Colombo (b) (4)	Data Entry: BPTG57	Initial Entry

5.b

Date	Location	User	Value	Reason
Aug-28-2020 16:02:43 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	Alan Colombo (b) (4)	Data Entry: Sample ID: BPTG58	Initial Entry

090177e196ae2ead\Final\Final On: 01-Apr-2021 03:20 (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: 12314583

Subject Initials: ---

Generated By: (b) (4)

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

5.b Sample ID

Date	Location	User	Value	Reason
Aug-28-2020 16:02:43 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	Alan Colombo (b) (4)	Data Entry: BPTG58	Initial Entry

5.c

Date	Location	User	Value	Reason
Aug-28-2020 16:02:50 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	Alan Colombo (b) (4)	Data Entry: Sample ID: BPTG59	Initial Entry

5.c Sample ID

Date	Location	User	Value	Reason
Aug-28-2020 16:02:50 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	Alan Colombo (b) (4)	Data Entry: BPTG59	Initial Entry

5.d

Date	Location	User	Value	Reason
Aug-28-2020 17:29:46 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	Alan Colombo (b) (4)	Data Entry: Sample ID: BLBJJ3	Initial Entry

090177e196ae2ead\Final\Final On: 01-Apr-2021 03:20 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1231

Subject No: 12314583

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.d Sample ID

Date	Location	User	Value	Reason
Aug-28-2020 17:29:46 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	Alan Colombo (b) (4)	Data Entry: BLBJJ3	Initial Entry

5.e

Date	Location	User	Value	Reason
Aug-28-2020 17:29:51 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	Alan Colombo (b) (4)	Data Entry: Sample ID: BLBJJ4	Initial Entry

5.e Sample ID

Date	Location	User	Value	Reason
Aug-28-2020 17:29:51 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	Alan Colombo (b) (4)	Data Entry: BLBJJ4	Initial Entry

090177e196ae2ead\Final\Final On: 01-Apr-2021 03:20 (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: 12314583

Subject Initials: ---

Generated By: (b) (4)

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

[Back to Form](#)

1. Data Origin

Date	Location	User	Value	Reason
Aug-27-2020 18:24:14 (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-27-2020 18:24:14 (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-28-2020 11:25:15 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Aug-28-2020 02:25:34 (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-27-2020 18:24:14 (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

090177e196ae2ead\Final\Final On: 01-Apr-2021 03:20 (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: 12314583 **Subject Initials:** ---
Generated By: (b) (4) **Generated Time (GMT):** 29-Mar-2021 20:34

				correct as appropriate.
Aug-27-2020 18:24:14 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Date of Collection: Aug/27/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Aug-28-2020 11:25:15 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BPT9YT	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Aug-28-2020 11:25:15 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BPT9YT	Initial Entry

090177e196ae2ead\Final\Final On: 01-Apr-2021 03:20 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:04

Site No: 1231

Subject No: 12314583

Generated By: (b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

[Back to Form](#)

1. Was there a temporary delay of vaccination?

Date	Location	User	Value	Reason
Aug-27-2020 18:24:33 (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-27-2020 18:24:33 (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-27-2020 18:24:33 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: INJECTION	Initial Entry

4. Dose Date Time:

Date	Location	User	Value	Reason
Aug-27-2020 18:24:33 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Aug/27/2020 17:10	Initial Entry

5. Anatomical Location:

Date	Location	User	Value	Reason
Aug-27-2020 18:24:33 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: DELTOID MUSCLE	Initial Entry

090177e196ae2ead\Final\Final On: 01-Apr-2021 03:20 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:04

Site No: 1231

Subject No: 12314583

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

Buenos Aires				
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6. Body Side:

Date	Location	User	Value	Reason
Aug-27-2020 18:24:33 (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-27-2020 18:24:33 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: INTRAMUSCULAR	Initial Entry

10. Timeframe Subject Was Observed

Date	Location	User	Value	Reason
Aug-27-2020 18:24:33 (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-27-2020 18:24:33 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

090177e196ae2ead\Final\Final On: 01-Apr-2021 03:20 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 06-Jul-2020 21:53

Site No: 1231

Subject No: 12314583

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

[Back to Form](#)

1. Select appropriate response - Reactogenicity diary collection

Date	Location	User	Value	Reason
Aug-27-2020 18:24:40 (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: 12314583

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](#)

I. Date of Visit

Date	Location	User	Value	Reason
Oct-23-2020 05:10:38 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	COVID illness visit updated per query
Oct-22-2020 08:59:34 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	COVID illness visit was done, information was uploaded Thank you
Oct-19-2020 12:58:21 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	Illness edairy: As per Illness edairy records, subject reported "Yes" for the question "Have you experienced any of the following?" for the COVID-19 symptoms or diagnosis on 15OCT2020. But corresponding COVID Illness visit not reported. Please clarify.
Sep-18-2020 17:53:49 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sep/15/2020	Initial Entry

090177e196ae2ead\Final\Final On: 01-Apr-2021 03:20 (GMT)

Header Text: C4591001

Visit: V2_VAX2_L

Form Version: 15-Sep-2020 21:54

Site No: 1231

Subject No: 12314583

Generated By: (b) (4)

Form: VITAL SIGNS - TEMP - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

[Back to Form](#)

1. Date:

Date	Location	User	Value	Reason
Sep-18-2020 17:53:59 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sep/15/2020	Initial Entry

2.a

Date	Location	User	Value	Reason
Sep-18-2020 17:53:59 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Record Identifier: Temperature: 37.1 Temperature Unit: Temperature Location: ORAL CAVITY	Initial Entry

2.a Record Identifier:

Date	Location	User	Value	Reason
Sep-18-2020 17:53:59 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 1	Initial Entry

2.a Temperature:

Date	Location	User	Value	Reason
Sep-18-2020 17:53:59 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 37.1	Initial Entry

2.a Unit:

090177e196ae2ead\Final\Final On: 01-Apr-2021 03:20 (GMT)

Header Text: C4591001

Visit: V2_VAX2_L

Form Version: 15-Sep-2020 21:54

Site No: 1231

Subject No: 12314583

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

Date	Location	User	Value	Reason
Sep-18-2020 17:53:59 (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 17:53:59 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: ORAL CAVITY	Initial Entry

Header Text: C4591001

Visit: V2_VAX2_L

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

Form Version: 21-Aug-2020 02:49

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1231

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

Subject No: 12314583

Subject Initials: ---

Generated By: (b) (4)

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

[Back to Form](#)

1. Lab Panel:

Date	Location	User	Value	Reason
Sep-18-2020 17:54:07 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: URINALYSIS	Initial Entry

2. Lab Sub-Panel:

Date	Location	User	Value	Reason
Sep-18-2020 17:54:07 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: PREGNANCY	Initial Entry

3. Collection Date:

Date	Location	User	Value	Reason
Sep-18-2020 17:54:07 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sep/15/2020	Initial Entry

4. Laboratory Name and Address (Derived)

Date	Location	User	Value	Reason
Sep-18-2020 17:54:07 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: STUDY SITE	Initial Entry

5. Specimen Type:

Date	Location	User	Value	Reason
Sep-18-2020 17:54:07 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: URINE	Initial Entry

090177e196ae2ead\Final\Final On: 01-Apr-2021 03:20 (GMT)

Header Text: C4591001

Visit: V2_VAX2_L

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

Form Version: 21-Aug-2020 02:49

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1231

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

Subject No: 12314583

Subject Initials: ---

Generated By: (b) (4)

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

6.a

Date	Location	User	Value	Reason
Sep-18-2020 17:54:07 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sponsor-Defined Identifier: Test:: Choriogonadotropin Beta_PX 113 Result:: NEGATIVE Not Done::	Initial Entry

6.a Sponsor ID:

Date	Location	User	Value	Reason
Sep-18-2020 17:54:07 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 113	Initial Entry

6.a Test:

Date	Location	User	Value	Reason
Sep-18-2020 17:54:07 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Choriogonadotropin Beta_PX113	Initial Entry

6.a Result:

Date	Location	User	Value	Reason
Sep-18-2020 17:54:07 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NEGATIVE	Initial Entry

090177e196ae2ead\Final\Final On: 01-Apr-2021 03:20 (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: 12314583

Subject Initials: ---

Generated By: (b) (4)

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

[Back to Form](#)

1. Data Origin

Date	Location	User	Value	Reason
Sep-16-2020 11:32:25 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Sep-16-2020 11:32:25 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: NASAL_SWAB	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Sep-16-2020 11:32:45 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Sep-16-2020 11:32:25 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Sep-16-2020 11:32:25 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Date of Collection: Sep/15/2020	Initial Entry

090177e196ae2ead\Final\Final On: 01-Apr-2021 03:20 (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: 12314583

Subject Initials: ---

Generated By: (b) (4)

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

5.a

Date	Location	User	Value	Reason
Sep-16-2020 11:32:45 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BP1RJ3	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Sep-16-2020 11:32:45 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BP1RJ3	Initial Entry

090177e196ae2ead\Final\Final On: 01-Apr-2021 03:20 (GMT)

Header Text: C4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:04

Site No: 1231

Subject No: 12314583

Generated By: (b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

[Back to Form](#)

1. Was there a temporary delay of vaccination?

Date	Location	User	Value	Reason
Sep-18-2020 17:54:25 (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 17:54:25 (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 17:54:25 (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 17:54:25 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sep/15/2020 18:00	Initial Entry

5. Anatomical Location:

Date	Location	User	Value	Reason
Sep-18-2020 17:54:25 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: DELTOID MUSCLE	Initial Entry

090177e196ae2ead\Final\Final On: 01-Apr-2021 03:20 (GMT)

Header Text: C4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:04

Site No: 1231

Subject No: 12314583

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

6. Body Side:

Date	Location	User	Value	Reason
Sep-18-2020 17:54:25 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: RIGHT	Initial Entry

7. Route:

Date	Location	User	Value	Reason
Sep-18-2020 17:54:25 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: INTRAMUSCULAR	Initial Entry

10. Timeframe Subject Was Observed

Date	Location	User	Value	Reason
Sep-18-2020 17:54:25 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: THE PROTOCOL SPECIFIED OBSERVATION PERIOD	Initial Entry

11. Was the subject observed for at least the protocol specified observation period after investigational product administration?

Date	Location	User	Value	Reason
Sep-18-2020 17:54:25 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

090177e196ae2ead\Final\Final On: 01-Apr-2021 03:20 (GMT)

Header Text: C4591001

Visit: V3_MONTH1_POSTVAX2_L

Form Version: 22-Apr-2020 21:02

Site No: 1231

Subject No: 12314583

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
Oct-19-2020 17:20:36 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Oct/19/2020	Initial Entry

Header Text: C4591001

Visit: V3_MONTH1_POSTVAX2_L

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1231

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

Subject No: 12314583

Subject Initials: ---

Generated By: (b) (4)

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

[Back to Form](#)

1. Data Origin

Date	Location	User	Value	Reason
Oct-19-2020 14:38:19 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Oct-19-2020 14:38:19 (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-19-2020 14:38:27 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Oct-19-2020 14:38:19 (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-19-2020 14:38:19 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Date of Collection: Oct/19/2020	Initial Entry

090177e196ae2ead\Final\Final On: 01-Apr-2021 03:20 (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: 12314583

Subject Initials: ---

Generated By: (b) (4)

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

5.a

Date	Location	User	Value	Reason
Oct-19-2020 14:38:27 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BLBKR7	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Oct-19-2020 14:38:27 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BLBKR7	Initial Entry

5.b

Date	Location	User	Value	Reason
Oct-19-2020 16:12:08 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	Alan Colombo (b) (4)	Data Entry: Sample ID: BLBGYB	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Oct-19-2020 16:12:08 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	Alan Colombo (b) (4)	Data Entry: BLBGYB	Initial Entry

5.c

Date	Location	User	Value	Reason
Oct-19-2020 17:04:28 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BP1PM1	Initial Entry

090177e196ae2ead\Final\Final On: 01-Apr-2021 03:20 (GMT)

Header Text: C4591001

Visit: V3_MONTH1_POSTVAX2_L

Form Version: 22-Apr-2020 21:03

Site No: 1231

Subject No: 12314583

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.c Sample ID

Date	Location	User	Value	Reason
Oct-19-2020 17:04:28 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BP1PM1	Initial Entry

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/20/2020

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: 12314583

Subject Initials: ---

Generated By: (b) (4)

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

[Back to Form](#)

1. Date of Visit

Date	Location	User	Value	Reason
Mar-05-2021 06:09:30 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Closed	data updated
Mar-04-2021 15:36:14 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	Adolfo Gonzalez (b) (4)	Query 3: Answered	the subject has the conva visit scheduled for 05/MAR/2021, thank you
Mar-04-2021 08:52:31 (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; if visit did not occur attempt to schedule visit even if OOW and obtain the CONVA sample else clarify.
Oct-22-2020 08:55:42 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query

090177e196ae2ead\Final\Final On: 01-Apr-2021 03:20 (GMT)

Header Text: C4591001**Visit:** POT_COVID_ILL 1 - Unscheduled
Visit on Oct/20/2020**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:** 12314583**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 20:34

Oct-22-2020 08:53:50 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Deleted	Close Auto Query
Oct-22-2020 08:51:31 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Candidate	Date of Visit is completed but Date of Assessment in the Signs and Symptoms form is missing. Please review and update as appropriate.
Oct-22-2020 08:51:31 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	Date of Visit is completed but Date of Collection in both Nasal Swab Self and Nasal Swab are missing. Please review and update as appropriate.
Oct-22-2020 08:51:31 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Oct/20/2020	Initial Entry

3. COVID-19 Illness Visit:

Date	Location	User	Value	Reason
Oct-22-2020 08:51:31 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: COVID_A	Initial Entry

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled
Visit on Oct/20/2020

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

Form Version: 10-Oct-2020 16:02

Form Status: Data Complete, Frozen, Verified

Site No: 1231

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

Subject No: 12314583

Subject Initials: ---

Generated By: (b) (4)

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

[Back to Form](#)

1. Date of Assessment:

Date	Location	User	Value	Reason
Oct-22-2020 08:53:50 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Oct/20/2020	Initial Entry

2. Date of First Symptom Started:

Date	Location	User	Value	Reason
Nov-02-2020 05:46:34 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Per site confirmation-was not associated to the covid visit
Oct-31-2020 19:27:13 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	the alarm activated on October 15th was the adverse event of epigastralgia. and was not associated to the covid visit
Oct-31-2020 05:10:32 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	Illness eduary: As per Illness eduary records, subject reported "Yes" for the COVID-19 symptoms or diagnosis on 15OCT2020. However symptom start for this Covid illness visit is 18Oct2020. Please clarify if

090177e196ae2ead\Final\Final On: 01-Apr-2021 03:20 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled
Visit on Oct/20/2020

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

Form Version: 10-Oct-2020 16:02

Form Status: Data Complete, Frozen, Verified

Site No: 1231

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

Subject No: 12314583

Subject Initials: ---

Generated By: (b) (4)

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

				symptoms were erroneously reported on 15Oct2020.
Oct-22-2020 08:53:50 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Oct/18/2020	Initial Entry

3. Symptoms Ongoing?

Date	Location	User	Value	Reason
Oct-22-2020 08:53:50 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO Date of Last Symptom Resolved: Oct/19/2020	Initial Entry

4.a

Date	Location	User	Value	Reason
Oct-22-2020 08:53:50 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptoms: FEVER Symptom Present: NO	Initial Entry

4.a Symptoms:

Date	Location	User	Value	Reason
Oct-22-2020 08:53:50 (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
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090177e196ae2ead\Final\Final On: 01-Apr-2021 03:20 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled
Visit on Oct/20/2020

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

Form Version: 10-Oct-2020 16:02

Form Status: Data Complete, Frozen, Verified

Site No: 1231

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

Subject No: 12314583

Subject Initials: ---

Generated By: (b) (4)

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

Oct-22-2020 08:53:50 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry
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4.b

Date	Location	User	Value	Reason
Oct-22-2020 08:53:50 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom NEW OR INCR s: EASED COUGH Symptom NO Present:	Initial Entry

4.b Symptoms:

Date	Location	User	Value	Reason
Oct-22-2020 08:53:50 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NEW OR INCREASED CO UGH	Initial Entry

4.b Was symptom present?

Date	Location	User	Value	Reason
Oct-22-2020 08:53:50 (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-22-2020 08:53:50 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sympto NEW OR INCREA ms: SED SHORTNESS OF BREATH	Initial Entry

090177e196ae2ead\Final\Final On: 01-Apr-2021 03:20 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled
Visit on Oct/20/2020

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

Form Version: 10-Oct-2020 16:02

Form Status: Data Complete, Frozen, Verified

Site No: 1231

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

Subject No: 12314583

Subject Initials: ---

Generated By: (b) (4)

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

			Symptom Present:	
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4.c Symptoms:

Date	Location	User	Value	Reason
Oct-22-2020 08:53:50 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NEW OR INCREASED SHORTNESS OF BREATH	Initial Entry

4.c Was symptom present?

Date	Location	User	Value	Reason
Oct-22-2020 08:53:50 (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-22-2020 08:53:50 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptoms: CHILLS Symptom Present: NO	Initial Entry

090177e196ae2ead\Final\Final On: 01-Apr-2021 03:20 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled
Visit on Oct/20/2020

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

Form Version: 10-Oct-2020 16:02

Form Status: Data Complete, Frozen, Verified

Site No: 1231

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

Subject No: 12314583

Subject Initials: ---

Generated By: (b) (4)

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

4.d Symptoms:

Date	Location	User	Value	Reason
Oct-22-2020 08:53:50 (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-22-2020 08:53:50 (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-22-2020 08:53:50 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom: NEW OR INCREASED MUSCLE PAIN Symptom Present: NO	Initial Entry

090177e196ae2ead\Final\Final On: 01-Apr-2021 03:20 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled
Visit on Oct/20/2020

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

Form Version: 10-Oct-2020 16:02

Form Status: Data Complete, Frozen, Verified

Site No: 1231

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

Subject No: 12314583

Subject Initials: ---

Generated By: (b) (4)

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

4.e Symptoms:

Date	Location	User	Value	Reason
Oct-22-2020 08:53:50 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NEW OR INCREASED MU SCLE PAIN	Initial Entry

4.e Was symptom present?

Date	Location	User	Value	Reason
Oct-22-2020 08:53:50 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

4.f

Date	Location	User	Value	Reason
Oct-22-2020 08:53:50 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom: NEW LOSS OF T ASTE OR SMEL L Symptom Present: NO	Initial Entry

090177e196ae2ead\Final\Final On: 01-Apr-2021 03:20 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled
Visit on Oct/20/2020

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

Form Version: 10-Oct-2020 16:02

Form Status: Data Complete, Frozen, Verified

Site No: 1231

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

Subject No: 12314583

Subject Initials: ---

Generated By: (b) (4)

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

4.f Symptoms:

Date	Location	User	Value	Reason
Oct-22-2020 08:53:50 (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-22-2020 08:53:50 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

4.g

Date	Location	User	Value	Reason
Oct-22-2020 08:53:50 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom: NEW OR INCREASED SORE THROAT Symptom Present: NO	Initial Entry

090177e196ae2ead\Final\Final On: 01-Apr-2021 03:20 (GMT)

Header Text: C4591001**Visit:** POT_COVID_ILL 1 - Unscheduled
Visit on Oct/20/2020**Form:** SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 -
eCRF Audit Trail History**Form Version:** 10-Oct-2020 16:02**Form Status:** Data Complete, Frozen, Verified**Site No:** 1231**Site Name:** (1231) Hospital Militar Central Cirujano Mayor Dr.
Cosme Argerich**Subject No:** 12314583**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 20:34**4.g Symptoms:**

Date	Location	User	Value	Reason
Oct-22-2020 08:53:50 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NEW OR INCREASED SOR E THROAT	Initial Entry

4.g Was symptom present?

Date	Location	User	Value	Reason
Oct-22-2020 08:53:50 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

4.h

Date	Location	User	Value	Reason
Oct-22-2020 08:53:50 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptoms: DIARRHE A Symptom Prese nt: YES	Initial Entry

4.h Symptoms:

Date	Location	User	Value	Reason
Oct-22-2020 08:53:50 (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-22-2020 08:53:50 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/20/2020

Form Version: 10-Oct-2020 16:02

Site No: 1231

Subject No: 12314583

Generated By: (b) (4)

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

Form Status: Data Complete, Frozen, Verified

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

Subject Initials: ---

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

4.i

Date	Location	User	Value	Reason
Oct-22-2020 08:53:50 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptoms: VOMITIN G Symptom Present: NO	Initial Entry

4.i Symptoms:

Date	Location	User	Value	Reason
Oct-22-2020 08:53:50 (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-22-2020 08:53:50 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

090177e196ae2ead\Final\Final On: 01-Apr-2021 03:20 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled **Form:** MICROBIOLOGY SPECIMEN - Audit Trail
Visit on Oct/20/2020

Form Version: 06-Jul-2020 21:54

Form Status:

Site No: 1231

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

Subject No: 12314583

Subject Initials: ---

Generated By: (b) (4)

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

[Back to Form](#)

Date	Location	User	Value	Reason
Oct-22-2020 08:55:02 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Created	

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled **Form:** MICROBIOLOGY SPECIMEN - eCRF Audit Trail History
Visit on Oct/20/2020

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen, Verified

Site No: 1231

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

Subject No: 12314583

Subject Initials: ---

Generated By: (b) (4)

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

[Back to Form](#)

1. Actual Date of Collection:

Date	Location	User	Value	Reason
Oct-22-2020 08:55:02 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Oct/20/2020	Initial Entry

2. Specimen Type:

Date	Location	User	Value	Reason
Oct-22-2020 08:55:02 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: RESPIRATORY SECRETIO NS	Initial Entry

3. Specimen Collection Location:

Date	Location	User	Value	Reason
Oct-22-2020 08:55:02 (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-22-2020 08:55:02 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SEVERE ACUTE RESP SYN DROME CORONAVIRUS 2	Initial Entry

5. Device Type:

Date	Location	User	Value	Reason
Oct-22-2020 08:55:02 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SARS-COV-2 DIAGNOSTIC TEST	Initial Entry

090177e196ae2ead\Final\Final On: 01-Apr-2021 03:20 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled **Form:** MICROBIOLOGY SPECIMEN - eCRF Audit Trail History
Visit on Oct/20/2020

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen, Verified

Site No: 1231

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

Subject No: 12314583

Subject Initials: ---

Generated By: (b) (4)

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

6. Trade Name:

Date	Location	User	Value	Reason
Oct-22-2020 08:55:02 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: ATILA BIOSYSTEMS IAM P COVID-19 DETECTION KIT	Initial Entry

7. Test Result:

Date	Location	User	Value	Reason
Oct-22-2020 08:55:02 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NEGATIVE	Initial Entry

090177e196ae2ead\Final\Final On: 01-Apr-2021 03:20 (GMT)

Header Text: C4591001**Visit:** POT_COVID_ILL 1 - Unscheduled
Visit on Oct/20/2020**Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB
SELF - eCRF Audit Trail History**Form Version:** 22-Apr-2020 21:03**Form Status:** Data Complete, Frozen, Verified**Site No:** 1231**Site Name:** (1231) Hospital Militar Central Cirujano Mayor Dr.
Cosme Argerich**Subject No:** 12314583**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 20:34[Back to Form](#)**1. Data Origin**

Date	Location	User	Value	Reason
Oct-22-2020 08:55:28 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Oct-22-2020 08:55:28 (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-22-2020 08:55:28 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

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

Date	Location	User	Value	Reason
Oct-22-2020 08:55:28 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample collected by team ph ysician	Initial Entry

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled
Visit on Oct/20/2020

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: 12314583

Subject Initials: ---

Generated By: (b) (4)

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

[Back to Form](#)

1. Data Origin

Date	Location	User	Value	Reason
Oct-22-2020 08:55:42 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Oct-22-2020 08:55:42 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: NASAL_SWAB	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Oct-22-2020 10:13:33 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Oct-22-2020 08:55:42 (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-22-2020 08:55:42 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Date of Collection: Oct/20/2020	Initial Entry

090177e196ae2ead\Final\Final On: 01-Apr-2021 03:20 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled
Visit on Oct/20/2020

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: 12314583

Subject Initials: ---

Generated By: (b) (4)

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

5.a

Date	Location	User	Value	Reason
Oct-22-2020 10:13:33 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BPT7WP	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Oct-22-2020 10:13:33 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BPT7WP	Initial Entry

Header Text: C4591001**Visit:** POT_COVID_ILL 1 - Unscheduled
Visit on Oct/20/2020**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:** 12314583**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 20:34[Back to Form](#)*I.a*

Date	Location	User	Value	Reason
Oct-22-2020 08:56:51 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Type of Practitioner: SPECIALIST Occurrence of Visits or Contacts: NO	Initial Entry

I.a Physician or Healthcare Professional:

Date	Location	User	Value	Reason
Oct-22-2020 08:56:51 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: SPECIALIST	Initial Entry

I.a Occurrence of Visits or Contacts:

Date	Location	User	Value	Reason
Oct-22-2020 08:56:51 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

I.b

Date	Location	User	Value	Reason
Oct-22-2020 08:56:51 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Type of Practitioner: EMERGENCY ROOM	Initial Entry

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/20/2020

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: 12314583

Subject Initials: ---

Generated By: (b) (4)

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

			Occurrence of Visits or Contacts:	YES Number of Visits or Contacts: 1
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1.b Physician or Healthcare Professional:

Date	Location	User	Value	Reason
Oct-22-2020 08:56:51 (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-22-2020 08:56:51 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Number of Visits or Contacts: 1	Initial Entry

1.c

Date	Location	User	Value	Reason
Oct-22-2020 08:56:51 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Type of Practitioner: PRIMARY CARE PHYSICIAN Occurrence of Visits or Contacts: NO	Initial Entry

090177e196ae2ead\Final\Final On: 01-Apr-2021 03:20 (GMT)

Header Text: C4591001**Visit:** POT_COVID_ILL 1 - Unscheduled
Visit on Oct/20/2020**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:** 12314583**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 20:34***I.c Physician or Healthcare Professional:***

Date	Location	User	Value	Reason
Oct-22-2020 08:56:51 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: PRIMARY CARE PHYSICI AN	Initial Entry

I.c Occurrence of Visits or Contacts:

Date	Location	User	Value	Reason
Oct-22-2020 08:56:51 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

I.d

Date	Location	User	Value	Reason
Oct-22-2020 08:56:51 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Type of Practitio URGEN ner: T CARE Occurrence of Vi NO sits or Contacts:	Initial Entry

I.d Physician or Healthcare Professional:

Date	Location	User	Value	Reason
Oct-22-2020 08:56:51 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: URGENT CARE	Initial Entry

I.d Occurrence of Visits or Contacts:

Date	Location	User	Value	Reason
Oct-22-2020 08:56:51 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled
Visit on Oct/20/2020

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: 12314583

Subject Initials: ---

Generated By: (b) (4)

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

I.e

Date	Location	User	Value	Reason
Oct-22-2020 08:56:51 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Type of Practitioner: TELEPHON E CONSULT ATION Occurrence of Visits or Contacts: NO	Initial Entry

I.e Physician or Healthcare Professional:

Date	Location	User	Value	Reason
Oct-22-2020 08:56:51 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: TELEPHONE CONSULTATION	Initial Entry

I.e Occurrence of Visits or Contacts:

Date	Location	User	Value	Reason
Oct-22-2020 08:56:51 (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-22-2020 08:56:51 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Type of Practitioner: OTHER Occurrence of Visits or Contacts: NO	Initial Entry

090177e196ae2ead\Final\Final On: 01-Apr-2021 03:20 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled
Visit on Oct/20/2020

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: 12314583

Subject Initials: ---

Generated By: (b) (4)

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

1.f Physician or Healthcare Professional:

Date	Location	User	Value	Reason
Oct-22-2020 08:56:51 (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-22-2020 08:56:51 (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-22-2020 08:56:51 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

090177e196ae2ead\Final\Final On: 01-Apr-2021 03:20 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled **Form:** ILLNESS DETAILS - eCRF Audit Trail History
Visit on Oct/20/2020

Form Version: 06-Jul-2020 21:52

Form Status: Data Complete, Frozen, Verified

Site No: 1231

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

Subject No: 12314583

Subject Initials: ---

Generated By: (b) (4)

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

[Back to Form](#)

1. Category of Clinical Event:

Date	Location	User	Value	Reason
Oct-22-2020 08:58:34 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: POTENTIAL COVID-19 ILL NESS	Initial Entry

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

Date	Location	User	Value	Reason
Oct-27-2020 16:51:57 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Oct-27-2020 10:04:36 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Transcription Error
Oct-27-2020 10:04:36 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES <i>Respiratory Illness Dia gnosis:</i> Gastroenteritis Date of Diagnosis: Oct/21/2020	Transcription Error
Oct-26-2020 17:33:46 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reissued:Opene d	CRA: please verify according to medical chart: there is mentioned Gastroenteritis. Please correct

090177e196ae2ead\Final\Final On: 01-Apr-2021 03:20 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled **Form:** ILLNESS DETAILS - eCRF Audit Trail History
Visit on Oct/20/2020

Form Version: 06-Jul-2020 21:52

Form Status: Data Complete, Frozen, Verified

Site No: 1231

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

Subject No: 12314583

Subject Initials: ---

Generated By: (b) (4)

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

				Thanks.
Oct-26-2020 16:16:06 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Original value is correct
Oct-24-2020 20:58:08 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	Per clinical chart the subject has "gastroenteritis". Please review chart and update if necessary. Thanks
Oct-22-2020 08:58:34 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES <i>Respiratory Illness Diagnosis:</i> Stomach flu Date of Diagnosis: Oct/21/2020	Initial Entry

3. Toxicity Grade:

Date	Location	User	Value	Reason
Oct-22-2020 08:58:34 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 1	Initial Entry

090177e196ae2ead\Final\Final On: 01-Apr-2021 03:20 (GMT)

Header Text: C4591001

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

Form: DATE OF VISIT - ILLNESS ONSET - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1231

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

Subject No: 12314583

Subject Initials: ---

Generated By: (b) (4)

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

[Back to Form](#)

1. Date of Visit

Date	Location	User	Value	Reason
Jan-28-2021 13:23:04 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Jan-28-2021 13:21:39 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Deleted	Close Auto Query
Jan-28-2021 13:20:43 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Candidate	Date of Visit is completed but Date of Assessment in the Signs and Symptoms form is missing. Please review and update as appropriate.
Jan-28-2021 13:20:43 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	Date of Visit is completed but Date of Collection in both Nasal Swab Self and Nasal Swab are missing. Please review and update as appropriate.
Jan-28-2021 13:20:43 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Jan/27/2021	Initial Entry

090177e196ae2ead\Final\Final On: 01-Apr-2021 03:20 (GMT)

Header Text: C4591001

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

Form: DATE OF VISIT - ILLNESS ONSET - eCRF Audit Trail
History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1231

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

Subject No: 12314583

Subject Initials: ---

Generated By: (b) (4)

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

3. COVID-19 Illness Visit:

Date	Location	User	Value	Reason
Jan-28-2021 13:20:43 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: COVID_B	Initial Entry

Header Text: C4591001**Visit:** POT_COVID_ILL 2 - Unscheduled
Visit on Jan/27/2021**Form:** SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 -
eCRF Audit Trail History**Form Version:** 14-Jan-2021 02:23**Form Status:** Data Complete**Site No:** 1231**Site Name:** (1231) Hospital Militar Central Cirujano Mayor Dr.
Cosme Argerich**Subject No:** 12314583**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 20:34[Back to Form](#)**1. Date of Assessment:**

Date	Location	User	Value	Reason
Jan-28-2021 13:21:39 (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-28-2021 13:21:39 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Jan/26/2021	Initial Entry

3. Symptoms Ongoing?

Date	Location	User	Value	Reason
Feb-05-2021 11:16:55 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO Date of Last Symptom Res olved: Feb/3/2021	New Information
Jan-28-2021 13:21:39 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

4.a

Date	Location	User	Value	Reason
Jan-28-2021 13:21:39 (UTC-03:00) City of	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Initial Entry

Header Text: C4591001

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

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

Form Version: 14-Jan-2021 02:23

Form Status: Data Complete

Site No: 1231

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

Subject No: 12314583

Subject Initials: ---

Generated By: (b) (4)

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

Buenos Aires	(b) (4), (b) (6)	Symptoms: FEVER Symptom Present: YES
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4.a Symptoms:

Date	Location	User	Value	Reason
Jan-28-2021 13:21:39 (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-28-2021 13:21:39 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

4.b

Date	Location	User	Value	Reason
Jan-28-2021 13:21:39 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptoms: NEW OR INCR EASED COUGH Symptom Present: NO	Initial Entry

090177e196ae2ead\Final\Final On: 01-Apr-2021 03:20 (GMT)

Header Text: C4591001

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

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

Form Version: 14-Jan-2021 02:23

Form Status: Data Complete

Site No: 1231

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

Subject No: 12314583

Subject Initials: ---

Generated By: (b) (4)

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

4.b Symptoms:

Date	Location	User	Value	Reason
Jan-28-2021 13:21:39 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NEW OR INCREASED CO UGH	Initial Entry

4.b Was symptom present?

Date	Location	User	Value	Reason
Jan-28-2021 13:21:39 (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-28-2021 13:21:39 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom: NEW OR INCREA SED SHORTNESS OF BREATH Symptom Present: NO	Initial Entry

090177e196ae2ead\Final\Final On: 01-Apr-2021 03:20 (GMT)

Header Text: C4591001

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

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

Form Version: 14-Jan-2021 02:23

Form Status: Data Complete

Site No: 1231

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

Subject No: 12314583

Subject Initials: ---

Generated By: (b) (4)

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

4.c Symptoms:

Date	Location	User	Value	Reason
Jan-28-2021 13:21:39 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NEW OR INCREASED SH ORTNESS OF BREATH	Initial Entry

4.c Was symptom present?

Date	Location	User	Value	Reason
Jan-28-2021 13:21:39 (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-28-2021 13:21:39 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptoms: CHILL S Symptom Present NO :	Initial Entry

090177e196ae2ead\Final\Final On: 01-Apr-2021 03:20 (GMT)

Header Text: C4591001

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

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

Form Version: 14-Jan-2021 02:23

Form Status: Data Complete

Site No: 1231

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

Subject No: 12314583

Subject Initials: ---

Generated By: (b) (4)

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

4.d Symptoms:

Date	Location	User	Value	Reason
Jan-28-2021 13:21:39 (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-28-2021 13:21:39 (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-28-2021 13:21:39 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptoms: NEW OR INCREASED MUSCLE PAIN Symptom Present: NO	Initial Entry

090177e196ae2ead\Final\Final On: 01-Apr-2021 03:20 (GMT)

Header Text: C4591001

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

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

Form Version: 14-Jan-2021 02:23

Form Status: Data Complete

Site No: 1231

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

Subject No: 12314583

Subject Initials: ---

Generated By: (b) (4)

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

4.e Symptoms:

Date	Location	User	Value	Reason
Jan-28-2021 13:21:39 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NEW OR INCREASED MU SCLE PAIN	Initial Entry

4.e Was symptom present?

Date	Location	User	Value	Reason
Jan-28-2021 13:21:39 (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-28-2021 13:21:39 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptoms: NEW LOSS OF T ASTE OR SMEL L Symptom Present: YES	Initial Entry

090177e196ae2ead\Final\Final On: 01-Apr-2021 03:20 (GMT)

Header Text: C4591001

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

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

Form Version: 14-Jan-2021 02:23

Form Status: Data Complete

Site No: 1231

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

Subject No: 12314583

Subject Initials: ---

Generated By: (b) (4)

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

4.f Symptoms:

Date	Location	User	Value	Reason
Jan-28-2021 13:21:39 (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
Jan-28-2021 13:21:39 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

4.g

Date	Location	User	Value	Reason
Jan-28-2021 13:21:39 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptoms: NEW OR INCREASED SORE THROAT Symptom Present: NO	Initial Entry

090177e196ae2ead\Final\Final On: 01-Apr-2021 03:20 (GMT)

Header Text: C4591001

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

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

Form Version: 14-Jan-2021 02:23

Form Status: Data Complete

Site No: 1231

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

Subject No: 12314583

Subject Initials: ---

Generated By: (b) (4)

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

4.g Symptoms:

Date	Location	User	Value	Reason
Jan-28-2021 13:21:39 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NEW OR INCREASED SO RE THROAT	Initial Entry

4.g Was symptom present?

Date	Location	User	Value	Reason
Jan-28-2021 13:21:39 (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-28-2021 13:21:39 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptoms: DIARRHEA Symptom Present: NO	Initial Entry

090177e196ae2ead\Final\Final On: 01-Apr-2021 03:20 (GMT)

Header Text: C4591001**Visit:** POT_COVID_ILL 2 - Unscheduled
Visit on Jan/27/2021**Form:** SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 -
eCRF Audit Trail History**Form Version:** 14-Jan-2021 02:23**Form Status:** Data Complete**Site No:** 1231**Site Name:** (1231) Hospital Militar Central Cirujano Mayor Dr.
Cosme Argerich**Subject No:** 12314583**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 20:34**4.h Symptoms:**

Date	Location	User	Value	Reason
Jan-28-2021 13:21:39 (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-28-2021 13:21:39 (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-28-2021 13:21:39 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptoms: VOMITIN G Symptom Present: NO	Initial Entry

Header Text: C4591001

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

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

Form Version: 14-Jan-2021 02:23

Form Status: Data Complete

Site No: 1231

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

Subject No: 12314583

Subject Initials: ---

Generated By: (b) (4)

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

4.i Symptoms:

Date	Location	User	Value	Reason
Jan-28-2021 13:21:39 (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-28-2021 13:21:39 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

5.a

Date	Location	User	Value	Reason
Jan-28-2021 13:21:53 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptoms - Other Headache	Initial Entry

5.a Symptoms - Other Text:

Date	Location	User	Value	Reason
Jan-28-2021 13:21:53 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Headache	Initial Entry

090177e196ae2ead\Final\Final On: 01-Apr-2021 03:20 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 2 - Unscheduled **Form:** MICROBIOLOGY SPECIMEN - Audit Trail
Visit on Jan/27/2021

Form Version: 06-Jul-2020 21:54

Form Status:

Site No: 1231

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

Subject No: 12314583

Subject Initials: ---

Generated By: (b) (4)

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

[Back to Form](#)

Date	Location	User	Value	Reason
Jan-28-2021 13:22:34 (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: MICROBIOLOGY SPECIMEN - eCRF Audit Trail History

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete

Site No: 1231

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

Subject No: 12314583

Subject Initials: ---

Generated By: (b) (4)

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

[Back to Form](#)

1. Actual Date of Collection:

Date	Location	User	Value	Reason
Jan-28-2021 13:22:34 (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-28-2021 13:22:34 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: SWABBED MATERIAL	Initial Entry

3. Specimen Collection Location:

Date	Location	User	Value	Reason
Jan-28-2021 13:22:34 (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-28-2021 13:22:34 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SEVERE ACUTE RESP SYN DROME CORONAVIRUS 2	Initial Entry

5. Device Type:

Date	Location	User	Value	Reason
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090177e196ae2ead\Final\Final On: 01-Apr-2021 03:20 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 2 - Unscheduled **Form:** MICROBIOLOGY SPECIMEN - eCRF Audit Trail History
Visit on Jan/27/2021

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete

Site No: 1231

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

Subject No: 12314583

Subject Initials: ---

Generated By: (b) (4)

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

Jan-28-2021 13:22:34 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SARS-COV-2 DIAGNOSTIC TEST	Initial Entry
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6. Trade Name:

Date	Location	User	Value	Reason
Jan-28-2021 13:22:34 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: ATILA BIOSYSTEMS IAM P COVID-19 DETECTION KIT	Initial Entry

7. Test Result:

Date	Location	User	Value	Reason
Jan-28-2021 13:22:34 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: POSITIVE	Initial Entry

090177e196ae2ead\Final\Final On: 01-Apr-2021 03:20 (GMT)

Header Text: C4591001**Visit:** POT_COVID_ILL 2 - Unscheduled
Visit on Jan/27/2021**Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB
SELF - eCRF Audit Trail History**Form Version:** 22-Apr-2020 21:03**Form Status:** Data Complete, Frozen, Verified**Site No:** 1231**Site Name:** (1231) Hospital Militar Central Cirujano Mayor Dr.
Cosme Argerich**Subject No:** 12314583**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 20:34[Back to Form](#)**1. Data Origin**

Date	Location	User	Value	Reason
Jan-28-2021 13:22:52 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Jan-28-2021 13:22:52 (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-28-2021 13:22:52 (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
Jan-28-2021 13:22:52 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample collected by team ph ysician	Initial Entry

Header Text: C4591001**Visit:** POT_COVID_ILL 2 - Unscheduled
Visit on Jan/27/2021**Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB -
eCRF Audit Trail History**Form Version:** 22-Apr-2020 21:03**Form Status:** Data Complete, Frozen, Verified**Site No:** 1231**Site Name:** (1231) Hospital Militar Central Cirujano Mayor Dr.
Cosme Argerich**Subject No:** 12314583**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 20:34[Back to Form](#)**1. Data Origin**

Date	Location	User	Value	Reason
Jan-28-2021 13:23:04 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Jan-28-2021 13:23:04 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: NASAL_SWAB	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Jan-28-2021 15:47:47 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Jan-28-2021 13:23:04 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Jan-28-2021 13:23:04 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Date of Collection: Jan/27/2021	Initial Entry

Header Text: C4591001

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

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1231

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

Subject No: 12314583

Subject Initials: ---

Generated By: (b) (4)

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

5.a

Date	Location	User	Value	Reason
Jan-28-2021 15:47:47 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BPW6JB	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Jan-28-2021 15:47:47 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BPW6JB	Initial Entry

090177e196ae2ead\Final\Final On: 01-Apr-2021 03:20 (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**Site No:** 1231**Site Name:** (1231) Hospital Militar Central Cirujano Mayor Dr.
Cosme Argerich**Subject No:** 12314583**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 20:34[Back to Form](#)**I.a**

Date	Location	User	Value	Reason
Jan-28-2021 13:23:22 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Type of Practitioner: SPECIALIST Occurrence of Visits or Contacts: NO	Initial Entry

I.a Physician or Healthcare Professional:

Date	Location	User	Value	Reason
Jan-28-2021 13:23:22 (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-28-2021 13:23:22 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

I.b

Date	Location	User	Value	Reason
Jan-28-2021 13:23:22 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Type of Practitioner: EMERGENCY ROOM	Initial Entry

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
Site No: 1231
Site Name: (1231) Hospital Militar Central Cirujano Mayor Dr. Cosme Argerich
Subject No: 12314583
Subject Initials: ---
Generated By: (b) (4)
Generated Time (GMT): 29-Mar-2021 20:34

			Occurrence of Visits or Contacts: NO
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I.b Physician or Healthcare Professional:

Date	Location	User	Value	Reason
Jan-28-2021 13:23:22 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: EMERGENCY ROOM	Initial Entry

I.b Occurrence of Visits or Contacts:

Date	Location	User	Value	Reason
Jan-28-2021 13:23:22 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

I.c

Date	Location	User	Value	Reason
Jan-28-2021 13:23:22 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Type of Practitioner: PRIMARY CARE PHYSICIAN Occurrence of Visits or Contacts: NO	Initial Entry

090177e196ae2ead\Final\Final On: 01-Apr-2021 03:20 (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**Site No:** 1231**Site Name:** (1231) Hospital Militar Central Cirujano Mayor Dr.
Cosme Argerich**Subject No:** 12314583**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 20:34***I.c Physician or Healthcare Professional:***

Date	Location	User	Value	Reason
Jan-28-2021 13:23:22 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: PRIMARY CARE PHYSICI AN	Initial Entry

I.c Occurrence of Visits or Contacts:

Date	Location	User	Value	Reason
Jan-28-2021 13:23:22 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

I.d

Date	Location	User	Value	Reason
Jan-28-2021 13:23:22 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Type of Practitioner: URGENT CARE Occurrence of Visits or Contacts: NO	Initial Entry

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

Site No: 1231

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

Subject No: 12314583

Subject Initials: ---

Generated By: (b) (4)

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

1.d Physician or Healthcare Professional:

Date	Location	User	Value	Reason
Jan-28-2021 13:23:22 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: URGENT CARE	Initial Entry

1.d Occurrence of Visits or Contacts:

Date	Location	User	Value	Reason
Jan-28-2021 13:23:22 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

1.e

Date	Location	User	Value	Reason
Jan-28-2021 13:23:22 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Type of Practitioner: TELEPHONE CONSULTATION Occurrence of Visits or Contacts: NO	Initial Entry

090177e196ae2ead\Final\Final On: 01-Apr-2021 03:20 (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

Site No: 1231

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

Subject No: 12314583

Subject Initials: ---

Generated By: (b) (4)

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

I.e Physician or Healthcare Professional:

Date	Location	User	Value	Reason
Jan-28-2021 13:23:22 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: TELEPHONE CONSULTATION	Initial Entry

I.e Occurrence of Visits or Contacts:

Date	Location	User	Value	Reason
Jan-28-2021 13:23:22 (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-28-2021 13:23:22 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Type of Practitioner: OTH ER Occurrence of Visits or Contacts: NO	Initial Entry

090177e196ae2ead\Final\Final On: 01-Apr-2021 03:20 (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

Site No: 1231

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

Subject No: 12314583

Subject Initials: ---

Generated By: (b) (4)

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

I.f Physician or Healthcare Professional:

Date	Location	User	Value	Reason
Jan-28-2021 13:23:22 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: OTHER	Initial Entry

I.f Occurrence of Visits or Contacts:

Date	Location	User	Value	Reason
Jan-28-2021 13:23:22 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

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

Date	Location	User	Value	Reason
Jan-28-2021 13:23:22 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

090177e196ae2ead\Final\Final On: 01-Apr-2021 03:20 (GMT)

Header Text: C4591001

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

Form: ILLNESS DETAILS - eCRF Audit Trail History

Form Version: 06-Jul-2020 21:52

Form Status: Data Complete

Site No: 1231

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

Subject No: 12314583

Subject Initials: ---

Generated By: (b) (4)

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

[Back to Form](#)

1. Category of Clinical Event:

Date	Location	User	Value	Reason
Jan-28-2021 13:23:53 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: POTENTIAL COVID-19 ILL NESS	Initial Entry

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

Date	Location	User	Value	Reason
Feb-05-2021 11:16:11 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES <i>Respiratory Illness Diagnosis:</i> Mild COV ID-1 9 illn ess Date of Diag nosis: Jan/2 7/20 21	Transcription Error
Jan-28-2021 23:54:29 (UTC-03:00)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	PFETMS Oracle (b) (4)	Query 1 : Closed	Discrepancy has been closed.

090177e196ae2ead\Final\Final On: 01-Apr-2021 03:20 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 2 - Unscheduled **Form:** ILLNESS DETAILS - eCRF Audit Trail History
Visit on Jan/27/2021

Form Version: 06-Jul-2020 21:52 **Form Status:** Data Complete

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

Subject No: 12314583 **Subject Initials:** ---

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

City of Buenos Aires				
Jan-28-2021 21:23:15 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1 : Answered	Transcription Error
Jan-28-2021 21:23:15 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	Santiago Corradetti (b) (4)	Data Entry: YES <i>Respiratory Illness Diagnosis:</i> Mild COVID-19 illness Date of Diagnosis: Jan/28/2021	Transcription Error
Jan-28-2021 15:20:27 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000.InFormAdapter.Discrepancy	PFETMS Oracle (b) (4)	Query 1 : Opened	Clarify MILD COVID ILLNESS as follows...The term appears incomplete. Are you

090177e196ae2ead\Final\Final On: 01-Apr-2021 03:20 (GMT)

Header Text: C4591001
Visit: POT_COVID_ILL 2 - Unscheduled **Form:** ILLNESS DETAILS - eCRF Audit Trail History
 Visit on Jan/27/2021
Form Version: 06-Jul-2020 21:52 **Form Status:** Data Complete
Site No: 1231 **Site Name:** (1231) Hospital Militar Central Cirujano Mayor Dr. Cosme Argerich
Subject No: 12314583 **Subject Initials:** ---
Generated By: (b) (4) **Generated Time (GMT):** 29-Mar-2021 20:34

				reporting MILD COVID-19 ILLNESS? If so, update the verbatim term as such. Otherwise clarify and edit the term. Thank you.
Jan-28-2021 13:23:53 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES <i>Respiratory Illness Diagnosis:</i> Mild COVID illness Date of Diagnosis: Jan/28/2021	Initial Entry

3. Toxicity Grade:

Date	Location	User	Value	Reason
Jan-28-2021 13:23:53 (UTC-03:00) City of	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 1	Initial Entry

Header Text: C4591001

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

Form: ILLNESS DETAILS - eCRF Audit Trail History

Form Version: 06-Jul-2020 21:52

Form Status: Data Complete

Site No: 1231

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

Subject No: 12314583

Subject Initials: ---

Generated By: (b) (4)

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

Buenos Aires

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

Header Text: C4591001

Visit: POT_COVID_CONVA 1 -
Unscheduled Visit on Jan/19/2021

Form Version: 22-Apr-2020 21:04

Site No: 1231

Subject No: 12314583

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

[Back to Form](#)

1. Date of Visit

Date	Location	User	Value	Reason
Jan-20-2021 12:22:34 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Jan/19/2021	Initial Entry

3. COVID-19 Illness Visit:

Date	Location	User	Value	Reason
Jan-20-2021 12:22:34 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: COVID_A1	Initial Entry

090177e196ae2ead\Final\Final On: 01-Apr-2021 03:20 (GMT)

Header Text: C4591001

Visit: POT_COVID_CONVA 1 -
Unscheduled Visit on Jan/19/2021

Form Version: 22-Apr-2020 21:03

Site No: 1231

Subject No: 12314583

Generated By: (b) (4)

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

Form Status: Data Complete, Frozen, Verified

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

Subject Initials: ---

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

[Back to Form](#)

1. Data Origin

Date	Location	User	Value	Reason
Jan-20-2021 12:22:43 (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-20-2021 12:22:43 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SERUM	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Jan-20-2021 14:52:17 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Jan-20-2021 12:22:43 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Jan-20-2021 12:22:43 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Date of Collection: Jan/19/2021	Initial Entry

090177e196ae2ead\Final\Final On: 01-Apr-2021 03:20 (GMT)

Header Text: C4591001

Visit: POT_COVID_CONVA 1 -
Unscheduled Visit on Jan/19/2021

Form Version: 22-Apr-2020 21:03

Site No: 1231

Subject No: 12314583

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

5.a

Date	Location	User	Value	Reason
Jan-20-2021 14:52:17 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BRYTCF	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Jan-20-2021 14:52:17 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BRYTCF	Initial Entry

5.b

Date	Location	User	Value	Reason
Jan-20-2021 14:52:49 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BRYTCG	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Jan-20-2021 14:52:49 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BRYTCG	Initial Entry

5.c

Date	Location	User	Value	Reason
Jan-20-2021 16:11:24 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BRYT9J	Initial Entry

090177e196ae2ead\Final\Final On: 01-Apr-2021 03:20 (GMT)

Header Text: C4591001

Visit: POT_COVID_CONVA 1 -
Unscheduled Visit on Jan/19/2021

Form Version: 22-Apr-2020 21:03

Site No: 1231

Subject No: 12314583

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

5.c Sample ID

Date	Location	User	Value	Reason
Jan-20-2021 16:11:24 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BRYT9J	Initial Entry

5.d

Date	Location	User	Value	Reason
Jan-20-2021 16:24:04 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BPWBF6	Initial Entry

5.d Sample ID

Date	Location	User	Value	Reason
Jan-20-2021 16:24:04 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BPWBF6	Initial Entry

090177e196ae2ead\Final\Final On: 01-Apr-2021 03:20 (GMT)

Header Text: C4591001

Visit: POT_COVID_CONVA 2 -
Unscheduled Visit on Mar/05/2021

Form Version: 22-Apr-2020 21:04

Site No: 1231

Subject No: 12314583

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

[Back to Form](#)

1. Date of Visit

Date	Location	User	Value	Reason
Mar-05-2021 10:43:50 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	Martina Davalli (b) (4)	Data Entry: Mar/5/2021	Initial Entry

3. COVID-19 Illness Visit:

Date	Location	User	Value	Reason
Mar-05-2021 10:43:50 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	Martina Davalli (b) (4)	Data Entry: COVID_B1	Initial Entry

090177e196ae2ead\Final\Final On: 01-Apr-2021 03:20 (GMT)

Header Text: C4591001

Visit: POT_COVID_CONVA 2 -
Unscheduled Visit on Mar/05/2021

Form Version: 22-Apr-2020 21:03

Site No: 1231

Subject No: 12314583

Generated By: (b) (4)

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

Form Status: Data Complete, Frozen, Verified

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

Subject Initials: ---

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

[Back to Form](#)

1. Data Origin

Date	Location	User	Value	Reason
Mar-05-2021 10:44:02 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Mar-05-2021 10:44:02 (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-05-2021 15:40:34 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Mar-05-2021 10:44:02 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Mar-05-2021 10:44:02 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	Martina Davalli (b) (4)	Data Entry: YES Date of Collection: Mar/5/2021	Initial Entry

090177e196ae2ead\Final\Final On: 01-Apr-2021 03:20 (GMT)

Header Text: C4591001

Visit: POT_COVID_CONVA 2 -
Unscheduled Visit on Mar/05/2021

Form Version: 22-Apr-2020 21:03

Site No: 1231

Subject No: 12314583

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

5.a

Date	Location	User	Value	Reason
Mar-05-2021 15:40:34 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BR22Z6	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Mar-05-2021 15:40:34 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BR22Z6	Initial Entry

5.b

Date	Location	User	Value	Reason
Mar-05-2021 15:44:49 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	Alan Colombo (b) (4)	Data Entry: Sample ID: BLBHC7	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Mar-05-2021 15:44:49 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	Alan Colombo (b) (4)	Data Entry: BLBHC7	Initial Entry

5.c

Date	Location	User	Value	Reason
Mar-05-2021	ACV0PFEINFP6000	Alan Colombo	Data Entry:	Initial Entry

090177e196ae2ead\Final\Final On: 01-Apr-2021 03:20 (GMT)

Header Text: C4591001

Visit: POT_COVID_CONVA 2 -
Unscheduled Visit on Mar/05/2021

Form Version: 22-Apr-2020 21:03

Site No: 1231

Subject No: 12314583

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

17:02:41 (UTC-03:00) City of Buenos Aires	(b) (4)	Sample ID: BLBHGDG
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5.c Sample ID

Date	Location	User	Value	Reason
Mar-05-2021 17:02:41 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	Alan Colombo (b) (4)	Data Entry: BLBHGDG	Initial Entry

Header Text: C4591001

Visit: End of Treatment - Unscheduled

Form Version: 15-Sep-2020 21:55

Site No: 1231

Subject No: 12314583

Generated By: (b) (4)

Form: DISPOSITION - TREATMENT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

[Back to Form](#)

1. Date of Completion/Discontinuation/Death :

Date	Location	User	Value	Reason
Oct-19-2020 17:20:51 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Oct/19/2020	Initial Entry

2. Phase of Disposition:

Date	Location	User	Value	Reason
Oct-19-2020 17:20:51 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: VACCINATION	Initial Entry

3. Status:

Date	Location	User	Value	Reason
Oct-19-2020 17:20:51 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: COMPLETED	Initial Entry

090177e196ae2ead\Final\Final On: 01-Apr-2021 03:20 (GMT)

Header Text: C4591001

Visit: Potential ReVax Initial Contact -
Unscheduled

Form: DATE OF VISIT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1231

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

Subject No: 12314583

Subject Initials: ---

Generated By: (b) (4)

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

[Back to Form](#)

1. Date of Visit

Date	Location	User	Value	Reason
Mar-10-2021 12:48:36 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Mar/10/2021	Initial Entry

Header Text: C4591001

Visit: Potential ReVax Initial Contact -
Unscheduled

Form Version: 10-Dec-2020 02:25

Site No: 1231

Subject No: 12314583

Generated By: (b) (4)

Form: FURTHER VACCINATION CONFIRMATION - 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. Select appropriate response - Is participant willing to return for Vaccination 3?

Date	Location	User	Value	Reason
Mar-10-2021 12:48:46 (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 other protocol allowance(s) and confirmed to have received only placebo at Vaccination 1/2	Initial Entry

Header Text: C4591001

Visit: V101_VAX3

Form Version: 22-Apr-2020 21:02

Site No: 1231

Subject No: 12314583

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
Mar-14-2021 10:31:04 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Mar/13/2021	Initial Entry

Header Text: C4591001

Visit: V101_VAX3

Form: INFORMED CONSENT - FURTHER VACCINATION - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:31

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1231

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

Subject No: 12314583

Subject Initials: ---

Generated By: (b) (4)

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

[Back to Form](#)

I. Consent Was:

Date	Location	User	Value	Reason
Mar-14-2021 10:31:13 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: OBTAINED Date Written Consent Obtained Mar/13/2021	Initial Entry

Header Text: C4591001

Visit: V101_VAX3

Form: DISPOSITION - SCREENING FOR FURTHER VACCINATION - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:31

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1231

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

Subject No: 12314583

Subject Initials: ---

Generated By: (b) (4)

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

[Back to Form](#)

1. Date of Completion/Discontinuation/Death :

Date	Location	User	Value	Reason
Mar-14-2021 10:31:40 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Mar/13/2021	Initial Entry

2. Phase of Disposition:

Date	Location	User	Value	Reason
Mar-14-2021 10:31:40 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: REPEAT SCREENING 1	Initial Entry

3. Status:

Date	Location	User	Value	Reason
Mar-14-2021 10:31:40 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: COMPLETED	Initial Entry

090177e196ae2ead\Final\Final On: 01-Apr-2021 03:20 (GMT)

Header Text: C4591001

Visit: V101_VAX3

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

Form Version: 20-Feb-2021 02:14

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1231

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

Subject No: 12314583

Subject Initials: ---

Generated By: (b) (4)

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

[Back to Form](#)

1. Lab Panel:

Date	Location	User	Value	Reason
Mar-14-2021 10:33:02 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: URINALYSIS	Initial Entry

2. Lab Sub-Panel:

Date	Location	User	Value	Reason
Mar-14-2021 10:33:02 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: PREGNANCY	Initial Entry

3. Collection Date:

Date	Location	User	Value	Reason
Mar-14-2021 10:33:02 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Mar/13/2021	Initial Entry

4. Laboratory Name and Address (Derived)

Date	Location	User	Value	Reason
Mar-14-2021 10:33:02 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: STUDY SITE	Initial Entry

5. Specimen Type:

Date	Location	User	Value	Reason
Mar-14-2021 10:33:02 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: URINE	Initial Entry

090177e196ae2ead\Final\Final On: 01-Apr-2021 03:20 (GMT)

Header Text: C4591001

Visit: V101_VAX3

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

Form Version: 20-Feb-2021 02:14

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1231

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

Subject No: 12314583

Subject Initials: ---

Generated By: (b) (4)

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

6.a

Date	Location	User	Value	Reason
Mar-14-2021 10:33:02 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sponsor-Def 113 ined Identifier: Test:: Choriogonadotropin Beta_PX 113 Result:: NEGATIVE Not Done::	Initial Entry

6.a Sponsor ID:

Date	Location	User	Value	Reason
Mar-14-2021 10:33:02 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 113	Initial Entry

6.a Test:

Date	Location	User	Value	Reason
Mar-14-2021 10:33:02 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Choriogonadotropin Beta_PX 113	Initial Entry

6.a Result:

Date	Location	User	Value	Reason
Mar-14-2021 10:33:02 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NEGATIVE	Initial Entry

090177e196ae2ead\Final\Final On: 01-Apr-2021 03:20 (GMT)

Header Text: C4591001

Visit: V101_VAX3

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1231

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

Subject No: 12314583

Subject Initials: ---

Generated By: (b) (4)

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

[Back to Form](#)

1. Data Origin

Date	Location	User	Value	Reason
Mar-14-2021 10:33:33 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Mar-14-2021 10:33:33 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SERUM	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Mar-15-2021 10:41:14 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Mar-15-2021 06:32:46 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Mar-14-2021 10:33:33 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please

090177e196ae2ead\Final\Final On: 01-Apr-2021 03:20 (GMT)

Header Text: C4591001

Visit: V101_VAX3

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1231

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

Subject No: 12314583

Subject Initials: ---

Generated By: (b) (4)

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

				review and correct as appropriate.
Mar-14-2021 10:33:33 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Date of Collection: Mar/13/2021	Initial Entry

5.a

Date	Location	User	Value	Reason
Mar-15-2021 10:41:14 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	Alan Colombo (b) (4)	Data Entry: Sample ID: BPT659	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Mar-15-2021 10:41:14 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	Alan Colombo (b) (4)	Data Entry: BPT659	Initial Entry

5.b

Date	Location	User	Value	Reason
Mar-15-2021 10:44:03 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BRYH4B	Initial Entry

090177e196ae2ead\Final\Final On: 01-Apr-2021 03:20 (GMT)

Header Text: C4591001

Visit: V101_VAX3

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1231

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

Subject No: 12314583

Subject Initials: ---

Generated By: (b) (4)

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

5.b Sample ID

Date	Location	User	Value	Reason
Mar-15-2021 10:44:03 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BRYH4B	Initial Entry

5.c

Date	Location	User	Value	Reason
Mar-15-2021 11:12:15 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BRYH2V	Initial Entry

5.c Sample ID

Date	Location	User	Value	Reason
Mar-15-2021 11:12:15 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BRYH2V	Initial Entry

090177e196ae2ead\Final\Final On: 01-Apr-2021 03:20 (GMT)

Header Text: C4591001

Visit: V101_VAX3

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1231

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

Subject No: 12314583

Subject Initials: ---

Generated By: (b) (4)

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

[Back to Form](#)

1. Data Origin

Date	Location	User	Value	Reason
Mar-14-2021 10:33:51 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Mar-14-2021 10:33:51 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: NASAL_SWAB	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Mar-15-2021 09:10:05 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Mar-15-2021 06:32:46 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Mar-14-2021 10:33:51 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please

090177e196ae2ead\Final\Final On: 01-Apr-2021 03:20 (GMT)

Header Text: C4591001

Visit: V101_VAX3

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1231

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

Subject No: 12314583

Subject Initials: ---

Generated By: (b) (4)

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

				review and correct as appropriate.
Mar-14-2021 10:33:51 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Date of Collection: Mar/13/2021	Initial Entry

5.a

Date	Location	User	Value	Reason
Mar-15-2021 09:10:05 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	Alan Colombo (b) (4)	Data Entry: Sample ID: BR1LKT	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Mar-15-2021 09:10:05 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	Alan Colombo (b) (4)	Data Entry: BR1LKT	Initial Entry

090177e196ae2ead\Final\Final On: 01-Apr-2021 03:20 (GMT)

Header Text: C4591001

Visit: V101_VAX3

Form Version: 10-Dec-2020 02:26

Site No: 1231

Subject No: 12314583

Generated By: (b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

[Back to Form](#)

1. Was there a temporary delay of vaccination?

Date	Location	User	Value	Reason
Mar-14-2021 10:32:12 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2. Treatment Name

Date	Location	User	Value	Reason
Mar-14-2021 10:32:12 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: BNT162b2	Initial Entry

3. Formulation:

Date	Location	User	Value	Reason
Mar-14-2021 10:32:12 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: INJECTION	Initial Entry

4. Dose Date Time:

Date	Location	User	Value	Reason
Mar-14-2021 10:32:12 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Mar/13/2021 16:17	Initial Entry

5. Anatomical Location:

Date	Location	User	Value	Reason
Mar-14-2021 10:32:12 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: DELTOID MUSCLE	Initial Entry

090177e196ae2ead\Final\Final On: 01-Apr-2021 03:20 (GMT)

Header Text: C4591001

Visit: V101_VAX3

Form Version: 10-Dec-2020 02:26

Site No: 1231

Subject No: 12314583

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

6. Body Side:

Date	Location	User	Value	Reason
Mar-14-2021 10:32:12 (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-14-2021 10:32:12 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: INTRAMUSCULAR	Initial Entry

8. Actual Dose:

Date	Location	User	Value	Reason
Mar-14-2021 10:32:12 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 30.0	Initial Entry

9. Unit:

Date	Location	User	Value	Reason
Mar-14-2021 10:32:12 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: ug	Initial Entry

10. Timeframe Subject Was Observed

Date	Location	User	Value	Reason
Mar-14-2021 10:32:12 (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?

090177e196ae2ead\Final\Final On: 01-Apr-2021 03:20 (GMT)

Header Text: C4591001

Visit: V101_VAX3

Form Version: 10-Dec-2020 02:26

Site No: 1231

Subject No: 12314583

Generated By: (b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

Date	Location	User	Value	Reason
Mar-14-2021 10:32:12 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

Header Text: C4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1231

Subject No: 12314583

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - Audit Trail

Form Status:

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

Subject Initials: ---

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

[Back to Form](#)

Date	Location	User	Value	Reason
Oct-16-2020 17:40:57 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Created	

Header Text: C4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1231

Subject No: 12314583

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - Audit Trail

Form Status:

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

Subject Initials: ---

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

[Back to Form](#)

Date	Location	User	Value	Reason
Dec-03-2020 12:23:24 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Created	

Header Text: C4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1231

Subject No: 12314583

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

[Back to Form](#)

1. Category:

Date	Location	User	Value	Reason
Oct-16-2020 17:40:57 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: ADVERSE EVENT	Initial Entry

2. AE ID:

Date	Location	User	Value	Reason
Oct-16-2020 17:40:57 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 1	Initial Entry

3. Adverse Event:

(If possible specify diagnosis, not individual symptoms)

Date	Location	User	Value	Reason
Oct-16-2020 17:40:57 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Epigastralgia	Initial Entry

4. Start Date Time:

Date	Location	User	Value	Reason
Oct-16-2020 17:40:57 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Oct/15/2020 06:30	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Oct-21-2020 19:31:52 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	New Information

090177e196ae2ead\Final\Final On: 01-Apr-2021 03:20 (GMT)

Header Text: C4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1231

Subject No: 12314583

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

Buenos Aires		(b) (4), (b) (6)	End Date Time: Oct/19/2020 17:00	
Oct-19-2020 15:46:23 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	New Information
Oct-16-2020 17:40:57 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO End Date Time: Oct/15/2020 06:40	Initial Entry

6. Toxicity Grade:

Date	Location	User	Value	Reason
Oct-16-2020 17:40:57 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 1	Initial Entry

7. Is the adverse event serious?

If Yes, NOTIFY PFIZER IMMEDIATELY.

Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).

Date	Location	User	Value	Reason
Oct-16-2020 17:40:57 (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
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090177e196ae2ead\Final\Final On: 01-Apr-2021 03:20 (GMT)

Header Text: C4591001**Visit:** Logs - Unscheduled**Form Version:** 22-Apr-2020 21:02**Site No:** 1231**Subject No:** 12314583**Generated By:** (b) (4)**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History**Form Status:** Data Complete, Locked, Frozen, Verified**Site Name:** (1231) Hospital Militar Central Cirujano Mayor Dr. Cosme Argerich**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 20:34

Oct-16-2020 17:40:57 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry
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9. Is this event related to study treatment:

Date	Location	User	Value	Reason
Oct-16-2020 17:40:57 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NOT RELATED If Not Related to study treatment(s), this event is due to: OTHER <i>If Other, specify:</i> unknown	Initial Entry

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Oct-16-2020 17:40:57 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NOT APPLICABLE	Initial Entry

11. Was a Concomitant Medication given?

Date	Location	User	Value	Reason
Oct-16-2020 17:40:57 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
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Header Text: C4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1231

Subject No: 12314583

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

Oct-16-2020 17:40:57 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry
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13. What was the outcome of this adverse event?:

Date	Location	User	Value	Reason
Oct-23-2020 12:22:00 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Closed	Close Auto Query
Oct-23-2020 12:22:00 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: RECOVERED/RESOLVED	New Information
Oct-21-2020 19:31:52 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Opened	For AE Epigastralgia: Response to "What was the outcome of this adverse event?" is 'Recovering/Resolving' but AE End Date/Time is present.
Oct-19-2020 15:47:26 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Oct-19-2020 15:47:26 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: RECOVERING/RESOLVING	New Information
Oct-19-2020 15:46:23 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	For AE Epigastralgia: Response to "What was the outcome of this adverse event?" is 3 but End Date/Time is

090177e196ae2ead\Final\Final On: 01-Apr-2021 03:20 (GMT)

Header Text: C4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1231

Subject No: 12314583

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

				missing.
Oct-16-2020 17:40:57 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: RECOVERED/RESOLVED	Initial Entry

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

Date	Location	User	Value	Reason
Oct-16-2020 17:40:57 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

090177e196ae2ead\Final\Final On: 01-Apr-2021 03:20 (GMT)

Header Text: C4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1231

Subject No: 12314583

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen

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

Subject Initials: ---

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

[Back to Form](#)

1. Category:

Date	Location	User	Value	Reason
Dec-03-2020 12:23:24 (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
Dec-03-2020 12:23:24 (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
Dec-18-2020 13:34:26 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 4: Closed	Response satisfies query
Dec-18-2020 11:27:41 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 4: Answered	Epicrisis and the results of the complementary studies carried out were not given to the volunteer, therefore, more specific information cannot be provided.

090177e196ae2ead\Final\Final On: 01-Apr-2021 03:20 (GMT)

Header Text: C4591001**Visit:** Logs - Unscheduled**Form Version:** 22-Apr-2020 21:02**Site No:** 1231**Subject No:** 12314583**Generated By:** (b) (4)**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History**Form Status:** Data Complete, Locked, Frozen**Site Name:** (1231) Hospital Militar Central Cirujano Mayor Dr. Cosme Argerich**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 20:34

Dec-17-2020 22:17:07 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Clo sed	Response satisfies query
Dec-17-2020 15:26:15 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	Santiago Corradetti (b) (4)	Query 3: An swere d	Subject does not have an eating disorder. Thank you.
Dec-17-2020 12:00:35 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Op ened	Clinical SAE report states that event started following an episode of binge eating; please clarify if subject has an eating disorder
Dec-16-2020 22:45:07 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 4: Op ened	CLINICAL With followup & event resolved, has further information clarified the etiology of Pancreatitis? Can relevant lab/imaging information from hospitalization be added to SAE now.
Dec-16-2020 22:43:15	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Ca	Clinical SAE report states that

Header Text: C4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1231

Subject No: 12314583

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen

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

Subject Initials: ---

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

(UTC-03:00) City of Buenos Aires			ndidate	event started following an episode of binge eating; please clarify if subject has an eating disorder
Dec-10-2020 13:58:38 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Closed	Query closed; will follow for SAE update with the requested info on pancreatitis evaluation in 21 yr old
Dec-10-2020 13:53:25 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Answered	I clarify that discharge summary/study reports were not provided to the patient, therefore specific information about complementary studies and treatment cannot be provided at this time. Further FU will be provided as soon as available.
Dec-09-2020 12:38:27 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Opened	CLINICAL Please submit a SAE followup with clinical course

090177e196ae2ead\Final\Final On: 01-Apr-2021 03:20 (GMT)

Header Text: C4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1231

Subject No: 12314583

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen

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

Subject Initials: ---

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

Aires				information (diagnostic ie labs, ultrasound, other), treatment and diagnostic opinion if etiology was identified
Dec-04-2020 13:11:24 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000.InFormAdapter.Discrepancy	PFETMS Oracle (b) (4)	Query 1: Closed	Discrepancy has been closed.
Dec-04-2020 10:26:35 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	New Information
Dec-04-2020 10:26:35 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry : acute pancreatitis	New Information
Dec-03-2020 13:53:57 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000.InFormAdapter.Discrepancy	PFETMS Oracle (b) (4)	Query 1: Opened	Clarify UNKNOWN as follow...Term appears incomplete. Are you reporting UNKNOWN DIAGNOSIS? UNKNOWN DIAGNOSTIC PROCEDURE? UNKNOWN

090177e196ae2ead\Final\Final On: 01-Apr-2021 03:20 (GMT)

Header Text: C4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1231

Subject No: 12314583

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen

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

Subject Initials: ---

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

				THERAPEUTIC PROCEDURE? Please edit and clarify further. Thank you.
Dec-03-2020 12:23:24 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry : unknown	Initial Entry

4. Start Date Time:

Date	Location	User	Value	Reason
Dec-04-2020 10:26:54 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Nov/30/2020 22:00	New Information
Dec-03-2020 12:23:24 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Dec/2/2020 10:00	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Dec-15-2020 10:33:50 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO End Date Time: Dec/14/2020 18:00	New Information
Dec-03-2020 12:23:24 (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
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090177e196ae2ead\Final\Final On: 01-Apr-2021 03:20 (GMT)

Header Text: C4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Locked, Frozen

Site No: 1231

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

Subject No: 12314583

Subject Initials: ---

Generated By: (b) (4)

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

Dec-03-2020 12:23:24 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 2	Initial Entry
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7. Is the adverse event serious?

If Yes, NOTIFY PFIZER IMMEDIATELY.

Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).

Date	Location	User	Value	Reason
Dec-10-2020 13:59:45 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Closed	Clinical – Thank you. If NO hospital COVID test was performed is known, please submit this information on a follow-up SAE form, as pertinent information for this trial.
Dec-10-2020 13:53:41 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Answered	I clarify that Covid testing was not performed because the AE is not related to COVID illness.
Dec-09-2020 12:32:15 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Opened	Clinical COVID test status (yes/no) during Hosp was not reported in the SAE. Please submit a follow-up SAE

090177e196ae2ead\Final\Final On: 01-Apr-2021 03:20 (GMT)

Header Text: C4591001
Visit: Logs - Unscheduled
Form Version: 22-Apr-2020 21:02
Site No: 1231
Subject No: 12314583
Generated By: (b) (4)

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

				form [#2020478859] to document if COVID testing was performed (YES/NO or info not available) and if yes, the date and results.
Dec-07-2020 08:00:14 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Dec-04-2020 10:27:17 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Is this serious event associated with congenital a nomaly 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	New Information

090177e196ae2ead\Final\Final On: 01-Apr-2021 03:20 (GMT)

Header Text: C4591001**Visit:** Logs - Unscheduled**Form Version:** 22-Apr-2020 21:02**Site No:** 1231**Subject No:** 12314583**Generated By:** (b) (4)**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History**Form Status:** Data Complete, Locked, Frozen**Site Name:** (1231) Hospital Militar Central Cirujano Mayor Dr. Cosme Argerich**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 20:34

			<p>Is this serious event life threatening?</p> <p>NO</p> <p>Other medically important serious event</p> <p>YES</p>	
Dec-04-2020 10:26:35 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	For AE acute pancreatitis: Response to "Is the adverse event serious?" is 'Yes' but "Serious Adverse Event Number" is blank.
Dec-03-2020 12:23:24 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	For AE unknown: Response to "Is the adverse event serious?" is 'Yes' but "Serious Adverse Event Number" is blank.
Dec-03-2020 12:23:24 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<p>Data Entry:</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 re</p>	Initial Entry

Header Text: C4591001**Visit:** Logs - Unscheduled**Form Version:** 22-Apr-2020 21:02**Site No:** 1231**Subject No:** 12314583**Generated By:** (b) (4)**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History**Form Status:** Data Complete, Locked, Frozen**Site Name:** (1231) Hospital Militar Central Cirujano Mayor Dr.
Cosme Argerich**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 20:34

			quire or prolong hospital ization? YES Did this serious event re sult in persistent or signi ficant disability/incapaci ty? NO Is this serious event life threatening? NO Other medically importa nt serious event 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
Dec-03-2020 12:23:24 (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
Dec-03-2020 12:23:24 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NOT RELATED If Not Related to study treat ment(s), this event is due to: OTHER	Initial Entry

Header Text: C4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1231

Subject No: 12314583

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen

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

Subject Initials: ---

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

				<i>If Other, specify:</i>
				unknown

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Dec-03-2020 12:23:24 (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
Dec-04-2020 10:27:35 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	New Information
Dec-03-2020 12:23:24 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Dec-03-2020 12:23:24 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

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

Date	Location	User	Value	Reason
Dec-15-2020 14:12:40 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Closed	Close Auto Query

090177e196ae2ead\Final\Final On: 01-Apr-2021 03:20 (GMT)

Header Text: C4591001**Visit:** Logs - Unscheduled**Form Version:** 22-Apr-2020 21:02**Site No:** 1231**Subject No:** 12314583**Generated By:** (b) (4)**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History**Form Status:** Data Complete, Locked, Frozen**Site Name:** (1231) Hospital Militar Central Cirujano Mayor Dr. Cosme Argerich**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 20:34

Dec-15-2020 14:12:40 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	Santiago Corradetti (b) (4)	Data Entry: RECOVERED/RESO LVED	New Information
Dec-15-2020 10:33:50 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Opened	For AE acute pancreatitis: Response to "What was the outcome of this adverse event?" is 'Recovering/Resolving' but AE End Date/Time is present.
Dec-04-2020 10:27:53 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Dec-04-2020 10:27:53 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: RECOVERING/RES OLVING	New Information
Dec-04-2020 10:26:35 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	For AE acute pancreatitis: Response to "What was the outcome of this adverse event?" is 'Unknown' but End Date/Time is provided or "Is the adverse event still ongoing?" is marked "Yes".
Dec-03-2020 12:23:24 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	For AE unknown: Response to "What was the outcome of this adverse event?" is 'Unknown' but End Date/Time is provided or "Is the adverse

Header Text: C4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1231

Subject No: 12314583

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen

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

Subject Initials: ---

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

				event still ongoing?" is marked "Yes".
Dec-03-2020 12:23:24 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: UNKNOWN	Initial Entry

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

Date	Location	User	Value	Reason
Dec-03-2020 12:23:24 (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
Dec-07-2020 08:00:14 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 2020478859	Initial Entry

090177e196ae2ead\Final\Final On: 01-Apr-2021 03:20 (GMT)

Header Text: C4591001

Visit: Disposition - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1231

Subject No: 12314583

Generated By: (b) (4)

Form: TREATMENT UNBLINDED - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

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

Subject Initials: ---

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

[Back to Form](#)

1. Date Treatment Unblinded :

Date	Location	User	Value	Reason
Mar-10-2021 12:48:23 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Mar/10/2021	Initial Entry

2. Primary Reason for Unblinding:

Date	Location	User	Value	Reason
Mar-10-2021 12:48:23 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: ASSESS ELIGIBILITY FOR ADDITIONAL VACCINATION	Initial Entry

090177e196ae2ead\Final\Final On: 01-Apr-2021 03:20 (GMT)

Header Text: C4591001

Visit: Subject Status - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1231

Subject No: 12314583

Generated By: (b) (4)

Form: SUBJECT STATUS - eCRF Audit Trail History

Form Status: Data Complete, Verified

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

Subject Initials: ---

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

[Back to Form](#)

1. Subject Status

Date	Location	User	Value	Reason
Oct-19-2020 17:20:51 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: FOLLOW-UP	Initial Entry
Aug-27-2020 18:23:57 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: ENROLLED/RANDOMIZED	Initial Entry
Aug-27-2020 18:22:32 (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-19-2020 17:20:51 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Oct/19/2020	Initial Entry
Aug-27-2020 18:23:57 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Aug/27/2020	Initial Entry
Aug-27-2020 18:22:32 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Aug/27/2020	Initial Entry

090177e196ae2ead\Final\Final On: 01-Apr-2021 03:20 (GMT)

Header Text: C4591001

Visit: Investigator Signature - Unscheduled **Form:** CASEBOOK SIGNATURE FORM - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Signed, Verified

Site No: 1231

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

Subject No: 12314583

Subject Initials: ---

Generated By: (b) (4)

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

[Back to Form](#)

1. Casebook Signature

Date	Location	User	Value	Reason
Oct-23-2020 18:51:44 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Click Here to Enable	Initial Entry