

**Header Text:** C4591001

**Visit:** COHORT\_SELECTION

**Form:** COHORT\_SELECTION

**Form Version:** 30-Jul-2020 21:29

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site No:** 1231

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

**Subject No:** 12314233

**Subject Initials:** ---

**Generated By:**

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

(b) (4)

[eCRF Audit Trail History](#)

**Cohort Selection**

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

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

090177e196ae2eda\Final\Final On: 01-Apr-2021 03:25 (GMT)

**Header Text:** C4591001

**Visit:** COHORT\_SELECTION

**Form Version:** 22-Apr-2020 21:02

**Site No:** 1231

**Subject No:** 12314233

**Generated By:**

(b) (4)

**Form:** MAIN INFORMED CONSENT

**Form Status:** Data Complete, Locked, Frozen, Verified

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

**Subject Initials:** ---

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

[eCRF Audit Trail History](#)

**Informed Consent**

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

**Visit:** COHORT\_SELECTION

**Form:** DEMOGRAPHY

**Form Version:** 06-Jul-2020 21:55

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site No:** 1231

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

**Subject No:** 12314233

**Subject Initials:** ---

**Generated By:**

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

(b) (4)

[eCRF Audit Trail History](#)

**Demography**

1.	Subject ID	[12314233]
2.	Birth Date:	(b) (6)/1958
3.	Sex:	MALE
4.	Ethnicity:	HISPANIC OR LATINO(A) OR OF SPANISH ORIGIN
5.	Race: (Check X all that apply):	WHITE
6.	Racial Designation:	

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**Header Text:** C4591001

**Visit:** V1\_DAY1\_VAX1\_L

**Form Version:** 22-Apr-2020 21:02

**Site No:** 1231

**Subject No:** 12314233

**Generated By:**

(b) (4)

**Form:** DATE OF VISIT

**Form Status:** Data Complete, Locked, Frozen, Verified

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

**Subject Initials:** ---

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

[eCRF Audit Trail History](#)

**Date of Visit**

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

**Header Text:** C4591001

**Visit:** V1\_DAY1\_VAX1\_L

**Form Version:** 30-Jul-2020 21:29

**Site No:** 1231

**Subject No:** 12314233

**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 _____
----	--	-------------------------

090177e196ae2eda\Final\Final On: 01-Apr-2021 03:25 (GMT)

**Header Text:** C4591001

**Visit:** V1\_DAY1\_VAX1\_L

**Form Version:** 22-Apr-2020 21:03

**Site No:** 1231

**Subject No:** 12314233

**Generated By:**

(b) (4)

**Form:** DISPOSITION - SCREENING

**Form Status:** Data Complete, Locked, Frozen, Verified

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

**Subject Initials:** ---

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

[eCRF Audit Trail History](#)

**Disposition - Screening**

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

**Header Text:** C4591001

**Visit:** V1\_DAY1\_VAX1\_L

**Form Version:** 22-Apr-2020 21:03

**Site No:** 1231

**Subject No:** 12314233

**Generated By:**

(b) (4)

**Form:** GENERAL MEDICAL HISTORY

**Form Status:** Data Complete, Locked, Frozen, Verified

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

**Subject Initials:** ---

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

[eCRF Audit Trail History](#)

**Medical History Details**

1.a	Line/MH Number:	[1]
	Disease/Syndrome /Surgery/Non-Drug Allergies/Drug Allergies:	[Non-hodking lymphoma]
	Start Date:	Mar/19/2013
	Ongoing:	NO End Date: Nov/30/2013

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**Header Text:** C4591001**Visit:** V1\_DAY1\_VAX1\_L**Form Version:** 21-Aug-2020 02:51**Site No:** 1231**Subject No:** 12314233**Generated By:**

(b) (4)

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

1.	Date:	Aug/26/2020
2.	Weight:	[91.0]
3.	Unit:	kg
4.	Height:	[182.0]
5.	Unit:	cm
6.	Body Mass Index:	[27.5]

**Vital Signs Details**

7.a	Record Identifier:	1
	Temperature:	[36.5]
	Unit:	C
	Temperature Location:	ORAL CAVITY



**Header Text:** C4591001

**Visit:** V1\_DAY1\_VAX1\_L

**Form Version:** 22-Apr-2020 21:03

**Site No:** 1231

**Subject No:** 12314233

**Generated By:**

(b) (4)

**Form:** RANDOMIZATION

**Form Status:** Data Complete, Locked, Frozen, Verified

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

**Subject Initials:** ---

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

[eCRF Audit Trail History](#)

**Disposition**

1.	Randomization Date :	Aug/26/2020
2.	Randomization Number:	[241678]
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:** 12314233

**Subject Initials:** ---

**Generated By:**

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

(b) (4)

[eCRF Audit Trail History](#)

**Electronic Sample Tracking**

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

**Aliquot**

Please enter barcode for each aliquot.

5.a	Sample ID	[BNV25M]
5.b	Sample ID	[BNV25N]
5.c	Sample ID	[BPTFC6]
5.d	Sample ID	[BPTFC7]
5.e	Sample ID	[BPTFC8]

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**Header Text:** C4591001

**Visit:** V1\_DAY1\_VAX1\_L

**Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB

**Form Version:** 22-Apr-2020 21:03

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site No:** 1231

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

**Subject No:** 12314233

**Subject Initials:** ---

**Generated By:**

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

(b) (4)

[eCRF Audit Trail History](#)

**Electronic Sample Tracking**

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

**Aliquot**

Please enter barcode for each aliquot.

5.a	Sample ID	[BPT9S9]
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090177e196ae2eda\Final\Final On: 01-Apr-2021 03:25 (GMT)

**Header Text:** C4591001

**Visit:** V1\_DAY1\_VAX1\_L

**Form Version:** 22-Apr-2020 21:04

**Site No:** 1231

**Subject No:** 12314233

**Generated By:**

(b) (4)

**Form:** VACCINATION

**Form Status:** Data Complete, Locked, Frozen, Verified

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

**Subject Initials:** ---

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

[eCRF Audit Trail History](#)

**Vaccination**

1.	Was there a temporary delay of vaccination?	NO
2.	Treatment Name	[BLINDED THERAPY]
3.	Formulation:	INJECTION
4.	Dose Date Time:	Aug/26/2020 15:07
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

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**Header Text:** C4591001

**Visit:** V1\_DAY1\_VAX1\_L

**Form Version:** 06-Jul-2020 21:53

**Site No:** 1231

**Subject No:** 12314233

**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:** 12314233

**Generated By:**

(b) (4)

**Form:** DATE OF VISIT

**Form Status:** Data Complete, Locked, Frozen, Verified

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

**Subject Initials:** ---

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

[eCRF Audit Trail History](#)

**Date of Visit**

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

**Header Text:** C4591001

**Visit:** V2\_VAX2\_L

**Form:** VITAL SIGNS - TEMP

**Form Version:** 15-Sep-2020 21:54

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site No:** 1231

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

**Subject No:** 12314233

**Subject Initials:** ---

**Generated By:**

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

(b) (4)

[eCRF Audit Trail History](#)

**Vital Signs**

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

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

090177e196ae2eda\Final\Final On: 01-Apr-2021 03:25 (GMT)

**Header Text:** C4591001

**Visit:** V2\_VAX2\_L

**Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB

**Form Version:** 22-Apr-2020 21:03

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site No:** 1231

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

**Subject No:** 12314233

**Subject Initials:** ---

**Generated By:**

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

(b) (4)

[eCRF Audit Trail History](#)

**Electronic Sample Tracking**

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

**Aliquot**

Please enter barcode for each aliquot.

5.a	Sample ID	[BP2FLJ]
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**Header Text:** C4591001

**Visit:** V2\_VAX2\_L

**Form Version:** 22-Apr-2020 21:04

**Site No:** 1231

**Subject No:** 12314233

**Generated By:**

(b) (4)

**Form:** VACCINATION

**Form Status:** Data Complete, Locked, Frozen, Verified

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

**Subject Initials:** ---

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

[eCRF Audit Trail History](#)

**Vaccination**

1.	Was there a temporary delay of vaccination?	NO
2.	Treatment Name	[BLINDED THERAPY]
3.	Formulation:	INJECTION
4.	Dose Date Time:	Sep/14/2020 12:15
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

090177e196ae2eda\Final\Final On: 01-Apr-2021 03:25 (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:** 12314233 **Subject Initials:** ---

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

(b) (4)

[eCRF Audit Trail History](#)

**Date of Visit**

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

**Header Text:** C4591001

**Visit:** V3\_MONTH1\_POSTVAX2\_L **Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

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

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

**Subject No:** 12314233 **Subject Initials:** ---

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

(b) (4)

[eCRF Audit Trail History](#)

**Electronic Sample Tracking**

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

**Aliquot**

Please enter barcode for each aliquot.

5.a	Sample ID	[BP1NLY]
5.b	Sample ID	[BRXS5S]
5.c	Sample ID	[BRXS6M]

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**Header Text:** C4591001

**Visit:** V4\_MONTH6\_L

**Form Version:** 22-Apr-2020 21:02

**Site No:** 1231

**Subject No:** 12314233

**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:** V4\_MONTH6\_L

**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

**Form Version:** 22-Apr-2020 21:03

**Form Status:** Not Started

**Site No:** 1231

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

**Subject No:** 12314233

**Subject Initials:** ---

**Generated By:**

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

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**Electronic Sample Tracking**

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

**Aliquot**

Please enter barcode for each aliquot.

5.	Sample ID	[ ]
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**Header Text:** C4591001

**Visit:** V5\_MONTH12\_L

**Form Version:** 22-Apr-2020 21:02

**Site No:** 1231

**Subject No:** 12314233

**Generated By:**

(b) (4)

**Form:** DATE OF VISIT

**Form Status:** Not Started

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

**Subject Initials:** ---

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

**Date of Visit**

1.	Date of Visit	//
2.	Erroneous Visit	

**Header Text:** C4591001

**Visit:** V5\_MONTH12\_L

**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

**Form Version:** 22-Apr-2020 21:03

**Form Status:** Not Started

**Site No:** 1231

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

**Subject No:** 12314233

**Subject Initials:** ---

**Generated By:**

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

(b) (4)

**Electronic Sample Tracking**

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

**Aliquot**

Please enter barcode for each aliquot.

5.	Sample ID	[ ]
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090177e196ae2eda\Final\Final On: 01-Apr-2021 03:25 (GMT)

**Header Text:** C4591001

**Visit:** V6\_MONTH24\_L

**Form Version:** 22-Apr-2020 21:02

**Site No:** 1231

**Subject No:** 12314233

**Generated By:**

(b) (4)

**Form:** DATE OF VISIT

**Form Status:** Not Started

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

**Subject Initials:** ---

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

**Date of Visit**

1.	Date of Visit	//
2.	Erroneous Visit	



**Header Text:** C4591001

**Visit:** V6\_MONTH24\_L

**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

**Form Version:** 22-Apr-2020 21:03

**Form Status:** Not Started

**Site No:** 1231

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

**Subject No:** 12314233

**Subject Initials:** ---

**Generated By:**

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

(b) (4)

**Electronic Sample Tracking**

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

**Aliquot**

Please enter barcode for each aliquot.

5.	Sample ID	[ ]
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090177e196ae2eda\Final\Final On: 01-Apr-2021 03:25 (GMT)

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Jan/12/2021

**Form Version:** 22-Apr-2020 21:03

**Site No:** 1231

**Subject No:** 12314233

**Generated By:**

(b) (4)

**Form:** DATE OF VISIT - ILLNESS ONSET

**Form Status:** Data Complete, Frozen, Verified

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

**Subject Initials:** ---

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

[eCRF Audit Trail History](#)

**Date of Visit**

1.	Date of Visit	Jan/12/2021
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 Jan/12/2021

**Form Version:** 14-Jan-2021 02:23

**Site No:** 1231

**Subject No:** 12314233

**Generated By:**

(b) (4)

**Form:** SIGNS AND SYMPTOMS OF POTENTIAL  
COVID-19

**Form Status:** Data Complete

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

**Subject Initials:** ---

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

[eCRF Audit Trail History](#)

**Signs and Symptoms**

1.	Date of Assessment:	Jan/12/2021
2.	Date of First Symptom Started:	Jan/11/2021
3.	Symptoms Ongoing?	NO Date of Last Symptom Resolved: Jan/12/2021

**Symptoms**

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

090177e196ae2eda\Final\Final On: 01-Apr-2021 03:25 (GMT)

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Jan/12/2021

**Form Version:** 14-Jan-2021 02:23

**Site No:** 1231

**Subject No:** 12314233

**Generated By:**

(b) (4)

**Form:** SIGNS AND SYMPTOMS OF POTENTIAL  
COVID-19

**Form Status:** Data Complete

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

**Subject Initials:** ---

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

4.f	Symptoms:	NEW LOSS OF TASTE OR SMELL
	Was symptom present?	NO
4.g	Symptoms:	NEW OR INCREASED SORE THROAT
	Was symptom present?	NO
4.h	Symptoms:	DIARRHEA
	Was symptom present?	YES
4.i	Symptoms:	VOMITING
	Was symptom present?	NO
<b>Symptoms - Other</b>		
5.a	Symptoms - Other Text:	[headache]
5.b	Symptoms - Other Text:	[asthenia]
5.c	Symptoms - Other Text:	[nasal congestion]

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**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1

**Form:** MICROBIOLOGY SPECIMEN

**Form Version:** 06-Jul-2020 21:54

**Site No:** 1231

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

**Subject No:** 12314233

**Subject Initials:** ---

**Generated By:**

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

(b) (4)

#	Date of Collection	Specimen Type	Specimen Collection Location	Assay Code and Description	Device Type	Form Instance
1.	Jan/12/2021	SWABBED MATERIAL	NASOPHARYNX	SEVERE ACUTE RESPIRATORY SYNDROME CORONAVIRUS 2	SARS-COV-2 DIAGNOSTIC TEST	<a href="#">Repeating Pages</a>

090177e196ae2eda\Final\Final On: 01-Apr-2021 03:25 (GMT)

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Jan/12/2021

**Form:** MICROBIOLOGY SPECIMEN

**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:** 12314233

**Subject Initials:** ---

**Generated By:**

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(b) (4)

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**Microbiology Specimen**

1.	Actual Date of Collection:	Jan/12/2021
2.	Specimen Type:	SWABBED MATERIAL
3.	Specimen Collection Location:	NASOPHARYNX
4.	Assay Code and Description:	SEVERE ACUTE RESP SYNDROME CORONAVIRUS 2
5.	Device Type:	SARS-COV-2 DIAGNOSTIC TEST
6.	Trade Name:	ATILA BIOSYSTEMS IAMP COVID-19 DETECTION KIT
7.	Test Result:	NEGATIVE
8.	Comments/Findings /Details:	[ ]
9.	Trade Name Other, Specify:	[ ]

090177e196ae2eda\Final\Final On: 01-Apr-2021 03:25 (GMT)

**Header Text:** C4591001**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Jan/12/2021**Form Version:** 22-Apr-2020 21:03**Site No:** 1231**Subject No:** 12314233**Generated By:**

(b) (4)

**Form:** ELECTRONIC SAMPLE TRACKING - NASAL  
SWAB SELF**Form Status:** Data Complete, Frozen, Verified**Site Name:** (1231) Hospital Militar Central Cirujano  
Mayor Dr. Cosme Argerich**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 20:34[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 a team physician]

**Aliquot**

Please enter barcode for each aliquot.

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

**Header Text:** C4591001**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Jan/12/2021**Form Version:** 22-Apr-2020 21:03**Site No:** 1231**Subject No:** 12314233**Generated By:**

(b) (4)

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

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB
3.	Sample Collected?	YES Date of Collection: Jan/12/2021
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	[BPTBZM]
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**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Jan/12/2021

**Form Version:** 14-Jan-2021 02:24

**Site No:** 1231

**Subject No:** 12314233

**Generated By:**

(b) (4)

**Form:** HEALTH CARE UTILIZATION

**Form Status:** Data Complete

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

**Subject Initials:** ---

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

[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

090177e196ae2eda\Final\Final On: 01-Apr-2021 03:25 (GMT)

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Jan/12/2021

**Form:** HEALTH CARE UTILIZATION

**Form Version:** 14-Jan-2021 02:24

**Form Status:** Data Complete

**Site No:** 1231

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

**Subject No:** 12314233

**Subject Initials:** ---

**Generated By:**

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

(b) (4)

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

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1

**Form:** RESPIRATORY TREATMENT

**Form Version:** 06-Jul-2020 21:53

**Site No:** 1231

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

**Subject No:** 12314233

**Subject Initials:** ---

**Generated By:**

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

(b) (4)

#	Treatment Identifier	Con Non-Drug Treatments Pre-specified	Treatm ent	Treatm ent	Start D ate	Form Instanc e
1.						<a href="#">Repeating Pages</a>

090177e196ae2eda\Final\Final On: 01-Apr-2021 03:25 (GMT)

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Jan/12/2021

**Form Version:** 06-Jul-2020 21:53

**Site No:** 1231

**Subject No:** 12314233

**Generated By:**

(b) (4)

**Form:** RESPIRATORY TREATMENT

**Form Status:** Not Started

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

**Subject Initials:** ---

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

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**Respiratory Treatment**

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

090177e196ae2eda\Final\Final On: 01-Apr-2021 03:25 (GMT)

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Jan/12/2021

**Form Version:** 06-Jul-2020 21:52

**Site No:** 1231

**Subject No:** 12314233

**Generated By:**

(b) (4)

**Form:** ILLNESS DETAILS

**Form Status:** Data Complete

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

**Subject Initials:** ---

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

[eCRF Audit Trail History](#)

**Illness Details**

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

090177e196ae2eda\Final\Final On: 01-Apr-2021 03:25 (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:** 12314233

**Subject Initials:** ---

**Generated By:**

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

(b) (4)

#	Category of Clinical Event:	Subcategory of Clinical Event	Diagnosis Obtained	Toxicity Grade	Form Instance
1.					<a href="#">Repeating Pages</a>

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Jan/12/2021

**Form Version:** 17-Jul-2020 21:55

**Site No:** 1231

**Subject No:** 12314233

**Generated By:**

(b) (4)

**Form:** ILLNESS DETAILS - SEVERE

**Form Status:** Not Started

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

**Subject Initials:** ---

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

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**Illness Details**

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

090177e196ae2eda\Final\Final On: 01-Apr-2021 03:25 (GMT)

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1

**Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY

**Form Version:** 21-Aug-2020 02:49

**Site No:** 1231

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

**Subject No:** 12314233

**Subject Initials:** ---

**Generated By:**

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

(b) (4)

#	Category for Lab Test	Vendor Name	Collection Date:	Specimen Type	Lab Result			Form Instance
1.					Sponsor-Defined Identifier	Test:	Result:	<a href="#">Repeating Pages</a>

090177e196ae2eda\Final\Final On: 01-Apr-2021 03:25 (GMT)



**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Jan/12/2021

**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:** 12314233

**Subject Initials:** ---

**Generated By:**

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

(b) (4)

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**Lab Chemistry Details**

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

**Lab Result**

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

090177e196ae2eda\Final\Final On: 01-Apr-2021 03:25 (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:** 12314233

**Subject Initials:** ---

**Generated By:**

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

(b) (4)

#	Category for Lab Test	Vendor Name (DERIVED)	Collection Date	Specimen Type	Lab Result			Form Instance
1.					Sponsor-Defined Identifier	Test:	Result:	<a href="#">Repeating Pages</a>

090177e196ae2eda\Final\Final On: 01-Apr-2021 03:25 (GMT)

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Jan/12/2021

**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:** 12314233

**Subject Initials:** ---

**Generated By:**

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

(b) (4)

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**Laboratory Data Hematology**

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

**Lab Result**

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

090177e196ae2eda\Final\Final On: 01-Apr-2021 03:25 (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:** 12314233

**Subject Initials:** ---

**Generated By:**

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

(b) (4)

#	Date:	Vital Signs Details			Form Instance
1.		<b>Record Identifier:</b>	<b>Systolic:</b>	<b>Diastolic:</b>	<a href="#">Repeating Pages</a>

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Jan/12/2021

**Form:** VITAL SIGNS - COVID

**Form Version:** 21-Aug-2020 02:50

**Form Status:** Not Started

**Site No:** 1231

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

**Subject No:** 12314233

**Subject Initials:** ---

**Generated By:**

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

(b) (4)

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**Vital Signs**

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

**Vital Signs Details**

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

090177e196ae2eda\Final\Final On: 01-Apr-2021 03:25 (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:** 12314233

**Subject Initials:** ---

**Generated By:**

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

(b) (4)

#	Date:	Vital Signs Details		Form Instance
1.		<b>Record Identifier:</b>	<b>Oxygen Saturation</b>	<a href="#">Repeating Pages</a>

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Jan/12/2021

**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:** 12314233

**Subject Initials:** ---

**Generated By:**

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

(b) (4)

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**Vital Signs**

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

**Vital Signs Details**

2.	Record Identifier:	
	SPO2 Pulse Oximetry %	[ ]

090177e196ae2eda\Final\Final On: 01-Apr-2021 03:25 (GMT)

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1

**Form:** OXYGENATION PARAMETERS

**Form Version:** 06-Jul-2020 21:52

**Site No:** 1231

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

**Subject No:** 12314233

**Subject Initials:** ---

**Generated By:**

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

(b) (4)

#	Date Time of Assessment	Arterial Blood Gases PaO2	FiO2 (Fraction of Inhaled Oxygen)	Form Instance
1.				<a href="#">Repeating Pages</a>



**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Jan/12/2021

**Form Version:** 06-Jul-2020 21:52

**Site No:** 1231

**Subject No:** 12314233

**Generated By:**

(b) (4)

**Form:** OXYGENATION PARAMETERS

**Form Status:** Not Started

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

**Subject Initials:** ---

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

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**Oxygenation Parameters**

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

090177e196ae2eda\Final\Final On: 01-Apr-2021 03:25 (GMT)

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1

**Form:** CONCOMITANT MEDICATIONS -  
VASOPRESSORS

**Form Version:** 06-Jul-2020 21:55

**Site No:** 1231

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

**Subject No:** 12314233

**Subject Initials:** ---

**Generated By:**

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

(b) (4)

#	Sponsor-Defined Identifier	Category for Medication	Concomitant Medications Pre-specified	Name of Medication	Start Date	Form Instance
1.						<a href="#">Repeating Pages</a>

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Jan/12/2021

**Form Version:** 06-Jul-2020 21:55

**Site No:** 1231

**Subject No:** 12314233

**Generated By:**

(b) (4)

**Form:** CONCOMITANT MEDICATIONS -  
VASOPRESSORS

**Form Status:** Not Started

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

**Subject Initials:** ---

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

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**Concomitant Medications**

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

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**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1

**Form:** IMAGING

**Form Version:** 06-Jul-2020 21:53

**Site No:** 1231

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

**Subject No:** 12314233

**Subject Initials:** ---

**Generated By:**

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

(b) (4)

#	Date of Assessment	Location of Assessment	Imaging Method	Overall Assessment	Form Instance
1.					<a href="#">Repeating Pages</a>

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Jan/12/2021

**Form:** IMAGING

**Form Version:** 06-Jul-2020 21:53

**Form Status:** Not Started

**Site No:** 1231

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

**Subject No:** 12314233

**Subject Initials:** ---

**Generated By:**

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

(b) (4)

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**Imaging**

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

090177e196ae2eda\Final\Final On: 01-Apr-2021 03:25 (GMT)

**Header Text:** C4591001

**Visit:** POT\_COVID\_CONVA 1 -  
Unscheduled Visit on Feb/09/2021

**Form:** DATE OF VISIT - ILLNESS CONVALESCENT

**Form Version:** 22-Apr-2020 21:04

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1231

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

**Subject No:** 12314233

**Subject Initials:** ---

**Generated By:**

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

(b) (4)

[eCRF Audit Trail History](#)

**Date of Visit**

1.	Date of Visit	Feb/9/2021
2.	Erroneous Visit	

**COVID-19 Illness Visit**

3.	COVID-19 Illness Visit:	COVID_A1
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**Header Text:** C4591001**Visit:** POT\_COVID\_CONVA 1 -  
Unscheduled Visit on Feb/09/2021**Form Version:** 22-Apr-2020 21:03**Site No:** 1231**Subject No:** 12314233**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: Feb/9/2021
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	[BNTZ93]
5.b	Sample ID	[BPXWWC]
5.c	Sample ID	[BNTZF8]

**Header Text:** C4591001

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

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

**Site No:** 1231

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

**Subject No:** 12314233

**Subject Initials:** ---

**Generated By:**

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

(b) (4)

**Date of Visit**

1.	Date of Visit	//
2.	Erroneous Visit	



**Header Text:** C4591001

**Visit:** Unplanned - 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:** 12314233    **Subject Initials:** ---

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

(b) (4)

**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:** 12314233

**Subject Initials:** ---

**Generated By:**

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

(b) (4)

[eCRF Audit Trail History](#)

**Disposition - Treatment**

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

**Header Text:** C4591001

**Visit:** Follow-Up - Unscheduled

**Form Version:** 15-Sep-2020 21:53

**Site No:** 1231

**Subject No:** 12314233

**Generated By:**

(b) (4)

**Form:** DISPOSITION - FOLLOW-UP

**Form Status:** Not Started

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

**Subject Initials:** ---

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

**Disposition - Follow-Up**

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

**Header Text:** C4591001

**Visit:** POT\_COVID\_REPEAT\_SWAB **Form:** DATE OF VISIT - REPEAT SWAB  
- New Unscheduled Visit

**Form Version:** 10-Oct-2020 15:57

**Form Status:** Not Started

**Site No:** 1231

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

**Subject No:** 12314233

**Subject Initials:** ---

**Generated By:**

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

(b) (4)

**Date of Visit**

1.	Date of Visit	//
2.	Erroneous Visit	

**COVID-19 Repeat Swab**

3.	COVID-19 Repeat Swab:	
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**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:** 12314233**Subject Initials:** ---**Generated By:****Generated Time (GMT):** 29-Mar-2021 20:34

(b) (4)

**Electronic Sample Tracking**

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

**Aliquot**

Please enter barcode for each aliquot.

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

**Header Text:** C4591001

**Visit:** 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:** 12314233

**Subject Initials:** ---

**Generated By:**

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

(b) (4)

**Date of Visit**

1.	Date of Visit	//
2.	Erroneous Visit	

**Header Text:** C4591001

**Visit:** Unplanned Vaccination -  
Unscheduled

**Form:** VITAL SIGNS - TEMP

**Form Version:** 28-Mar-2021 02:28

**Form Status:** Not Started

**Site No:** 1231

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

**Subject No:** 12314233

**Subject Initials:** ---

**Generated By:**

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

(b) (4)

**Vital Signs**

1.	Date:	//
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**Vital Signs Details**

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

090177e196ae2eda\Final\Final On: 01-Apr-2021 03:25 (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:** 12314233

**Subject Initials:** ---

**Generated By:**

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

(b) (4)

**Vaccination**

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

090177e196ae2eda\Final\Final On: 01-Apr-2021 03:25 (GMT)



**Header Text:** C4591001

**Visit:** Unplanned Vaccination -  
Unscheduled

**Form Version:** 10-Oct-2020 15:57

**Site No:** 1231

**Subject No:** 12314233

**Generated By:**

(b) (4)

**Form:** CONTACT OUTCOME - MONTH 1

**Form Status:** Not Started

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

**Subject Initials:** ---

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

**Contact Outcome**

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

**Header Text:** C4591001

**Visit:** Unplanned Vaccination -  
Unscheduled

**Form:** CONTACT OUTCOME - MONTH 6

**Form Version:** 10-Oct-2020 16:01

**Form Status:** Not Started

**Site No:** 1231

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

**Subject No:** 12314233

**Subject Initials:** ---

**Generated By:**

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

(b) (4)

**Contact Outcome**

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

**Header Text:** C4591001

**Visit:** V201\_SURVEIL\_CONSENT - **Form:** DATE OF VISIT  
Unscheduled

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

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

**Subject No:** 12314233 **Subject Initials:** ---

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

(b) (4)

**Date of Visit**

1.	Date of Visit	//
2.	Erroneous Visit	

**Header Text:** C4591001

**Visit:** V201\_SURVEIL\_CONSENT -  
Unscheduled

**Form:** INFORMED CONSENT - ASYMPTOMATIC  
SURVEILLANCE

**Form Version:** 14-Jan-2021 02:29

**Form Status:** Not Started

**Site No:** 1231

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

**Subject No:** 12314233

**Subject Initials:** ---

**Generated By:**

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

(b) (4)

**Informed Consent - Asymptomatic Surveillance**

1.	Consent Was:	
----	--------------	--

**Header Text:** C4591001**Visit:** V201\_SURVEIL\_CONSENT -  
Unscheduled**Form:** ELECTRONIC SAMPLE TRACKING -  
IMMUNOGENICITY**Form Version:** 22-Apr-2020 21:03**Form Status:** Not Started**Site No:** 1231**Site Name:** (1231) Hospital Militar Central Cirujano  
Mayor Dr. Cosme Argerich**Subject No:** 12314233**Subject Initials:** ---**Generated By:****Generated Time (GMT):** 29-Mar-2021 20:34

(b) (4)

**Electronic Sample Tracking**

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

**Aliquot**

Please enter barcode for each aliquot.

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

**Header Text:** C4591001**Visit:** V201\_SURVEIL\_CONSENT -  
Unscheduled**Form:** ELECTRONIC SAMPLE TRACKING - NASAL  
SWAB**Form Version:** 22-Apr-2020 21:03**Form Status:** Not Started**Site No:** 1231**Site Name:** (1231) Hospital Militar Central Cirujano  
Mayor Dr. Cosme Argerich**Subject No:** 12314233**Subject Initials:** ---**Generated By:****Generated Time (GMT):** 29-Mar-2021 20:34

(b) (4)

**Electronic Sample Tracking**

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

**Aliquot**

Please enter barcode for each aliquot.

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

**Header Text:** C4591001

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

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

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

**Subject No:** 12314233      **Subject Initials:** ---

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

(b) (4)

**Date of Visit**

1.	Date of Visit	//
2.	Erroneous Visit	

**Header Text:** C4591001

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

**Form Version:** 10-Dec-2020 02:25      **Form Status:** Not Started

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

**Subject No:** 12314233      **Subject Initials:** ---

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

(b) (4)

**Further Vaccination Confirmation**

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



**Header Text:** C4591001

**Visit:** Logs

**Form:** ADVERSE EVENT REPORT

**Form Version:** 22-Apr-2020 21:02

**Site No:** 1231

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

**Subject No:** 12314233

**Subject Initials:** ---

**Generated By:**

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

(b) (4)

#	Category	AE Identifier	Adverse Event	Start Date	Is the Adverse Event Still Ongoing	Form Instance
1.	ADVERSE EVENT	1	Recurrence of Non-Hodgkin Lymphoma	Nov/20/2020 12:00	YES	<a href="#">Repeating Pages</a>

090177e196ae2eda\Final\Final On: 01-Apr-2021 03:25 (GMT)

**Header Text:** C4591001

**Visit:** Logs - Unscheduled

**Form Version:** 22-Apr-2020 21:02

**Site No:** 1231

**Subject No:** 12314233

**Generated By:**

(b) (4)

**Form:** ADVERSE EVENT REPORT

**Form Status:** Data Complete

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

**Subject Initials:** ---

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

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[Form Audit Trail](#)

### Adverse Event Report

1.	Category:	ADVERSE EVENT
2.	AE ID:	[1]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[Recurrence of Non-Hodgkin Lymphoma]
4.	Start Date Time:	Nov/20/2020 12:00
5.	Is the adverse event still ongoing?	YES
6.	Toxicity Grade:	2

090177e196ae2eda\Final\Final On: 01-Apr-2021 03:25 (GMT)

**Header Text:** C4591001

**Visit:** Logs - Unscheduled

**Form Version:** 22-Apr-2020 21:02

**Site No:** 1231

**Subject No:** 12314233

**Generated By:**

(b) (4)

**Form:** ADVERSE EVENT REPORT

**Form Status:** Data Complete

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

**Subject Initials:** ---

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

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

090177e196ae2eda\Final\Final On: 01-Apr-2021 03:25 (GMT)

**Header Text:** C4591001

**Visit:** Logs - Unscheduled

**Form:** ADVERSE EVENT REPORT

**Form Version:** 22-Apr-2020 21:02

**Form Status:** Data Complete

**Site No:** 1231

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

**Subject No:** 12314233

**Subject Initials:** ---

**Generated By:**

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

(b) (4)

10.	Latest Action Taken with Study Treatment:	NOT APPLICABLE
11.	Was a Concomitant Medication given?	NO
12.	Was a Non-Drug Treatment given?	NO
13.	What was the outcome of this adverse event?:	NOT RECOVERED/NOT 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	[2021036146]

090177e196ae2eda\Final\Final On: 01-Apr-2021 03:25 (GMT)

**Header Text:** C4591001

**Visit:** Logs

**Form:** MEDICATION ERROR

**Form Version:** 17-Jul-2020 21:54

**Site No:** 1231

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

**Subject No:** 12314233

**Subject Initials:** ---

**Generated By:**

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

(b) (4)

#	Category	Medication Error	Start Date	Is the medication error Still Ongoing	Study Medication Errors Action	Form Instance
1.						<a href="#">Repeating Pages</a>

**Header Text:** C4591001

**Visit:** Logs - Unscheduled

**Form:** MEDICATION ERROR

**Form Version:** 17-Jul-2020 21:54

**Form Status:** Not Started

**Site No:** 1231

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

**Subject No:** 12314233

**Subject Initials:** ---

**Generated By:**

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

(b) (4)

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**Medication Error**

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

090177e196ae2eda\Final\Final On: 01-Apr-2021 03:25 (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:** 12314233

**Subject Initials:** ---

**Generated By:**

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

(b) (4)

#	Sponsor-Defined Identifier	Category for Medication	Concomitant Medications Pre-specified	Name of Medication	Start Date	Form Instance
1.						<a href="#">Repeating Pages</a>

090177e196ae2eda\Final\Final On: 01-Apr-2021 03:25 (GMT)

**Header Text:** C4591001

**Visit:** Logs - Unscheduled

**Form:** CONCOMITANT MEDICATIONS - NON STUDY VACCINATIONS

**Form Version:** 22-Apr-2020 21:03

**Form Status:** Not Started

**Site No:** 1231

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

**Subject No:** 12314233

**Subject Initials:** ---

**Generated By:**

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

(b) (4)

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**Concomitant Medications**

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

090177e196ae2eda\Final\Final On: 01-Apr-2021 03:25 (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:** 12314233

**Subject Initials:** ---

**Generated By:**

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

(b) (4)

#	Sponsor-Defined Identifier	Category for Medication	Concomitant Medications Pre-specified	Name of Medication	Dose Description	Form Instance
1.						<a href="#">Repeating Pages</a>

**Header Text:** C4591001

**Visit:** Logs - Unscheduled

**Form:** CONCOMITANT MEDICATIONS - PROHIBITED

**Form Version:** 22-Apr-2020 21:03

**Form Status:** Not Started

**Site No:** 1231

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

**Subject No:** 12314233

**Subject Initials:** ---

**Generated By:**

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

(b) (4)

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**Concomitant Medications**

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

090177e196ae2eda\Final\Final On: 01-Apr-2021 03:25 (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:** 12314233

**Subject Initials:** ---

**Generated By:**

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

(b) (4)

#	Category	Treatment Identifier	Con Non-Drug Treatments Pre-specified	Treatment	Start Date	Form Instance
1.						<a href="#">Repeating Pages</a>

**Header Text:** C4591001

**Visit:** Logs - Unscheduled

**Form Version:** 22-Apr-2020 21:02

**Site No:** 1231

**Subject No:** 12314233

**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?	

090177e196ae2eda\Final\Final On: 01-Apr-2021 03:25 (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:** 12314233

**Subject Initials:** ---

**Generated By:**

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

(b) (4)

#	Transfusion Type	Date of Transfusion	Form Instance
1.			<a href="#">Repeating Pages</a>

**Header Text:** C4591001

**Visit:** Logs - Unscheduled

**Form:** TRANSFUSIONS

**Form Version:** 22-Apr-2020 21:03

**Form Status:** Not Started

**Site No:** 1231

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

**Subject No:** 12314233

**Subject Initials:** ---

**Generated By:**

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

(b) (4)

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

**Header Text:** C4591001

**Visit:**  
UNPLANNED\_BOOSTER\_CONTACT  
- Unscheduled

**Form:** DATE OF VISIT

**Form Version:** 22-Apr-2020 21:02

**Form Status:** Not Started

**Site No:** 1231

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

**Subject No:** 12314233

**Subject Initials:** ---

**Generated By:** (b) (4)

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

**Date of Visit**

1.	Date of Visit	//
2.	Erroneous Visit	

**Header Text:** C4591001

**Visit:**  
UNPLANNED\_BOOSTER\_CONTACT  
- Unscheduled

**Form:** BOOSTER DOSE TRIGGER FORM

**Form Version:** 20-Feb-2021 02:20

**Form Status:** Not Started

**Site No:** 1231

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

**Subject No:** 12314233

**Subject Initials:** ---

**Generated By:** (b) (4)

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

**Booster Dose Trigger Form**

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



**Header Text:** C4591001

**Visit:** Disposition - Unscheduled

**Form:** TREATMENT UNBLINDED

**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:** 12314233

**Subject Initials:** ---

**Generated By:**

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

(b) (4)

**Treatment Unblinded**

1.	Date Treatment Unblinded :	//
2.	Primary Reason for Unblinding:	

**Header Text:** C4591001

**Visit:** Disposition - Unscheduled

**Form Version:** 22-Apr-2020 21:03

**Site No:** 1231

**Subject No:** 12314233

**Generated By:**

(b) (4)

**Form:** WITHDRAWAL OF CONSENT

**Form Status:** Not Started

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

**Subject Initials:** ---

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

**Withdrawal Of Consent**

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

//

**Header Text:** C4591001

**Visit:** Disposition - Unscheduled

**Form Version:** 22-Apr-2020 21:03

**Site No:** 1231

**Subject No:** 12314233

**Generated By:**

(b) (4)

**Form:** DEATH DETAILS CODED

**Form Status:** Not Started

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

**Subject Initials:** ---

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

**Death Details**

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

**Cause of Death**

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

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**Header Text:** C4591001

**Visit:** Subject Status - Unscheduled

**Form:** SUBJECT STATUS

**Form Version:** 22-Apr-2020 21:03

**Form Status:** Data Complete, Verified

**Site No:** 1231

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

**Subject No:** 12314233

**Subject Initials:** ---

**Generated By:**

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

(b) (4)

[eCRF Audit Trail History](#)

**Subject Status**

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

**Header Text:** C4591001

**Visit:** Investigator Signature -  
Unscheduled

**Form Version:** 22-Apr-2020 21:04

**Site No:** 1231

**Subject No:** 12314233

**Generated By:**

(b) (4)

**Form:** CASEBOOK SIGNATURE FORM

**Form Status:** Data Complete, Signed, Verified

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

**Subject Initials:** ---

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

[eCRF Audit Trail History](#)

**Casebook Signature Form**

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

**Visit:** Investigator Signature -  
Unscheduled

**Form:** CASEBOOK SIGNATURE FORM

**Form Version:** 22-Apr-2020 21:04

**Form Status:** Data Complete, Signed, Verified

**Site No:** 1231

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

**Subject No:** 12314233

**Subject Initials:** ---

**Generated By:**

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

(b) (4)

[Audit Trail](#)

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

- CRF\_Sign

Name	Signature Meaning	Date	Type	Action
Maria Beretta	Approved	Feb-16-2021 13:09:38 (UTC-03:00) City of Buenos Aires	BOOK	Signed

**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.

**Header Text:** C4591001

**Visit:** V1\_DAY1\_VAX1\_L

**Form Version:** 30-Jul-2020 21:29

**Site No:** 1231

**Subject No:** 12314233

**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

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Item	Date	User	Comment
Form	Aug-26-2020 16:13:43 (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:** 12314233

**Subject Initials:** ---

**Generated By:**

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

(b) (4)

[Back to Form](#)

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

- CRF\_Sign

Name	Signature Meaning	Date	Type	Action
Maria Beretta	Approved	Feb-16-2021 13:09:38 (UTC-03:00) City of Buenos Aires	BOOK	Signed

**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.

(b) (6)	N/A	Feb-09-2021 11:15:18 (UTC-03:00) City of Buenos Aires		Edit - All signatures invalidated
---------	-----	--	--	-----------------------------------

**Affidavit:**

N/A

(b) (6)	Approved	Jan-22-2021 10:31:37 (UTC-03:00) City of Buenos Aires	BOOK	Signed
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090177e196ae2eda\Final\Final On: 01-Apr-2021 03:25 (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:** 12314233

**Subject Initials:** ---

**Generated By:**

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

(b) (4)

**Affidavit:**

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

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

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

(b) (6)	N/A	Jan-14-2021 13:49:33 (UTC-03:00) City of Buenos Aires		Edit - All signatures invalidated
---------	-----	--	--	-----------------------------------

**Affidavit:**

N/A

(b) (6)	Approved	Oct-21-2020 17:38:15 (UTC-03:00) City of Buenos Aires	BOOK	Signed
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090177e196ae2eda\Final\Final On: 01-Apr-2021 03:25 (GMT)

**Header Text:** C4591001

**Visit:** Investigator Signature -  
Unscheduled

**Form Version:** 22-Apr-2020 21:04

**Site No:** 1231

**Subject No:** 12314233

**Generated By:**

(b) (4)

**Form:** CASEBOOK SIGNATURE FORM - Signature  
History

**Form Status:** Data Complete, Signed, Verified

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

**Subject Initials:** ---

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

**Affidavit:**

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

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

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

**Header Text:** C4591001

**Visit:** COHORT\_SELECTION

**Form:** COHORT SELECTION - eCRF Audit Trail History

**Form Version:** 30-Jul-2020 21:29

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site No:** 1231

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

**Subject No:** 12314233

**Subject Initials:** ---

**Generated By:**

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

(b) (4)

[Back to Form](#)

*1. Select appropriate response - Protocol version*

Date	Location	User	Value	Reason
Aug-26-2020 16:12:40 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 24 JUL 2020	Initial Entry

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

Date	Location	User	Value	Reason
Aug-26-2020 16:12:40 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> STAGE 3 COHORTS	Initial Entry

090177e196ae2eda\Final\Final On: 01-Apr-2021 03:25 (GMT)

**Header Text:** C4591001

**Visit:** COHORT\_SELECTION

**Form Version:** 22-Apr-2020 21:02

**Site No:** 1231

**Subject No:** 12314233

**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

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**1. Consent Was:**

Date	Location	User	Value	Reason
Aug-26-2020 16:13:02 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> OBTAINED Date Written Consent Obtained  Aug/26/2020	Initial Entry

090177e196ae2eda\Final\Final On: 01-Apr-2021 03:25 (GMT)

**Header Text:** C4591001

**Visit:** COHORT\_SELECTION

**Form Version:** 06-Jul-2020 21:55

**Site No:** 1231

**Subject No:** 12314233

**Generated By:**

(b) (4)

**Form:** DEMOGRAPHY - eCRF Audit Trail History

**Form Status:** Data Complete, Locked, Frozen, Verified

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

**Subject Initials:** ---

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

[Back to Form](#)

**1. Subject ID**

Date	Location	User	Value	Reason
Aug-26-2020 14:06:54 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 12314233	Item copied from previous form

**2. Birth Date:**

Date	Location	User	Value	Reason
Aug-26-2020 14:06:46 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> (b) (6)/1958	Enrollment Entry

**3. Sex:**

Date	Location	User	Value	Reason
Aug-26-2020 16:13:18 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> MALE	Initial Entry

**4. Ethnicity:**

Date	Location	User	Value	Reason
Aug-26-2020	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>	Initial Entry

090177e196ae2eda\Final\Final On: 01-Apr-2021 03:25 (GMT)

**Header Text:** C4591001

**Visit:** COHORT\_SELECTION

**Form:** DEMOGRAPHY - eCRF Audit Trail History

**Form Version:** 06-Jul-2020 21:55

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site No:** 1231

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

**Subject No:** 12314233

**Subject Initials:** ---

**Generated By:**

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

(b) (4)

16:13:18 (UTC-03:00) City of Buenos Aires	(b) (4), (b) (6)	HISPANIC OR LATI NO(A) OR OF SPANI SH ORIGIN
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**5. Race: (Check X all that apply):**

Date	Location	User	Value	Reason
Aug-26-2020 16:13:18 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> WHITE	Initial Entry

090177e196ae2eda\Final\Final On: 01-Apr-2021 03:25 (GMT)

**Header Text:** C4591001

**Visit:** V1\_DAY1\_VAX1\_L

**Form Version:** 22-Apr-2020 21:02

**Site No:** 1231

**Subject No:** 12314233

**Generated By:**

(b) (4)

**Form:** DATE OF VISIT - eCRF Audit Trail History

**Form Status:** Data Complete, Locked, Frozen, Verified

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

**Subject Initials:** ---

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

[Back to Form](#)

*1. Date of Visit*

Date	Location	User	Value	Reason
Aug-26-2020 16:13:31 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Aug/26/2020	Initial Entry

090177e196ae2eda\Final\Final On: 01-Apr-2021 03:25 (GMT)

**Header Text:** C4591001

**Visit:** V1\_DAY1\_VAX1\_L

**Form Version:** 22-Apr-2020 21:03

**Site No:** 1231

**Subject No:** 12314233

**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

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**1. Date of Completion/Discontinuation/Death**

Date	Location	User	Value	Reason
Aug-26-2020 16:14:01 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Aug/26/2020	Initial Entry

**2. Phase of Disposition:**

Date	Location	User	Value	Reason
Aug-26-2020 16:14:01 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SCREENING	Initial Entry

**3. Status:**

Date	Location	User	Value	Reason
Aug-26-2020 16:14:01 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> COMPLETED	Initial Entry

090177e196ae2eda\Final\Final On: 01-Apr-2021 03:25 (GMT)



**Header Text:** C4591001**Visit:** V1\_DAY1\_VAX1\_L**Form Version:** 22-Apr-2020 21:03**Site No:** 1231**Subject No:** 12314233**Generated By:**

(b) (4)

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

Date	Location	User	Value	Reason
Aug-26-2020 16:19:13 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Line/MH</b> 1 <b>Number:</b> <b>Medical</b> Non-hodkin <b>History T</b> g lymphom <b>erm:</b> a <b>Start Dat</b> Mar/19/201 <b>e:</b> 3 <b>Ongoing:</b> NO End Date:  Nov/30/ 2013	Initial Entry

*1.a Line/MH Number:*

Date	Location	User	Value	Reason
Aug-26-2020 16:19:13 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 1	Initial Entry

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

Date	Location	User	Value	Reason
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**Header Text:** C4591001

**Visit:** V1\_DAY1\_VAX1\_L

**Form:** GENERAL MEDICAL HISTORY - eCRF Audit Trail History

**Form Version:** 22-Apr-2020 21:03

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site No:** 1231

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

**Subject No:** 12314233

**Subject Initials:** ---

**Generated By:**

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

(b) (4)

Aug-26-2020 16:19:13 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Non-hodking lymphoma	Initial Entry
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**1.a Start Date:**

Date	Location	User	Value	Reason
Aug-26-2020 16:19:13 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Mar/19/2013	Initial Entry

**1.a Ongoing:**

Date	Location	User	Value	Reason
Aug-26-2020 16:19:13 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO End Date: Nov/30/2013	Initial Entry

090177e196ae2eda\Final\Final On: 01-Apr-2021 03:25 (GMT)

**Header Text:** C4591001

**Visit:** V1\_DAY1\_VAX1\_L

**Form:** VITAL SIGNS - BASELINE - eCRF Audit Trail History

**Form Version:** 21-Aug-2020 02:51

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site No:** 1231

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

**Subject No:** 12314233

**Subject Initials:** ---

**Generated By:**

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

(b) (4)

[Back to Form](#)

**1. Date:**

Date	Location	User	Value	Reason
Aug-26-2020 16:19:58 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Aug/26/2020	Initial Entry

**2. Weight:**

Date	Location	User	Value	Reason
Aug-26-2020 16:19:58 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 91.0	Initial Entry

**3. Unit:**

Date	Location	User	Value	Reason
Aug-26-2020 16:19:58 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> kg	Initial Entry

**4. Height:**

Date	Location	User	Value	Reason
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090177e196ae2eda\Final\Final On: 01-Apr-2021 03:25 (GMT)

**Header Text:** C4591001

**Visit:** V1\_DAY1\_VAX1\_L

**Form:** VITAL SIGNS - BASELINE - eCRF Audit Trail History

**Form Version:** 21-Aug-2020 02:51

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site No:** 1231

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

**Subject No:** 12314233

**Subject Initials:** ---

**Generated By:**

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

(b) (4)

Aug-26-2020 16:19:58 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 182.0	Initial Entry
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**5. Unit:**

Date	Location	User	Value	Reason
Aug-26-2020 16:19:58 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> cm	Initial Entry

**6. Body Mass Index:**

Date	Location	User	Value	Reason
Aug-26-2020 16:19:58 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 27.5	Initial Entry

**7.a**

Date	Location	User	Value	Reason
Aug-26-2020 16:19:58 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Record Identifier:</b> 1 <b>Temperature:</b> 36.5	Initial Entry

090177e196ae2eda\Final\Final On: 01-Apr-2021 03:25 (GMT)

**Header Text:** C4591001

**Visit:** V1\_DAY1\_VAX1\_L

**Form:** VITAL SIGNS - BASELINE - eCRF Audit Trail History

**Form Version:** 21-Aug-2020 02:51

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site No:** 1231

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

**Subject No:** 12314233

**Subject Initials:** ---

**Generated By:**

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

(b) (4)

			<b>Temperatur C e Unit:</b> <b>Temperatur ORAL e Location: CAVIT : Y</b>	
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**7.a Record Identifier:**

Date	Location	User	Value	Reason
Aug-26-2020 16:19:58 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 1	Initial Entry

**7.a Temperature:**

Date	Location	User	Value	Reason
Aug-26-2020 16:19:58 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 36.5	Initial Entry

**7.a Unit:**

Date	Location	User	Value	Reason
Aug-26-2020 16:19:58 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> C	Initial Entry

090177e196ae2eda\Final\Final On: 01-Apr-2021 03:25 (GMT)

**Header Text:** C4591001

**Visit:** V1\_DAY1\_VAX1\_L

**Form:** VITAL SIGNS - BASELINE - eCRF Audit Trail History

**Form Version:** 21-Aug-2020 02:51

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site No:** 1231

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

**Subject No:** 12314233

**Subject Initials:** ---

**Generated By:**

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

(b) (4)

**7.a Temperature Location:**

Date	Location	User	Value	Reason
Aug-26-2020 16:19:58 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> ORAL CAVITY	Initial Entry

**Header Text:** C4591001

**Visit:** V1\_DAY1\_VAX1\_L

**Form Version:** 22-Apr-2020 21:03

**Site No:** 1231

**Subject No:** 12314233

**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-26-2020 16:20:17 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Aug/26/2020	Initial Entry

**2. Randomization Number:**

Date	Location	User	Value	Reason
Aug-26-2020 16:20:17 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 241678	Initial Entry

090177e196ae2eda\Final\Final On: 01-Apr-2021 03:25 (GMT)

**Header Text:** C4591001

**Visit:** V1\_DAY1\_VAX1\_L

**Form Version:** 22-Apr-2020 21:03

**Site No:** 1231

**Subject No:** 12314233

**Generated By:**

(b) (4)

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

**Form Status:** Data Complete, Locked, Frozen, Verified

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

**Subject Initials:** ---

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

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**1. Data Origin**

Date	Location	User	Value	Reason
Aug-26-2020 16:20:27 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SITE	Initial Entry

**2. Sample Type**

Date	Location	User	Value	Reason
Aug-26-2020 16:20:27 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SERUM	Initial Entry

**3. Sample Collected?**

Date	Location	User	Value	Reason
Aug-27-2020 08:44:30 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Aug-27-2020 02:18:20 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	'Sample Collected?' is Yes, however no barcodes

090177e196ae2eda\Final\Final On: 01-Apr-2021 03:25 (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:** 12314233

**Subject Initials:** ---

**Generated By:**

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

(b) (4)

				are entered. Please review and correct as appropriate.
Aug-26-2020 16:20:27 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Aug-26-2020 16:20:27 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES Date of Collection:  Aug/26/2020	Initial Entry

**5.a**

Date	Location	User	Value	Reason
Aug-27-2020 08:44:30 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample I</b> BNV25 <b>D:</b> M	Initial Entry

**5.a Sample ID**

Date	Location	User	Value	Reason
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090177e196ae2eda\Final\Final On: 01-Apr-2021 03:25 (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:** 12314233

**Subject Initials:** ---

**Generated By:**

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

(b) (4)

Aug-27-2020 08:44:30 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BNV25M	Initial Entry
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**5.b**

Date	Location	User	Value	Reason
Aug-27-2020 08:44:38 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample I</b> BNV25 <b>D:</b> N	Initial Entry

**5.b Sample ID**

Date	Location	User	Value	Reason
Aug-27-2020 08:44:38 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BNV25N	Initial Entry

**5.c**

Date	Location	User	Value	Reason
Aug-27-2020 17:17:17 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	Alan Colombo (b) (4)	<b>Data Entry:</b> <b>Sample I</b> BPTFC <b>D:</b> 6	Initial Entry

090177e196ae2eda\Final\Final On: 01-Apr-2021 03:25 (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:** 12314233

**Subject Initials:** ---

**Generated By:**

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

(b) (4)

**5.c Sample ID**

Date	Location	User	Value	Reason
Aug-27-2020 17:17:17 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	Alan Colombo (b) (4)	<b>Data Entry:</b> BPTFC6	Initial Entry

**5.d**

Date	Location	User	Value	Reason
Aug-27-2020 17:17:26 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	Alan Colombo (b) (4)	<b>Data Entry:</b> Sample I BPTFC D: 7	Initial Entry

**5.d Sample ID**

Date	Location	User	Value	Reason
Aug-27-2020 17:17:26 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	Alan Colombo (b) (4)	<b>Data Entry:</b> BPTFC7	Initial Entry

**5.e**

Date	Location	User	Value	Reason
Aug-27-2020 17:17:32 (UTC-03:00) City	ACV0PFEINFP6000	Alan Colombo (b) (4)	<b>Data Entry:</b> Sample I BPTFC D: 8	Initial Entry

090177e196ae2eda\Final\Final On: 01-Apr-2021 03:25 (GMT)

**Header Text:** C4591001

**Visit:** V1\_DAY1\_VAX1\_L

**Form Version:** 22-Apr-2020 21:03

**Site No:** 1231

**Subject No:** 12314233

**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

of Buenos Aires

**5.e Sample ID**

<b>Date</b>	<b>Location</b>	<b>User</b>	<b>Value</b>	<b>Reason</b>
Aug-27-2020 17:17:32 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	Alan Colombo (b) (4)	<b>Data Entry:</b> BPTFC8	Initial Entry

**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:** 12314233

**Subject Initials:** ---

**Generated By:**

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

(b) (4)

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**1. Data Origin**

Date	Location	User	Value	Reason
Aug-26-2020 16:20:35 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SITE	Initial Entry

**2. Sample Type**

Date	Location	User	Value	Reason
Aug-26-2020 16:20:35 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> NASAL_SWAB	Initial Entry

**3. Sample Collected?**

Date	Location	User	Value	Reason
Aug-27-2020 15:10:48 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Aug-27-2020 02:18:20 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	'Sample Collected?' is Yes, however no barcodes

090177e196ae2eda\Final\Final On: 01-Apr-2021 03:25 (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: 12314233

Subject Initials: ---

Generated By:

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

(b) (4)

				are entered. Please review and correct as appropriate.
Aug-26-2020 16:20:35 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Aug-26-2020 16:20:35 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES Date of Collection:  Aug/26/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Aug-27-2020 15:10:48 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	Alan Colombo (b) (4)	<b>Data Entry:</b> Sample I BPT9S D: 9	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
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090177e196ae2eda\Final\Final On: 01-Apr-2021 03:25 (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:** 12314233

**Subject Initials:** ---

**Generated By:**

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

(b) (4)

Aug-27-2020 15:10:48 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	Alan Colombo (b) (4)	<b>Data Entry:</b> BPT9S9	Initial Entry
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090177e196ae2eda\Final\Final On: 01-Apr-2021 03:25 (GMT)

**Header Text:** C4591001

**Visit:** V1\_DAY1\_VAX1\_L

**Form Version:** 22-Apr-2020 21:04

**Site No:** 1231

**Subject No:** 12314233

**Generated By:**

(b) (4)

**Form:** VACCINATION - eCRF Audit Trail History

**Form Status:** Data Complete, Locked, Frozen, Verified

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

**Subject Initials:** ---

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

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**1. Was there a temporary delay of vaccination?**

Date	Location	User	Value	Reason
Aug-26-2020 16:20:55 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**2. Treatment Name**

Date	Location	User	Value	Reason
Aug-26-2020 16:20:55 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> BLINDED THERAPY	Initial Entry

**3. Formulation:**

Date	Location	User	Value	Reason
Aug-26-2020 16:20:55 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> INJECTION	Initial Entry

**4. Dose Date Time:**

Date	Location	User	Value	Reason
Aug-26-2020	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>	Initial Entry

090177e196ae2eda\Final\Final On: 01-Apr-2021 03:25 (GMT)



**Header Text:** C4591001

**Visit:** V1\_DAY1\_VAX1\_L

**Form Version:** 22-Apr-2020 21:04

**Site No:** 1231

**Subject No:** 12314233

**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

16:20:55  
(UTC-03:00) City  
of Buenos Aires

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

Aug/26/2020 15:07

**5. Anatomical Location:**

Date	Location	User	Value	Reason
Aug-26-2020 16:20:55 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> DELTOID MUSCLE	Initial Entry

**6. Body Side:**

Date	Location	User	Value	Reason
Aug-26-2020 16:20:55 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> LEFT	Initial Entry

**7. Route:**

Date	Location	User	Value	Reason
Aug-26-2020 16:20:55 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> INTRAMUSCULAR	Initial Entry

**10. Timeframe Subject Was Observed**

Date	Location	User	Value	Reason
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090177e196ae2eda\Final\Final On: 01-Apr-2021 03:25 (GMT)

**Header Text:** C4591001

**Visit:** V1\_DAY1\_VAX1\_L

**Form:** VACCINATION - eCRF Audit Trail History

**Form Version:** 22-Apr-2020 21:04

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site No:** 1231

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

**Subject No:** 12314233

**Subject Initials:** ---

**Generated By:**

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

(b) (4)

Aug-26-2020 16:20:55 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> THE PROTOCOL SPE CIFIED OBSERVATIO N PERIOD	Initial Entry
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***11. Was the subject observed for at least the protocol specified observation period after investigational product administration?***

Date	Location	User	Value	Reason
Aug-26-2020 16:20:55 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

090177e196ae2eda\Final\Final On: 01-Apr-2021 03:25 (GMT)

**Header Text:** C4591001

**Visit:** V1\_DAY1\_VAX1\_L

**Form Version:** 06-Jul-2020 21:53

**Site No:** 1231

**Subject No:** 12314233

**Generated By:**

(b) (4)

**Form:** REACTOGENICITY DIARY - eCRF Audit Trail History

**Form Status:** Data Complete, Locked, Frozen, Verified

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

**Subject Initials:** ---

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

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*1. Select appropriate response - Reactogenicity diary collection*

Date	Location	User	Value	Reason
Aug-26-2020 16:21:03 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO - REACTOGENI CITY E-DIARY NOT COLLECTED FOR T HIS SUBJECT	Initial Entry

090177e196ae2eda\Final\Final On: 01-Apr-2021 03:25 (GMT)

**Header Text:** C4591001

**Visit:** V2\_VAX2\_L

**Form Version:** 22-Apr-2020 21:02

**Site No:** 1231

**Subject No:** 12314233

**Generated By:**

(b) (4)

**Form:** DATE OF VISIT - eCRF Audit Trail History

**Form Status:** Data Complete, Locked, Frozen, Verified

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

**Subject Initials:** ---

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

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*1. Date of Visit*

Date	Location	User	Value	Reason
Sep-18-2020 10:17:10 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sep/14/2020	Initial Entry

090177e196ae2eda\Final\Final On: 01-Apr-2021 03:25 (GMT)

**Header Text:** C4591001

**Visit:** V2\_VAX2\_L

**Form Version:** 15-Sep-2020 21:54

**Site No:** 1231

**Subject No:** 12314233

**Generated By:**

(b) (4)

**Form:** VITAL SIGNS - TEMP - eCRF Audit Trail History

**Form Status:** Data Complete, Locked, Frozen, Verified

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

**Subject Initials:** ---

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

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**1. Date:**

Date	Location	User	Value	Reason
Sep-18-2020 10:17:23 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sep/14/2020	Initial Entry

**2.a**

Date	Location	User	Value	Reason
Sep-18-2020 10:17:23 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Record Identifier::</b> <b>Temperature:</b> 36.3 <b>Temperature Unit:</b> C <b>Temperature Location:</b> ORAL CAVITY <b>:</b> Y	Initial Entry

**2.a Record Identifier:**

Date	Location	User	Value	Reason
Sep-18-2020 10:17:23 (UTC-03:00) City	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 1	Initial Entry

090177e196ae2eda\Final\Final On: 01-Apr-2021 03:25 (GMT)

**Header Text:** C4591001

**Visit:** V2\_VAX2\_L

**Form:** VITAL SIGNS - TEMP - eCRF Audit Trail History

**Form Version:** 15-Sep-2020 21:54

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site No:** 1231

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

**Subject No:** 12314233

**Subject Initials:** ---

**Generated By:**

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

(b) (4)

of Buenos Aires

**2.a Temperature:**

Date	Location	User	Value	Reason
Sep-18-2020 10:17:23 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 36.3	Initial Entry

**2.a Unit:**

Date	Location	User	Value	Reason
Sep-18-2020 10:17:23 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> C	Initial Entry

**2.a Temperature Location:**

Date	Location	User	Value	Reason
Sep-18-2020 10:17:23 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> ORAL CAVITY	Initial Entry

090177e196ae2eda\Final\Final On: 01-Apr-2021 03:25 (GMT)

**Header Text:** C4591001

**Visit:** V2\_VAX2\_L

**Form Version:** 22-Apr-2020 21:03

**Site No:** 1231

**Subject No:** 12314233

**Generated By:**

(b) (4)

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

**Form Status:** Data Complete, Locked, Frozen, Verified

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

**Subject Initials:** ---

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

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**1. Data Origin**

Date	Location	User	Value	Reason
Sep-14-2020 16:07:12 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SITE	Initial Entry

**2. Sample Type**

Date	Location	User	Value	Reason
Sep-14-2020 16:07:12 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> NASAL_SWAB	Initial Entry

**3. Sample Collected?**

Date	Location	User	Value	Reason
Sep-14-2020 16:07:25 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Sep-14-2020 16:07:12 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes

090177e196ae2eda\Final\Final On: 01-Apr-2021 03:25 (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:** 12314233

**Subject Initials:** ---

**Generated By:**

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

(b) (4)

				are entered. Please review and correct as appropriate.
Sep-14-2020 16:07:12 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES Date of Collection :  Sep/14/2020	Initial Entry

**5.a**

Date	Location	User	Value	Reason
Sep-14-2020 16:07:25 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample ID</b> BP2FL : J	Initial Entry

**5.a Sample ID**

Date	Location	User	Value	Reason
Sep-14-2020 16:07:25 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BP2FLJ	Initial Entry

090177e196ae2eda\Final\Final On: 01-Apr-2021 03:25 (GMT)



**Header Text:** C4591001

**Visit:** V2\_VAX2\_L

**Form Version:** 22-Apr-2020 21:04

**Site No:** 1231

**Subject No:** 12314233

**Generated By:**

(b) (4)

**Form:** VACCINATION - eCRF Audit Trail History

**Form Status:** Data Complete, Locked, Frozen, Verified

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

**Subject Initials:** ---

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

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**1. Was there a temporary delay of vaccination?**

Date	Location	User	Value	Reason
Sep-18-2020 10:18:13 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**2. Treatment Name**

Date	Location	User	Value	Reason
Sep-18-2020 10:18:13 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> BLINDED THERAPY	Initial Entry

**3. Formulation:**

Date	Location	User	Value	Reason
Sep-18-2020 10:18:13 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> INJECTION	Initial Entry

**4. Dose Date Time:**

Date	Location	User	Value	Reason
Sep-18-2020	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>	Initial Entry

090177e196ae2eda\Final\Final On: 01-Apr-2021 03:25 (GMT)

**Header Text:** C4591001

**Visit:** V2\_VAX2\_L

**Form Version:** 22-Apr-2020 21:04

**Site No:** 1231

**Subject No:** 12314233

**Generated By:**

(b) (4)

**Form:** VACCINATION - eCRF Audit Trail History

**Form Status:** Data Complete, Locked, Frozen, Verified

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

**Subject Initials:** ---

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

10:18:13  
(UTC-03:00) City  
of Buenos Aires

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

Sep/14/2020 12:15

**5. Anatomical Location:**

Date	Location	User	Value	Reason
Sep-18-2020 10:18:13 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> DELTOID MUSCLE	Initial Entry

**6. Body Side:**

Date	Location	User	Value	Reason
Sep-18-2020 10:18:13 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> RIGHT	Initial Entry

**7. Route:**

Date	Location	User	Value	Reason
Sep-18-2020 10:18:13 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> INTRAMUSCULAR	Initial Entry

**10. Timeframe Subject Was Observed**

Date	Location	User	Value	Reason
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090177e196ae2eda\Final\Final On: 01-Apr-2021 03:25 (GMT)

**Header Text:** C4591001

**Visit:** V2\_VAX2\_L

**Form:** VACCINATION - eCRF Audit Trail History

**Form Version:** 22-Apr-2020 21:04

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site No:** 1231

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

**Subject No:** 12314233

**Subject Initials:** ---

**Generated By:**

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

(b) (4)

Sep-18-2020 10:18:13 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> THE PROTOCOL SPECIFIED OBSERVATION PERIOD	Initial Entry
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*11. Was the subject observed for at least the protocol specified observation period after investigational product administration?*

Date	Location	User	Value	Reason
Sep-18-2020 10:18:13 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

090177e196ae2eda\Final\Final On: 01-Apr-2021 03:25 (GMT)

**Header Text:** C4591001

**Visit:** V3\_MONTH1\_POSTVAX2\_L

**Form:** DATE OF VISIT - eCRF Audit Trail History

**Form Version:** 22-Apr-2020 21:02

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site No:** 1231

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

**Subject No:** 12314233

**Subject Initials:** ---

**Generated By:**

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

(b) (4)

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*1. Date of Visit*

Date	Location	User	Value	Reason
Oct-15-2020 11:08:39 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Oct/14/2020	Initial Entry

090177e196ae2eda\Final\Final On: 01-Apr-2021 03:25 (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:** 12314233 **Subject Initials:** ---

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

(b) (4)

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**1. Data Origin**

Date	Location	User	Value	Reason
Oct-15-2020 10:13:26 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SITE	Initial Entry

**2. Sample Type**

Date	Location	User	Value	Reason
Oct-15-2020 10:13:26 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SERUM	Initial Entry

**3. Sample Collected?**

Date	Location	User	Value	Reason
Oct-15-2020 10:13:43 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Oct-15-2020 10:13:26 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes

090177e196ae2eda\Final\Final On: 01-Apr-2021 03:25 (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: 12314233 Subject Initials: ---

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

				are entered. Please review and correct as appropriate.
Oct-15-2020 10:13:26 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	Agustin Morato Cabral (b) (4)	<b>Data Entry:</b> YES Date of Collection :  Oct/14/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Oct-15-2020 10:13:43 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	Agustin Morato Cabral (b) (4)	<b>Data Entry:</b> Sample ID BP1NL : Y	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Oct-15-2020 10:13:43 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	Agustin Morato Cabral (b) (4)	<b>Data Entry:</b> BPINLY	Initial Entry

5.b

Date	Location	User	Value	Reason
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090177e196ae2eda\Final\Final On: 01-Apr-2021 03:25 (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: 12314233 Subject Initials: ---

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

(b) (4)

Oct-15-2020 11:19:16 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample ID BRXS5</b> : S	Initial Entry
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5.b Sample ID

Date	Location	User	Value	Reason
Oct-15-2020 11:19:16 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BRXS5S	Initial Entry

5.c

Date	Location	User	Value	Reason
Oct-15-2020 12:15:35 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample I BRXS6</b> <b>D: M</b>	Initial Entry

5.c Sample ID

Date	Location	User	Value	Reason
Oct-15-2020 12:15:35 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BRXS6M	Initial Entry

090177e196ae2eda\Final\Final On: 01-Apr-2021 03:25 (GMT)

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Jan/12/2021

**Form Version:** 22-Apr-2020 21:03

**Site No:** 1231

**Subject No:** 12314233

**Generated By:**

(b) (4)

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

**Form Status:** Data Complete, Frozen, Verified

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

**Subject Initials:** ---

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

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*1. Date of Visit*

Date	Location	User	Value	Reason
Jan-14-2021 13:52:33 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Jan-14-2021 13:50:46 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Deleted	Close Auto Query
Jan-14-2021 13:49:32 (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-14-2021 13:49:32 (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

090177e196ae2eda\Final\Final On: 01-Apr-2021 03:25 (GMT)



**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Jan/12/2021

**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:** 12314233

**Subject Initials:** ---

**Generated By:**

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

(b) (4)

				Swab Self and Nasal Swab are missing. Please review and update as appropriate.
Jan-14-2021 13:49:32 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Jan/12/2021	Initial Entry

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

Date	Location	User	Value	Reason
Jan-14-2021 13:49:32 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> COVID_A	Initial Entry

090177e196ae2eda\Final\Final On: 01-Apr-2021 03:25 (GMT)

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Jan/12/2021

**Form Version:** 14-Jan-2021 02:23

**Site No:** 1231

**Subject No:** 12314233

**Generated By:**

(b) (4)

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

**Form Status:** Data Complete

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

**Subject Initials:** ---

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

[Back to Form](#)

**1. Date of Assessment:**

Date	Location	User	Value	Reason
Jan-14-2021 13:50:46 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Jan/12/2021	Initial Entry

**2. Date of First Symptom Started:**

Date	Location	User	Value	Reason
Jan-14-2021 13:50:46 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Jan/11/2021	Initial Entry

**3. Symptoms Ongoing?**

Date	Location	User	Value	Reason
Jan-14-2021 13:53:27 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO Date of Last Symptom Resolved: Jan/12/2021	Transcription Error
Jan-14-2021 13:50:46	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

090177e196ae2eda\Final\Final On: 01-Apr-2021 03:25 (GMT)

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Jan/12/2021

**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:** 12314233

**Subject Initials:** ---

**Generated By:**

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

(b) (4)

(UTC-03:00) City  
of Buenos Aires

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

**4.a**

Date	Location	User	Value	Reason
Jan-14-2021 13:50:46 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptoms:</b> FEV ER <b>Symptom Pr</b> YES <b>esent:</b>	Initial Entry

**4.a Symptoms:**

Date	Location	User	Value	Reason
Jan-14-2021 13:50:46 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> FEVER	Initial Entry

**4.a Was symptom present?**

Date	Location	User	Value	Reason
Jan-14-2021 13:50:46 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

**4.b**

090177e196ae2eda\Final\Final On: 01-Apr-2021 03:25 (GMT)

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Jan/12/2021

**Form Version:** 14-Jan-2021 02:23

**Site No:** 1231

**Subject No:** 12314233

**Generated By:**

(b) (4)

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

**Form Status:** Data Complete

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

**Subject Initials:** ---

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

Date	Location	User	Value	Reason
Jan-14-2021 13:50:46 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptom:</b> NEW OR I NCREASE D COUGH <b>Symptom Present:</b> YES	Initial Entry

**4.b Symptoms:**

Date	Location	User	Value	Reason
Jan-14-2021 13:50:46 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NEW OR INCREASED COUGH	Initial Entry

**4.b Was symptom present?**

Date	Location	User	Value	Reason
Jan-14-2021 13:50:46 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

**4.c**

Date	Location	User	Value	Reason
Jan-14-2021	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>	Initial Entry

090177e196ae2eda\Final\Final On: 01-Apr-2021 03:25 (GMT)

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Jan/12/2021

**Form Version:** 14-Jan-2021 02:23

**Site No:** 1231

**Subject No:** 12314233

**Generated By:**

(b) (4)

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

**Form Status:** Data Complete

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

**Subject Initials:** ---

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

13:50:46 (UTC-03:00) City of Buenos Aires		(b) (4), (b) (6)	<b>Symp</b> NEW OR IN <b>toms:</b> CREAS S HORTNESS OF BREATH  <b>Symp</b> NO <b>tom</b> <b>Prese</b> <b>nt:</b>	
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**4.c Symptoms:**

Date	Location	User	Value	Reason
Jan-14-2021 13:50:46 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NEW OR INCREAS ED SHORTNESS OF BREATH	Initial Entry

**4.c Was symptom present?**

Date	Location	User	Value	Reason
Jan-14-2021 13:50:46 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**4.d**

Date	Location	User	Value	Reason
Jan-14-2021 13:50:46	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptoms:</b> CHIL	Initial Entry

090177e196ae2eda\Final\Final On: 01-Apr-2021 03:25 (GMT)

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Jan/12/2021

**Form Version:** 14-Jan-2021 02:23

**Site No:** 1231

**Subject No:** 12314233

**Generated By:**

(b) (4)

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

**Form Status:** Data Complete

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

**Subject Initials:** ---

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

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

Date	Location	User	Value	Reason
Jan-14-2021 13:50:46 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> CHILLS	Initial Entry

**4.d Was symptom present?**

Date	Location	User	Value	Reason
Jan-14-2021 13:50:46 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**4.e**

Date	Location	User	Value	Reason
Jan-14-2021 13:50:46 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sympt NEW OR IN oms:CREASED MUSCLE P AIN	Initial Entry

090177e196ae2eda\Final\Final On: 01-Apr-2021 03:25 (GMT)

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Jan/12/2021

**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:** 12314233

**Subject Initials:** ---

**Generated By:**

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

(b) (4)

			<b>Sympt NO om Pr esent:</b>	
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**4.e Symptoms:**

Date	Location	User	Value	Reason
Jan-14-2021 13:50:46 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NEW OR INCREAS ED MUSCLE PAIN	Initial Entry

**4.e Was symptom present?**

Date	Location	User	Value	Reason
Jan-14-2021 13:50:46 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**4.f**

Date	Location	User	Value	Reason
Jan-14-2021 13:50:46 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sympt</b> NEW LOSS <b>oms:</b> OF TASTE OR SMELL  <b>Sympt</b> NO <b>om Pr</b> <b>esent:</b>	Initial Entry

090177e196ae2eda\Final\Final On: 01-Apr-2021 03:25 (GMT)

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Jan/12/2021

**Form Version:** 14-Jan-2021 02:23

**Site No:** 1231

**Subject No:** 12314233

**Generated By:**

(b) (4)

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

**Form Status:** Data Complete

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

**Subject Initials:** ---

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

**4.f Symptoms:**

Date	Location	User	Value	Reason
Jan-14-2021 13:50:46 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NEW LOSS OF TAS TE OR SMELL	Initial Entry

**4.f Was symptom present?**

Date	Location	User	Value	Reason
Jan-14-2021 13:50:46 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**4.g**

Date	Location	User	Value	Reason
Jan-14-2021 13:50:46 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sympt NEW OR IN</b> <b>oms: CREASED S</b> <b>ORE THRO</b> <b>AT</b> <b>Sympt NO</b> <b>om Pr</b> <b>esent:</b>	Initial Entry

090177e196ae2eda\Final\Final On: 01-Apr-2021 03:25 (GMT)



**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Jan/12/2021

**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:** 12314233

**Subject Initials:** ---

**Generated By:**

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

(b) (4)

**4.g Symptoms:**

Date	Location	User	Value	Reason
Jan-14-2021 13:50:46 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NEW OR INCREAS ED SORE THROAT	Initial Entry

**4.g Was symptom present?**

Date	Location	User	Value	Reason
Jan-14-2021 13:50:46 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**4.h**

Date	Location	User	Value	Reason
Jan-14-2021 13:50:46 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptoms:</b> DIARR HEA <b>Symptom YES</b> <b>Present:</b>	Initial Entry

090177e196ae2eda\Final\Final On: 01-Apr-2021 03:25 (GMT)

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Jan/12/2021

**Form Version:** 14-Jan-2021 02:23

**Site No:** 1231

**Subject No:** 12314233

**Generated By:**

(b) (4)

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

**Form Status:** Data Complete

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

**Subject Initials:** ---

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

**4.h Symptoms:**

Date	Location	User	Value	Reason
Jan-14-2021 13:50:46 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> DIARRHEA	Initial Entry

**4.h Was symptom present?**

Date	Location	User	Value	Reason
Jan-14-2021 13:50:46 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

**4.i**

Date	Location	User	Value	Reason
Jan-14-2021 13:50:46 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptoms:</b> VOMIT ING <b>Symptom</b> NO <b>Present:</b>	Initial Entry

090177e196ae2eda\Final\Final On: 01-Apr-2021 03:25 (GMT)

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Jan/12/2021

**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:** 12314233

**Subject Initials:** ---

**Generated By:**

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

(b) (4)

**4.i Symptoms:**

Date	Location	User	Value	Reason
Jan-14-2021 13:50:46 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> VOMITING	Initial Entry

**4.i Was symptom present?**

Date	Location	User	Value	Reason
Jan-14-2021 13:50:46 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**5.a**

Date	Location	User	Value	Reason
Jan-14-2021 13:51:13 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptoms -</b> heada <b>Other:</b> che	Initial Entry

**5.a Symptoms - Other Text:**

Date	Location	User	Value	Reason
Jan-14-2021 13:51:13 (UTC-03:00) City	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> headache	Initial Entry

090177e196ae2eda\Final\Final On: 01-Apr-2021 03:25 (GMT)

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Jan/12/2021

**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:** 12314233

**Subject Initials:** ---

**Generated By:**

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

(b) (4)

of Buenos Aires

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

**5.b**

Date	Location	User	Value	Reason
Jan-14-2021 13:51:22 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptoms -</b> asthe <b>Other:</b> nia	Initial Entry

**5.b Symptoms - Other Text:**

Date	Location	User	Value	Reason
Jan-14-2021 13:51:22 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> asthenia	Initial Entry

**5.c**

Date	Location	User	Value	Reason
Jan-14-2021 13:51:32 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptoms</b> nasal co <b>- Other:</b> ngestion	Initial Entry

090177e196ae2eda\Final\Final On: 01-Apr-2021 03:25 (GMT)

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Jan/12/2021

**Form Version:** 14-Jan-2021 02:23

**Site No:** 1231

**Subject No:** 12314233

**Generated By:**

(b) (4)

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

**Form Status:** Data Complete

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

**Subject Initials:** ---

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

**5.c Symptoms - Other Text:**

Date	Location	User	Value	Reason
Jan-14-2021 13:51:32 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> nasal congestion	Initial Entry

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Jan/12/2021

**Form Version:** 06-Jul-2020 21:54

**Site No:** 1231

**Subject No:** 12314233

**Generated By:**

(b) (4)

**Form:** MICROBIOLOGY SPECIMEN - Audit Trail

**Form Status:**

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

**Subject Initials:** ---

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

[Back to Form](#)

Date	Location	User	Value	Reason
Jan-14-2021 13:52:10 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Created	

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Jan/12/2021

**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:** 12314233

**Subject Initials:** ---

**Generated By:**

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

(b) (4)

[Back to Form](#)

**1. Actual Date of Collection:**

Date	Location	User	Value	Reason
Jan-14-2021 13:52:10 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Jan/12/2021	Initial Entry

**2. Specimen Type:**

Date	Location	User	Value	Reason
Jan-14-2021 13:52:10 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> SWABBED MATERI AL	Initial Entry

**3. Specimen Collection Location:**

Date	Location	User	Value	Reason
Jan-14-2021 13:52:10 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NASOPHARYNX	Initial Entry

**4. Assay Code and Description:**

Date	Location	User	Value	Reason
Jan-14-2021	ACV0PFEINFP6000	auto calc	<b>Data Entry:</b>	Initial Entry

090177e196ae2eda\Final\Final On: 01-Apr-2021 03:25 (GMT)

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Jan/12/2021

**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:** 12314233

**Subject Initials:** ---

**Generated By:**

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

(b) (4)

13:52:10 (UTC-03:00) City of Buenos Aires		(autocalc)	SEVERE ACUTE RES P SYNDROME CORO NAVIRUS 2	
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**5. Device Type:**

Date	Location	User	Value	Reason
Jan-14-2021 13:52:10 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SARS-COV-2 DIAGN OSTIC TEST	Initial Entry

**6. Trade Name:**

Date	Location	User	Value	Reason
Jan-14-2021 13:52:10 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> ATILA BIOSYSTEM S IAMP COVID-19 DETECTION KIT	Initial Entry

**7. Test Result:**

Date	Location	User	Value	Reason
Jan-14-2021 13:52:10 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NEGATIVE	Initial Entry

090177e196ae2eda\Final\Final On: 01-Apr-2021 03:25 (GMT)



**Header Text:** C4591001**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Jan/12/2021**Form Version:** 22-Apr-2020 21:03**Site No:** 1231**Subject No:** 12314233**Generated By:**

(b) (4)

**Form:** ELECTRONIC SAMPLE TRACKING - NASAL  
SWAB SELF - eCRF Audit Trail History**Form Status:** Data Complete, Frozen, Verified**Site Name:** (1231) Hospital Militar Central Cirujano  
Mayor Dr. Cosme Argerich**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 20:34[Back to Form](#)**1. Data Origin**

Date	Location	User	Value	Reason
Jan-14-2021 13:52:25 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SITE	Initial Entry

**2. Sample Type**

Date	Location	User	Value	Reason
Jan-14-2021 13:52:25 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> NASAL_SWAB_SELF	Initial Entry

**3. Sample Collected?**

Date	Location	User	Value	Reason
Jan-14-2021 13:52:25 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

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

Date	Location	User	Value	Reason
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**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Jan/12/2021

**Form Version:** 22-Apr-2020 21:03

**Site No:** 1231

**Subject No:** 12314233

**Generated By:**

(b) (4)

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

**Form Status:** Data Complete, Frozen, Verified

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

**Subject Initials:** ---

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

Jan-14-2021 13:52:25 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> sample collected by a team physician	Initial Entry
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**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Jan/12/2021

**Form Version:** 22-Apr-2020 21:03

**Site No:** 1231

**Subject No:** 12314233

**Generated By:**

(b) (4)

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

**Form Status:** Data Complete, Frozen, Verified

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

**Subject Initials:** ---

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

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**1. Data Origin**

Date	Location	User	Value	Reason
Jan-14-2021 13:52:33 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SITE	Initial Entry

**2. Sample Type**

Date	Location	User	Value	Reason
Jan-14-2021 13:52:33 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> NASAL_SWAB	Initial Entry

**3. Sample Collected?**

Date	Location	User	Value	Reason
Jan-15-2021 10:39:58 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Jan-15-2021 00:35:40 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	'Sample Collected?' is Yes, however no barcodes

090177e196ae2eda\Final\Final On: 01-Apr-2021 03:25 (GMT)

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Jan/12/2021

**Form Version:** 22-Apr-2020 21:03

**Site No:** 1231

**Subject No:** 12314233

**Generated By:**

(b) (4)

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

**Form Status:** Data Complete, Frozen, Verified

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

**Subject Initials:** ---

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

				are entered. Please review and correct as appropriate.
Jan-14-2021 13:52:33 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Jan-14-2021 13:52:33 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES Date of Collectio n:  Jan/12/2021	Initial Entry

**5.a**

Date	Location	User	Value	Reason
Jan-15-2021 10:39:58 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample I</b> BPTBZ <b>D:</b> M	Initial Entry

**5.a Sample ID**

Date	Location	User	Value	Reason
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090177e196ae2eda\Final\Final On: 01-Apr-2021 03:25 (GMT)

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Jan/12/2021

**Form Version:** 22-Apr-2020 21:03

**Site No:** 1231

**Subject No:** 12314233

**Generated By:**

(b) (4)

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

**Form Status:** Data Complete, Frozen, Verified

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

**Subject Initials:** ---

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

Jan-15-2021 10:39:58 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	<b><u>Data Entry:</u></b> BPTBZM	Initial Entry
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**Header Text:** C4591001**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Jan/12/2021**Form Version:** 14-Jan-2021 02:24**Site No:** 1231**Subject No:** 12314233**Generated By:**

(b) (4)

**Form:** HEALTH CARE UTILIZATION - eCRF Audit  
Trail History**Form Status:** Data Complete**Site Name:** (1231) Hospital Militar Central Cirujano  
Mayor Dr. Cosme Argerich**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 20:34[Back to Form](#)*I.a*

Date	Location	User	Value	Reason
Jan-14-2021 13:52:48 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Type of Prac</b> SPEC <b>titioner:</b> IALI ST <b>Occurrence</b> NO <b>of Visits or C</b> <b>ontacts:</b>	Initial Entry

*I.a Physician or Healthcare Professional:*

Date	Location	User	Value	Reason
Jan-14-2021 13:52:48 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> SPECIALIST	Initial Entry

*I.a Occurrence of Visits or Contacts:*

Date	Location	User	Value	Reason
Jan-14-2021 13:52:48 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

Header Text: C4591001

Visit: POT\_COVID\_ILL 1 -  
Unscheduled Visit on Jan/12/2021

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: 12314233

Subject Initials: ---

Generated By:

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

(b) (4)

***1.b***

Date	Location	User	Value	Reason
Jan-14-2021 13:52:48 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Type of Pr</b> EMER <b>actitioner:</b> GENC Y ROO M <b>Occurrence</b> NO <b>e of Visits</b> <b>or Contact</b> <b>s:</b>	Initial Entry

***1.b Physician or Healthcare Professional:***

Date	Location	User	Value	Reason
Jan-14-2021 13:52:48 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> EMERGENCY ROO M	Initial Entry

***1.b Occurrence of Visits or Contacts:***

Date	Location	User	Value	Reason
Jan-14-2021 13:52:48 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

***1.c***

090177e196ae2eda\Final\Final On: 01-Apr-2021 03:25 (GMT)

**Header Text:** C4591001**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Jan/12/2021**Form Version:** 14-Jan-2021 02:24**Site No:** 1231**Subject No:** 12314233**Generated By:**

(b) (4)

**Form:** HEALTH CARE UTILIZATION - eCRF Audit  
Trail History**Form Status:** Data Complete**Site Name:** (1231) Hospital Militar Central Cirujano  
Mayor Dr. Cosme Argerich**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 20:34

Date	Location	User	Value	Reason
Jan-14-2021 13:52:48 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Type of P</b> PRIMAR <b>ractitione</b> Y CARE <b>r:</b> PHYSICI AN <b>Occurren</b> NO <b>ce of Visit</b> <b>s or Cont</b> <b>acts:</b>	Initial Entry

***1.c Physician or Healthcare Professional:***

Date	Location	User	Value	Reason
Jan-14-2021 13:52:48 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> PRIMARY CARE P HYSICIAN	Initial Entry

***1.c Occurrence of Visits or Contacts:***

Date	Location	User	Value	Reason
Jan-14-2021 13:52:48 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

***1.d***

Date	Location	User	Value	Reason
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**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Jan/12/2021

**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:** 12314233

**Subject Initials:** ---

**Generated By:**

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

(b) (4)

Jan-14-2021 13:52:48 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Type of Pra</b> URGE <b>ctitioner:</b> NT C ARE <b>Occurrence</b> NO <b>of Visits or</b> <b>Contacts:</b>	Initial Entry
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***1.d Physician or Healthcare Professional:***

Date	Location	User	Value	Reason
Jan-14-2021 13:52:48 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> URGENT CARE	Initial Entry

***1.d Occurrence of Visits or Contacts:***

Date	Location	User	Value	Reason
Jan-14-2021 13:52:48 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

***1.e***

Date	Location	User	Value	Reason
Jan-14-2021 13:52:48 (UTC-03:00) City	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Type of P</b> TELEPH <b>ractitione</b> ONE CO	Initial Entry

090177e196ae2eda\Final\Final On: 01-Apr-2021 03:25 (GMT)

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Jan/12/2021

**Form Version:** 14-Jan-2021 02:24

**Site No:** 1231

**Subject No:** 12314233

**Generated By:**

(b) (4)

**Form:** HEALTH CARE UTILIZATION - eCRF Audit  
Trail History

**Form Status:** Data Complete

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

**Subject Initials:** ---

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

of Buenos Aires	(b) (4), (b) (6)	r: NSULTA TION	Occurren NO ce of Visit s or Cont acts:
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*I.e Physician or Healthcare Professional:*

Date	Location	User	Value	Reason
Jan-14-2021 13:52:48 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> TELEPHONE CONS ULTATION	Initial Entry

*I.e Occurrence of Visits or Contacts:*

Date	Location	User	Value	Reason
Jan-14-2021 13:52:48 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

*I.f*

Date	Location	User	Value	Reason
Jan-14-2021 13:52:48 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Type of Practit</b> OT <b>ioner:</b> HE R	Initial Entry

090177e196ae2eda\Final\Final On: 01-Apr-2021 03:25 (GMT)

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Jan/12/2021

**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:** 12314233

**Subject Initials:** ---

**Generated By:**

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

(b) (4)

			<b>Occurrence of NO Visits or Contacts:</b>	
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***1.f Physician or Healthcare Professional:***

Date	Location	User	Value	Reason
Jan-14-2021 13:52:48 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> OTHER	Initial Entry

***1.f Occurrence of Visits or Contacts:***

Date	Location	User	Value	Reason
Jan-14-2021 13:52:48 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

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

Date	Location	User	Value	Reason
Jan-14-2021 13:52:48 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

090177e196ae2eda\Final\Final On: 01-Apr-2021 03:25 (GMT)

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Jan/12/2021

**Form Version:** 06-Jul-2020 21:52

**Site No:** 1231

**Subject No:** 12314233

**Generated By:**

(b) (4)

**Form:** ILLNESS DETAILS - eCRF Audit Trail History

**Form Status:** Data Complete

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

**Subject Initials:** ---

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

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**1. Category of Clinical Event:**

Date	Location	User	Value	Reason
Jan-14-2021 13:53:14 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> POTENTIAL COVID- 19 ILLNESS	Initial Entry

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

Date	Location	User	Value	Reason
Jan-14-2021 13:53:14 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**3. Toxicity Grade:**

Date	Location	User	Value	Reason
Jan-14-2021 13:53:14 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 1	Initial Entry

090177e196ae2eda\Final\Final On: 01-Apr-2021 03:25 (GMT)

**Header Text:** C4591001

**Visit:** POT\_COVID\_CONVA 1 -  
Unscheduled Visit on Feb/09/2021

**Form Version:** 22-Apr-2020 21:04

**Site No:** 1231

**Subject No:** 12314233

**Generated By:**

(b) (4)

**Form:** DATE OF VISIT - ILLNESS CONVALESCENT -  
eCRF Audit Trail History

**Form Status:** Data Complete, Frozen, Verified

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

**Subject Initials:** ---

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

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**1. Date of Visit**

Date	Location	User	Value	Reason
Feb-09-2021 11:15:18 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Feb/9/2021	Initial Entry

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

Date	Location	User	Value	Reason
Feb-09-2021 11:15:18 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> COVID_A1	Initial Entry

090177e196ae2eda\Final\Final On: 01-Apr-2021 03:25 (GMT)

**Header Text:** C4591001

**Visit:** POT\_COVID\_CONVA 1 -  
Unscheduled Visit on Feb/09/2021

**Form Version:** 22-Apr-2020 21:03

**Site No:** 1231

**Subject No:** 12314233

**Generated By:**

(b) (4)

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

**Form Status:** Data Complete, Frozen, Verified

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

**Subject Initials:** ---

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

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**1. Data Origin**

Date	Location	User	Value	Reason
Feb-09-2021 11:15:33 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SITE	Initial Entry

**2. Sample Type**

Date	Location	User	Value	Reason
Feb-09-2021 11:15:33 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SERUM	Initial Entry

**3. Sample Collected?**

Date	Location	User	Value	Reason
Feb-09-2021 17:55:11 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Feb-09-2021 17:54:15 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	'Sample Collected?' is Yes, however no barcodes

090177e196ae2eda\Final\Final On: 01-Apr-2021 03:25 (GMT)

**Header Text:** C4591001

**Visit:** POT\_COVID\_CONVA 1 -  
 Unscheduled Visit on Feb/09/2021

**Form Version:** 22-Apr-2020 21:03

**Site No:** 1231

**Subject No:** 12314233

**Generated By:**

(b) (4)

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

**Form Status:** Data Complete, Frozen, Verified

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

**Subject Initials:** ---

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

				are entered. Please review and correct as appropriate.
Feb-09-2021 11:15:33 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Feb-09-2021 11:15:33 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES Date of Collection:  Feb/9/2021	Initial Entry

**5.a**

Date	Location	User	Value	Reason
Feb-09-2021 17:55:11 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	Agustin Morato Cabral (b) (4)	<b>Data Entry:</b> Sample ID BNTZ9 : 3	Initial Entry

**5.a Sample ID**

Date	Location	User	Value	Reason
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**Header Text:** C4591001

**Visit:** POT\_COVID\_CONVA 1 -  
Unscheduled Visit on Feb/09/2021

**Form Version:** 22-Apr-2020 21:03

**Site No:** 1231

**Subject No:** 12314233

**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

Feb-09-2021 17:55:11 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	Agustin Morato Cabral (b) (4)	<b>Data Entry:</b> BNTZ93	Initial Entry
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**5.b**

Date	Location	User	Value	Reason
Feb-10-2021 09:16:26 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	Azul Mozzi (b) (4)	<b>Data Entry:</b> Sample I BPXWW D: C	Initial Entry

**5.b Sample ID**

Date	Location	User	Value	Reason
Feb-10-2021 09:16:26 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	Azul Mozzi (b) (4)	<b>Data Entry:</b> BPXWWC	Initial Entry

**5.c**

Date	Location	User	Value	Reason
Feb-10-2021 09:55:49 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	Azul Mozzi (b) (4)	<b>Data Entry:</b> Sample ID BNTZF : 8	Initial Entry

090177e196ae2eda\Final\Final On: 01-Apr-2021 03:25 (GMT)



**Header Text:** C4591001

**Visit:** POT\_COVID\_CONVA 1 -  
Unscheduled Visit on Feb/09/2021

**Form Version:** 22-Apr-2020 21:03

**Site No:** 1231

**Subject No:** 12314233

**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
Feb-10-2021 09:55:49 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	Azul Mozzi (b) (4)	<b>Data Entry:</b> BNTZF8	Initial Entry

090177e196ae2eda\Final\Final On: 01-Apr-2021 03:25 (GMT)

**Header Text:** C4591001

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

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

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

**Subject No:** 12314233 **Subject Initials:** ---

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

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**1. Date of Completion/Discontinuation/Death :**

Date	Location	User	Value	Reason
Oct-15-2020 11:09:04 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Oct/14/2020	Initial Entry

**2. Phase of Disposition:**

Date	Location	User	Value	Reason
Oct-15-2020 11:09:04 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> VACCINATION	Initial Entry

**3. Status:**

Date	Location	User	Value	Reason
Oct-15-2020 11:09:04 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> COMPLETED	Initial Entry

090177e196ae2eda\Final\Final On: 01-Apr-2021 03:25 (GMT)

**Header Text:** C4591001

**Visit:** Logs - Unscheduled

**Form Version:** 22-Apr-2020 21:02

**Site No:** 1231

**Subject No:** 12314233

**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

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Date	Location	User	Value	Reason
Jan-15-2021 13:51:28 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Created	

090177e196ae2eda\Final\Final On: 01-Apr-2021 03:25 (GMT)

Header Text: C4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete

Site No: 1231

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

Subject No: 12314233

Subject Initials: ---

Generated By:

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

(b) (4)

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**1. Category:**

Date	Location	User	Value	Reason
Jan-15-2021 13:51:28 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> ADVERSE EVENT	Initial Entry

**2. AE ID:**

Date	Location	User	Value	Reason
Jan-15-2021 13:51:28 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 1	Initial Entry

**3. Adverse Event:**

*(If possible specify diagnosis, not individual symptoms)*

Date	Location	User	Value	Reason
Jan-15-2021 13:51:28 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Recurrence of Non-Hodgkin Lymphoma	Initial Entry

**4. Start Date Time:**

Date	Location	User	Value	Reason
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090177e196ae2eda\Final\Final On: 01-Apr-2021 03:25 (GMT)

Header Text: C4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete

Site No: 1231

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

Subject No: 12314233

Subject Initials: ---

Generated By:

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

(b) (4)

Jan-15-2021 13:51:28 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Nov/20/2020 12:00	Initial Entry
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5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Jan-15-2021 13:51:28 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

6. Toxicity Grade:

Date	Location	User	Value	Reason
Jan-15-2021 13:51:28 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 2	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
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090177e196ae2eda\Final\Final On: 01-Apr-2021 03:25 (GMT)

**Header Text:** C4591001

**Visit:** Logs - Unscheduled

**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History

**Form Version:** 22-Apr-2020 21:02

**Form Status:** Data Complete

**Site No:** 1231

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

**Subject No:** 12314233

**Subject Initials:** ---

**Generated By:**

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

(b) (4)

Jan-18-2021 08:15:26 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Deleted	Query can be addressed internally
Jan-15-2021 13:51:28 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	For AE Recurrence of Non-Hodgkin Lymphoma: Response to "Is the adverse event serious?" is 'Yes' but "Serious Adverse Event Number" is blank.
Jan-15-2021 13:51:28 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES Is this serious event associated with congenital anomaly or birth defect?  NO Did this serious event result in death?  NO Did this serious eve	Initial Entry

090177e196ae2eda\Final\Final On: 01-Apr-2021 03:25 (GMT)

**Header Text:** C4591001

**Visit:** Logs - Unscheduled

**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History

**Form Version:** 22-Apr-2020 21:02

**Form Status:** Data Complete

**Site No:** 1231

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

**Subject No:** 12314233

**Subject Initials:** ---

**Generated By:**

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

(b) (4)

			nt require or prolong hospitalization?  NO  Did this serious event result in persistent or significant disability/incapacity?  NO  Is this serious event life threatening?  NO  Other medically important serious event  YES	
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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
Jan-15-2021 13:51:28 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

090177e196ae2eda\Final\Final On: 01-Apr-2021 03:25 (GMT)

**Header Text:** C4591001

**Visit:** Logs - Unscheduled

**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History

**Form Version:** 22-Apr-2020 21:02

**Form Status:** Data Complete

**Site No:** 1231

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

**Subject No:** 12314233

**Subject Initials:** ---

**Generated By:**

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

(b) (4)

**9. Is this event related to study treatment:**

Date	Location	User	Value	Reason
Jan-15-2021 13:51:28 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 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
Jan-15-2021 13:51:28 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NOT APPLICABLE	Initial Entry

**11. Was a Concomitant Medication given?**

Date	Location	User	Value	Reason
Jan-15-2021 13:51:28 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

090177e196ae2eda\Final\Final On: 01-Apr-2021 03:25 (GMT)



**Header Text:** C4591001

**Visit:** Logs - Unscheduled

**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History

**Form Version:** 22-Apr-2020 21:02

**Form Status:** Data Complete

**Site No:** 1231

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

**Subject No:** 12314233

**Subject Initials:** ---

**Generated By:**

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

(b) (4)

**12. Was a Non-Drug Treatment given?**

Date	Location	User	Value	Reason
Jan-15-2021 13:51:28 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

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

Date	Location	User	Value	Reason
Jan-15-2021 13:51:28 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NOT RECOVERED/NOT RESOLVED	Initial Entry

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

Date	Location	User	Value	Reason
Jan-15-2021 13:51:28 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**15. Serious Adverse Event Number: For Pfizer Use Only**

Date	Location	User	Value	Reason
Jan-21-2021 03:18:18 (UTC-03:00) City	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 2021036146	Initial Entry

090177e196ae2eda\Final\Final On: 01-Apr-2021 03:25 (GMT)

**Header Text:** C4591001

**Visit:** Logs - Unscheduled

**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History

**Form Version:** 22-Apr-2020 21:02

**Form Status:** Data Complete

**Site No:** 1231

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

**Subject No:** 12314233

**Subject Initials:** ---

**Generated By:**

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

(b) (4)

of Buenos Aires

**Header Text:** C4591001

**Visit:** Subject Status - Unscheduled

**Form Version:** 22-Apr-2020 21:03

**Site No:** 1231

**Subject No:** 12314233

**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

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**1. Subject Status**

Date	Location	User	Value	Reason
Oct-15-2020 11:09:04 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> FOLLOW-UP	Initial Entry
Aug-26-2020 16:20:17 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> ENROLLED/RANDOMIZED	Initial Entry
Aug-26-2020 16:14:01 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SCREENED	Initial Entry

**2. Subject Status Date**

Date	Location	User	Value	Reason
Oct-15-2020 11:09:04 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> Oct/14/2020	Initial Entry
Aug-26-2020 16:20:17 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> Aug/26/2020	Initial Entry

090177e196ae2eda\Final\Final On: 01-Apr-2021 03:25 (GMT)

**Header Text:** C4591001

**Visit:** Subject Status - Unscheduled

**Form:** SUBJECT STATUS - eCRF Audit Trail History

**Form Version:** 22-Apr-2020 21:03

**Form Status:** Data Complete, Verified

**Site No:** 1231

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

**Subject No:** 12314233

**Subject Initials:** ---

**Generated By:**

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

(b) (4)

Aug-26-2020 16:14:01 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> Aug/26/2020	Initial Entry
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**Header Text:** C4591001

**Visit:** Investigator Signature -  
Unscheduled

**Form Version:** 22-Apr-2020 21:04

**Site No:** 1231

**Subject No:** 12314233

**Generated By:**

(b) (4)

**Form:** CASEBOOK SIGNATURE FORM - eCRF Audit  
Trail History

**Form Status:** Data Complete, Signed, Verified

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

**Subject Initials:** ---

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

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*1. Casebook Signature*

Date	Location	User	Value	Reason
Oct-21-2020 17:38:02 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Click Here to Enable	Initial Entry

090177e196ae2eda\Final\Final On: 01-Apr-2021 03:25 (GMT)