

Header Text: c4591001

Visit: COHORT_SELECTION

Form: COHORT_SELECTION

Form Version: 15-Sep-2020 21:55

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 4444

Site Name: (4444) Hospital Militar Central Cirujano
Mayor Dr Cosme Argerich

Subject No: 44441161

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 17:38

[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	08 SEP 2020
2.	Select appropriate response - What cohort does the subject belong to?	STAGE 3 COHORTS

090177e196ae2ede\Final\Final On: 01-Apr-2021 03:26 (GMT)

Header Text: c4591001

Visit: COHORT_SELECTION

Form Version: 22-Apr-2020 21:02

Site No: 4444

Subject No: 44441161

Generated By: (b) (4)

Form: MAIN INFORMED CONSENT

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (4444) Hospital Militar Central Cirujano
Mayor Dr Cosme Argerich

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 17:38

[eCRF Audit Trail History](#)

Informed Consent

1.	Consent Was:	OBTAINED Date Written Consent Obtained Sep/21/2020
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Header Text: c4591001

Visit: COHORT_SELECTION

Form: DEMOGRAPHY

Form Version: 15-Sep-2020 21:54

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 4444

Site Name: (4444) Hospital Militar Central Cirujano
Mayor Dr Cosme Argerich

Subject No: 44441161

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 17:38

[eCRF Audit Trail History](#)

Demography

1.	Subject ID	[44441161]
2.	Birth Date:	(b) (6)/1951
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: 4444

Subject No: 44441161

Generated By: (b) (4)

Form: DATE OF VISIT

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (4444) Hospital Militar Central Cirujano
Mayor Dr Cosme Argerich

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 17:38

[eCRF Audit Trail History](#)

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

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 15-Sep-2020 21:53

Site No: 4444

Subject No: 44441161

Generated By: (b) (4)

Form: INCLUSION/EXCLUSION CRITERIA

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (4444) Hospital Militar Central Cirujano Mayor Dr Cosme Argerich

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 17:38

Form Comments

Inclusion Criteria Not Met

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

Exclusion Criteria Met

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

090177e196ae2ede\Final\Final On: 01-Apr-2021 03:26 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 15-Sep-2020 21:52

Site No: 4444

Subject No: 44441161

Generated By: (b) (4)

Form: DISPOSITION - SCREENING

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (4444) Hospital Militar Central Cirujano
Mayor Dr Cosme Argerich

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 17:38

[eCRF Audit Trail History](#)

Disposition - Screening

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

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Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 4444

Subject No: 44441161

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY

Form Status: Data Complete, Frozen, Verified

Site Name: (4444) Hospital Militar Central Cirujano Mayor Dr Cosme Argerich

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 17:38

[eCRF Audit Trail History](#)

Medical History Details

1.a	Line/MH Number:	[1]
	Disease/Syndrome /Surgery/Non-Drug Allergies/Drug Allergies:	[Arterial hypertension]
	Start Date:	Sep/8/2010
	Ongoing:	YES
1.b	Line/MH Number:	[2]
	Disease/Syndrome /Surgery/Non-Drug Allergies/Drug Allergies:	[Insomnia]
	Start Date:	Nov/1/2015
	Ongoing:	YES
1.c	Line/MH Number:	[3]
	Disease/Syndrome /Surgery/Non-Drug Allergies/Drug Allergies:	[Obesity]
	Start Date:	UNK/UNK/2015
	Ongoing:	YES

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Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: GENERAL MEDICAL HISTORY

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 4444

Site Name: (4444) Hospital Militar Central Cirujano
Mayor Dr Cosme Argerich

Subject No: 44441161

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 17:38

1.d	Line/MH Number:	[4]
	Disease/Syndrome /Surgery/Non-Drug Allergies/Drug Allergies:	[Alcoholic cirrhosis]
	Start Date:	UNK/UNK/2013
	Ongoing:	YES
1.e	Line/MH Number:	[5]
	Disease/Syndrome /Surgery/Non-Drug Allergies/Drug Allergies:	[Benign prostatic hyperplasia]
	Start Date:	UNK/UNK/2018
	Ongoing:	YES
1.f	Line/MH Number:	[6]
	Disease/Syndrome /Surgery/Non-Drug Allergies/Drug Allergies:	[smoking]
	Start Date:	UNK/UNK/1996
	Ongoing:	YES
1.g	Line/MH Number:	[7]
	Disease/Syndrome /Surgery/Non-Drug Allergies/Drug Allergies:	[COPD]
	Start Date:	May/20/2013
	Ongoing:	YES

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Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: GENERAL MEDICAL HISTORY

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 4444

Site Name: (4444) Hospital Militar Central Cirujano
Mayor Dr Cosme Argerich

Subject No: 44441161

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 17:38

1.h	Line/MH Number:	[8]
	Disease/Syndrome /Surgery/Non-Drug Allergies/Drug Allergies:	[portal hypertension]
	Start Date:	May/10/2014
	Ongoing:	YES
1.i	Line/MH Number:	[9]
	Disease/Syndrome /Surgery/Non-Drug Allergies/Drug Allergies:	[esophageal varices]
	Start Date:	May/10/2014
	Ongoing:	YES

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Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 15-Sep-2020 21:57

Site No: 4444

Subject No: 44441161

Generated By: (b) (4)

Form: HIV STATUS

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (4444) Hospital Militar Central Cirujano
Mayor Dr Cosme Argerich

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 17:38

[eCRF Audit Trail History](#)

HIV Status

1.	Select appropriate response - What is the subject HIV status?	The subject is NOT known to be HIV POSITIVE
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Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: VITAL SIGNS - BASELINE

Form Version: 15-Sep-2020 21:56

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 4444

Site Name: (4444) Hospital Militar Central Cirujano Mayor Dr Cosme Argerich

Subject No: 44441161

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 17:38

[eCRF Audit Trail History](#)

Vital Signs

1.	Date:	Sep/21/2020
2.	Weight:	[117.0]
3.	Unit:	kg
4.	Height:	[172.0]
5.	Unit:	cm
6.	Body Mass Index:	[39.5]

Vital Signs Details

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

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Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 4444

Subject No: 44441161

Generated By: (b) (4)

Form: RANDOMIZATION

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (4444) Hospital Militar Central Cirujano
Mayor Dr Cosme Argerich

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 17:38

[eCRF Audit Trail History](#)

Disposition

1.	Randomization Date :	Sep/21/2020
2.	Randomization Number:	[262992]
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:** 4444**Site Name:** (4444) Hospital Militar Central Cirujano Mayor Dr Cosme Argerich**Subject No:** 44441161**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 17:38[eCRF Audit Trail History](#)**Electronic Sample Tracking**

1.	Data Origin	SITE
2.	Sample Type	SERUM
3.	Sample Collected?	YES Date of Collection: Sep/21/2020
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[]

Aliquot

Please enter barcode for each aliquot.

5.a	Sample ID	[BRXSVX]
5.b	Sample ID	[BRXSW7]
5.c	Sample ID	[BHXG0M]

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: 4444

Site Name: (4444) Hospital Militar Central Cirujano Mayor Dr Cosme Argerich

Subject No: 44441161

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 17:38

[eCRF Audit Trail History](#)

Electronic Sample Tracking

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB
3.	Sample Collected?	YES Date of Collection: Sep/21/2020
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[]

Aliquot

Please enter barcode for each aliquot.

5.a	Sample ID	[BPWT4K]
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Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:04

Site No: 4444

Subject No: 44441161

Generated By: (b) (4)

Form: VACCINATION

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (4444) Hospital Militar Central Cirujano Mayor Dr Cosme Argerich

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 17:38

[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/21/2020 18:10
5.	Anatomical Location:	DELTOID MUSCLE
6.	Body Side:	LEFT
7.	Route:	INTRAMUSCULAR
8.	Actual Dose:	[]
9.	Unit:	
10.	Timeframe Subject Was Observed	THE PROTOCOL SPECIFIED OBSERVATION PERIOD
11.	Was the subject observed for at least the protocol specified observation period after investigational product administration?	YES

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Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 06-Jul-2020 21:53

Site No: 4444

Subject No: 44441161

Generated By: (b) (4)

Form: REACTOGENICITY DIARY

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (4444) Hospital Militar Central Cirujano
Mayor Dr Cosme Argerich

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 17:38

[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: 4444

Subject No: 44441161

Generated By: (b) (4)

Form: DATE OF VISIT

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (4444) Hospital Militar Central Cirujano
Mayor Dr Cosme Argerich

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 17:38

[eCRF Audit Trail History](#)

Date of Visit		
1.	Date of Visit	Oct/13/2020
2.	Erroneous Visit	

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 10-Oct-2020 16:01

Site No: 4444

Subject No: 44441161

Generated By: (b) (4)

Form: VITAL SIGNS - TEMP

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (4444) Hospital Militar Central Cirujano
Mayor Dr Cosme Argerich

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 17:38

[eCRF Audit Trail History](#)

Vital Signs

1.	Date:	Oct/13/2020
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Vital Signs Details

2.a	Record Identifier:	1
	Temperature:	[36.8]
	Unit:	C
	Temperature Location:	ORAL CAVITY

090177e196ae2ede\Final\Final On: 01-Apr-2021 03:26 (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:** 4444**Site Name:** (4444) Hospital Militar Central Cirujano Mayor Dr Cosme Argerich**Subject No:** 44441161**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 17:38[eCRF Audit Trail History](#)**Electronic Sample Tracking**

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB
3.	Sample Collected?	YES Date of Collection: Oct/13/2020
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	[BP1VC1]
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Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:04

Site No: 4444

Subject No: 44441161

Generated By: (b) (4)

Form: VACCINATION

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (4444) Hospital Militar Central Cirujano Mayor Dr Cosme Argerich

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 17:38

[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:	Oct/13/2020 17:00
5.	Anatomical Location:	DELTOID MUSCLE
6.	Body Side:	LEFT
7.	Route:	INTRAMUSCULAR
8.	Actual Dose:	[]
9.	Unit:	
10.	Timeframe Subject Was Observed	THE PROTOCOL SPECIFIED OBSERVATION PERIOD
11.	Was the subject observed for at least the protocol specified observation period after investigational product administration?	YES

090177e196ae2ede\Final\Final On: 01-Apr-2021 03:26 (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: 4444 **Site Name:** (4444) Hospital Militar Central Cirujano
Mayor Dr Cosme Argerich

Subject No: 44441161 **Subject Initials:** ---

Generated By: (b) (4) **Generated Time (GMT):** 29-Mar-2021 17:38

[eCRF Audit Trail History](#)

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

Header Text: c4591001**Visit:** V3_MONTH1_POSTVAX2_L **Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY**Form Version:** 22-Apr-2020 21:03 **Form Status:** Data Complete, Locked, Frozen, Verified**Site No:** 4444**Site Name:** (4444) Hospital Militar Central Cirujano Mayor Dr Cosme Argerich**Subject No:** 44441161**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 17:38[eCRF Audit Trail History](#)**Electronic Sample Tracking**

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

Aliquot

Please enter barcode for each aliquot.

5.a	Sample ID	[BP1PBZ]
5.b	Sample ID	[BJ4F4X]
5.c	Sample ID	[BJ4F3L]

Header Text: c4591001

Visit: V4_MONTH6_L

Form Version: 22-Apr-2020 21:02

Site No: 4444

Subject No: 44441161

Generated By: (b) (4)

Form: DATE OF VISIT

Form Status: Not Started

Site Name: (4444) Hospital Militar Central Cirujano
Mayor Dr Cosme Argerich

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 17:38

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:** 4444**Site Name:** (4444) Hospital Militar Central Cirujano Mayor Dr Cosme Argerich**Subject No:** 44441161**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 17:38**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: 4444

Subject No: 44441161

Generated By: (b) (4)

Form: DATE OF VISIT

Form Status: Not Started

Site Name: (4444) Hospital Militar Central Cirujano
Mayor Dr Cosme Argerich

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 17:38

Date of Visit

1.	Date of Visit	//
2.	Erroneous Visit	

Header Text: c4591001**Visit:** V5_MONTH12_L**Form Version:** 22-Apr-2020 21:03**Site No:** 4444**Subject No:** 44441161**Generated By:** (b) (4)**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY**Form Status:** Not Started**Site Name:** (4444) Hospital Militar Central Cirujano Mayor Dr Cosme Argerich**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 17:38**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: V6_MONTH24_L

Form Version: 22-Apr-2020 21:02

Site No: 4444

Subject No: 44441161

Generated By: (b) (4)

Form: DATE OF VISIT

Form Status: Not Started

Site Name: (4444) Hospital Militar Central Cirujano
Mayor Dr Cosme Argerich

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 17:38

Date of Visit

1.	Date of Visit	//
2.	Erroneous Visit	

Header Text: c4591001**Visit:** V6_MONTH24_L**Form Version:** 22-Apr-2020 21:03**Site No:** 4444**Subject No:** 44441161**Generated By:** (b) (4)**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY**Form Status:** Not Started**Site Name:** (4444) Hospital Militar Central Cirujano Mayor Dr Cosme Argerich**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 17:38**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: POT_COVID_ILL - New
Unscheduled Visit

Form: DATE OF VISIT - ILLNESS ONSET

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 4444

Site Name: (4444) Hospital Militar Central Cirujano
Mayor Dr Cosme Argerich

Subject No: 44441161

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 17:38

Date of Visit

1.	Date of Visit	//
2.	Erroneous Visit	

COVID-19 Illness Visit

3.	COVID-19 Illness Visit:	
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090177e196ae2ede\Final\Final On: 01-Apr-2021 03:26 (GMT)

Header Text: c4591001**Visit:** POT_COVID_ILL - New
Unscheduled Visit**Form Version:** 20-Feb-2021 02:17**Site No:** 4444**Subject No:** 44441161**Generated By:** (b) (4)**Form:** SIGNS AND SYMPTOMS OF POTENTIAL
COVID-19**Form Status:** Not Started**Site Name:** (4444) Hospital Militar Central Cirujano
Mayor Dr Cosme Argerich**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 17:38**Signs and Symptoms**

1.	Date of Assessment:	//
2.	Date of First Symptom Started:	//
3.	Symptoms Ongoing?	

Symptoms

4.	Symptoms:	
	Was symptom present?	

Symptoms - Other

5.	Symptoms - Other Text:	[]
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Header Text: c4591001

Visit: POT_COVID_ILL - New
Unscheduled Visit

Form Version: 22-Apr-2020 21:03

Site No: 4444

Subject No: 44441161

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING - NASAL
SWAB SELF

Form Status: Not Started

Site Name: (4444) Hospital Militar Central Cirujano
Mayor Dr Cosme Argerich

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 17:38

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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090177e196ae2ede\Final\Final On: 01-Apr-2021 03:26 (GMT)

Header Text: c4591001**Visit:** POT_COVID_ILL - New
Unscheduled Visit**Form:** ELECTRONIC SAMPLE TRACKING - NASAL
SWAB**Form Version:** 22-Apr-2020 21:03**Form Status:** Not Started**Site No:** 4444**Site Name:** (4444) Hospital Militar Central Cirujano
Mayor Dr Cosme Argerich**Subject No:** 44441161**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 17:38**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: POT_COVID_ILL - New
Unscheduled Visit

Form: HEALTH CARE UTILIZATION

Form Version: 20-Feb-2021 02:19

Form Status: Not Started

Site No: 4444

Site Name: (4444) Hospital Militar Central Cirujano
Mayor Dr Cosme Argerich

Subject No: 44441161

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 17:38

Health Care Utilization

1.	Physician or Healthcare Professional:	
	Occurrence of Visits or Contacts:	

Health Care Utilization Other

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

3.	Has the subject been hospitalized due to potential COVID-19 illness?	
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090177e196ae2ede\Final\Final On: 01-Apr-2021 03:26 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL - New
Unscheduled Visit

Form: ILLNESS DETAILS

Form Version: 06-Jul-2020 21:52

Form Status: Not Started

Site No: 4444

Site Name: (4444) Hospital Militar Central Cirujano
Mayor Dr Cosme Argerich

Subject No: 44441161

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 17:38

Illness Details

1.	Category of Clinical Event:	
2.	Was a diagnosis obtained for Potential COVID-19 Illness?	
3.	Toxicity Grade:	

Header Text: c4591001

Visit: POT_COVID_CONVA - New
Unscheduled Visit

Form: DATE OF VISIT - ILLNESS CONVALESCENT

Form Version: 22-Apr-2020 21:04

Form Status: Not Started

Site No: 4444

Site Name: (4444) Hospital Militar Central Cirujano
Mayor Dr Cosme Argerich

Subject No: 44441161

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 17:38

Date of Visit

1.	Date of Visit	//
2.	Erroneous Visit	

COVID-19 Illness Visit

3.	COVID-19 Illness Visit:	
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090177e196ae2ede\Final\Final On: 01-Apr-2021 03:26 (GMT)

Header Text: c4591001**Visit:** POT_COVID_CONVA - New
Unscheduled Visit**Form:** ELECTRONIC SAMPLE TRACKING -
IMMUNOGENICITY**Form Version:** 22-Apr-2020 21:03**Form Status:** Not Started**Site No:** 4444**Site Name:** (4444) Hospital Militar Central Cirujano
Mayor Dr Cosme Argerich**Subject No:** 44441161**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 17:38**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: 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: 4444

Site Name: (4444) Hospital Militar Central Cirujano
Mayor Dr Cosme Argerich

Subject No: 44441161

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 17:38

Date of Visit		
1.	Date of Visit	//
2.	Erroneous Visit	
COVID-19 Repeat Swab		
3.	COVID-19 Repeat Swab:	

Header Text: c4591001**Visit:** POT_COVID_REPEAT_SWAB - New Unscheduled Visit **Form:** ELECTRONIC SAMPLE TRACKING - REPEAT SWAB**Form Version:** 10-Oct-2020 15:57 **Form Status:** Not Started**Site No:** 4444**Site Name:** (4444) Hospital Militar Central Cirujano Mayor Dr Cosme Argerich**Subject No:** 44441161**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 17:38**Electronic Sample Tracking**

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

Aliquot

Please enter barcode for each aliquot.

5.	Sample ID	[]
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Header Text: c4591001

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

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

Site No: 4444

Site Name: (4444) Hospital Militar Central Cirujano
Mayor Dr Cosme Argerich

Subject No: 44441161

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 17:38

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: 4444 **Site Name:** (4444) Hospital Militar Central Cirujano
Mayor Dr Cosme Argerich

Subject No: 44441161 **Subject Initials:** ---

Generated By: (b) (4) **Generated Time (GMT):** 29-Mar-2021 17:38

Unplanned Assessments

1.	Assessments	
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Header Text: c4591001

Visit: Logs

Form: ADVERSE EVENT REPORT

Form Version: 22-Apr-2020 21:02

Site No: 4444

Site Name: (4444) Hospital Militar Central Cirujano
Mayor Dr Cosme Argerich

Subject No: 44441161

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 17:38

#	Category	AE Identifier	Adverse Event	Start Date	Is the Adverse Event Still Ongoing	Form Instance
1.	ADVERSE EVENT	1	Coronary heart disease	Oct/1/2020 10:00	NO End Date Time: Feb/17/2021 10:00	Repeating Pages

090177e196ae2ede\Final\Final On: 01-Apr-2021 03:26 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen

Site No: 4444

Site Name: (4444) Hospital Militar Central Cirujano
Mayor Dr Cosme Argerich

Subject No: 44441161

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 17:38

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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)	[Coronary heart disease]
4.	Start Date Time:	Oct/1/2020 10:00
5.	Is the adverse event still ongoing?	NO End Date Time: Feb/17/2021 10:00
6.	Toxicity Grade:	2

090177e196ae2ede\Final\Final On: 01-Apr-2021 03:26 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 4444

Subject No: 44441161

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Frozen

Site Name: (4444) Hospital Militar Central Cirujano
Mayor Dr Cosme Argerich

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 17:38

7.	<p>Is the adverse event serious?</p> <p>If Yes, NOTIFY PFIZER IMMEDIATELY.</p> <p>Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).</p>	<p>YES</p> <p>Is this serious event associated with congenital anomaly or birth defect? NO</p> <p>Did this serious event result in death? NO</p> <p>Did this serious event require or prolong hospitalization? YES</p> <p>Did this serious event result in persistent or significant disability/incapacity? NO</p> <p>Is this serious event life threatening? NO</p> <p>Other medically important serious event 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: [Cardiovascular risk factors (hypertension, smoker, obesity, sex and age)]</p>

090177e196ae2ede\Final\Final On: 01-Apr-2021 03:26 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen

Site No: 4444

Site Name: (4444) Hospital Militar Central Cirujano
Mayor Dr Cosme Argerich

Subject No: 44441161

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 17:38

10.	Latest Action Taken with Study Treatment:	NOT APPLICABLE
11.	Was a Concomitant Medication given?	YES
12.	Was a Non-Drug Treatment given?	YES
13.	What was the outcome of this adverse event?:	RECOVERED/RESOLVED
14.	Did the adverse event cause the subject to be discontinued from the study?	NO
15.	Serious Adverse Event Number: For Pfizer Use Only	[2021115175]

090177e196ae2ede\Final\Final On: 01-Apr-2021 03:26 (GMT)

Header Text: c4591001

Visit: Logs

Form: MEDICATION ERROR

Form Version: 17-Jul-2020 21:54

Site No: 4444

Site Name: (4444) Hospital Militar Central Cirujano
Mayor Dr Cosme Argerich

Subject No: 44441161

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 17:38

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

090177e196ae2ede\Final\Final On: 01-Apr-2021 03:26 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 17-Jul-2020 21:54

Site No: 4444

Subject No: 44441161

Generated By: (b) (4)

Form: MEDICATION ERROR

Form Status: Not Started

Site Name: (4444) Hospital Militar Central Cirujano
Mayor Dr Cosme Argerich

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 17:38

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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	[]

090177e196ae2ede\Final\Final On: 01-Apr-2021 03:26 (GMT)

Header Text: c4591001

Visit: Logs

Form: CONCOMITANT MEDICATIONS - NON STUDY VACCINATIONS

Form Version: 22-Apr-2020 21:03

Site No: 4444

Site Name: (4444) Hospital Militar Central Cirujano Mayor Dr Cosme Argerich

Subject No: 44441161

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 17:38

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

090177e196ae2ede\Final\Final On: 01-Apr-2021 03:26 (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: 4444

Site Name: (4444) Hospital Militar Central Cirujano Mayor Dr Cosme Argerich

Subject No: 44441161

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 17:38

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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:	//

090177e196ae2ede\Final\Final On: 01-Apr-2021 03:26 (GMT)

Header Text: c4591001

Visit: Logs

Form: CONCOMITANT MEDICATIONS - PROHIBITED

Form Version: 22-Apr-2020 21:03

Site No: 4444

Site Name: (4444) Hospital Militar Central Cirujano Mayor Dr Cosme Argerich

Subject No: 44441161

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 17:38

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

090177e196ae2ede\Final\Final On: 01-Apr-2021 03:26 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: CONCOMITANT MEDICATIONS - PROHIBITED

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 4444

Site Name: (4444) Hospital Militar Central Cirujano Mayor Dr Cosme Argerich

Subject No: 44441161

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 17:38

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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?	

090177e196ae2ede\Final\Final On: 01-Apr-2021 03:26 (GMT)

Header Text: c4591001

Visit: Logs

Form: RADIATION TREATMENT

Form Version: 22-Apr-2020 21:02

Site No: 4444

Site Name: (4444) Hospital Militar Central Cirujano Mayor Dr Cosme Argerich

Subject No: 44441161

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 17:38

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

090177e196ae2ede\Final\Final On: 01-Apr-2021 03:26 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: RADIATION TREATMENT

Form Version: 22-Apr-2020 21:02

Form Status: Not Started

Site No: 4444

Site Name: (4444) Hospital Militar Central Cirujano
Mayor Dr Cosme Argerich

Subject No: 44441161

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 17:38

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Radiation Treatment

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

090177e196ae2ede\Final\Final On: 01-Apr-2021 03:26 (GMT)

Header Text: c4591001

Visit: Logs

Form: TRANSFUSIONS

Form Version: 22-Apr-2020 21:03

Site No: 4444

Site Name: (4444) Hospital Militar Central Cirujano
Mayor Dr Cosme Argerich

Subject No: 44441161

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 17:38

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

090177e196ae2ede\Final\Final On: 01-Apr-2021 03:26 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: TRANSFUSIONS

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 4444

Site Name: (4444) Hospital Militar Central Cirujano
Mayor Dr Cosme Argerich

Subject No: 44441161

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 17:38

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

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: 4444

Site Name: (4444) Hospital Militar Central Cirujano
Mayor Dr Cosme Argerich

Subject No: 44441161

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 17:38

[eCRF Audit Trail History](#)

Disposition - Treatment

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

090177e196ae2ede\Final\Final On: 01-Apr-2021 03:26 (GMT)

Header Text: c4591001

Visit: Unplanned Vaccination -
Unscheduled

Form: DATE OF VISIT

Form Version: 22-Apr-2020 21:02

Form Status: Not Started

Site No: 4444

Site Name: (4444) Hospital Militar Central Cirujano
Mayor Dr Cosme Argerich

Subject No: 44441161

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 17:38

Date of Visit

1.	Date of Visit	//
2.	Erroneous Visit	

Header Text: c4591001

Visit: Unplanned Vaccination -
Unscheduled

Form: VITAL SIGNS - TEMP

Form Version: 20-Feb-2021 02:16

Form Status: Not Started

Site No: 4444

Site Name: (4444) Hospital Militar Central Cirujano
Mayor Dr Cosme Argerich

Subject No: 44441161

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 17:38

Vital Signs

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

Vital Signs Details

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

090177e196ae2ede\Final\Final On: 01-Apr-2021 03:26 (GMT)

Header Text: c4591001

Visit: Unplanned Vaccination -
Unscheduled

Form: VACCINATION

Form Version: 10-Dec-2020 02:26

Form Status: Not Started

Site No: 4444

Site Name: (4444) Hospital Militar Central Cirujano
Mayor Dr Cosme Argerich

Subject No: 44441161

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 17:38

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?	

090177e196ae2ede\Final\Final On: 01-Apr-2021 03:26 (GMT)

Header Text: c4591001

Visit: Unplanned Vaccination -
Unscheduled

Form: CONTACT OUTCOME - MONTH 1

Form Version: 10-Oct-2020 15:57

Form Status: Not Started

Site No: 4444

Site Name: (4444) Hospital Militar Central Cirujano
Mayor Dr Cosme Argerich

Subject No: 44441161

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 17:38

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: 4444

Site Name: (4444) Hospital Militar Central Cirujano
Mayor Dr Cosme Argerich

Subject No: 44441161

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 17:38

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: 4444

Site Name: (4444) Hospital Militar Central Cirujano
Mayor Dr Cosme Argerich

Subject No: 44441161

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 17:38

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: 4444

Site Name: (4444) Hospital Militar Central Cirujano
Mayor Dr Cosme Argerich

Subject No: 44441161

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 17:38

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:** 4444**Site Name:** (4444) Hospital Militar Central Cirujano
Mayor Dr Cosme Argerich**Subject No:** 44441161**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 17:38**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:** V201_SURVEIL_CONSENT -
Unscheduled**Form:** ELECTRONIC SAMPLE TRACKING - NASAL
SWAB**Form Version:** 22-Apr-2020 21:03**Form Status:** Not Started**Site No:** 4444**Site Name:** (4444) Hospital Militar Central Cirujano
Mayor Dr Cosme Argerich**Subject No:** 44441161**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 17:38**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: Follow-Up - Unscheduled

Form: DISPOSITION - FOLLOW-UP

Form Version: 15-Sep-2020 21:53

Form Status: Not Started

Site No: 4444

Site Name: (4444) Hospital Militar Central Cirujano
Mayor Dr Cosme Argerich

Subject No: 44441161

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 17:38

Disposition - Follow-Up

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

Header Text: c4591001

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

Unscheduled

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen, Verified

Site No: 4444

Site Name: (4444) Hospital Militar Central Cirujano
Mayor Dr Cosme Argerich

Subject No: 44441161

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 17:38

[eCRF Audit Trail History](#)

Date of Visit

1.	Date of Visit	Feb/11/2021
2.	Erroneous Visit	

Header Text: c4591001

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

Form Version: 10-Dec-2020 02:25 **Form Status:** Data Complete, Frozen

Site No: 4444

Site Name: (4444) Hospital Militar Central Cirujano
Mayor Dr Cosme Argerich

Subject No: 44441161

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 17:38

[eCRF Audit Trail History](#)

Further Vaccination Confirmation

1.	Select appropriate response - Is participant willing to return for Vaccination 3?	Participant is willing to return for Vaccination 3 Participant is: eligible and NOT confirmed to have received only placebo at Vaccination 1/2
----	---	---

Header Text: c4591001

Visit: Disposition - Unscheduled

Form: TREATMENT UNBLINDED

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 4444

Site Name: (4444) Hospital Militar Central Cirujano
Mayor Dr Cosme Argerich

Subject No: 44441161

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 17:38

[eCRF Audit Trail History](#)

Treatment Unblinded

1.	Date Treatment Unblinded :	Feb/11/2021
2.	Primary Reason for Unblinding:	ASSESS ELIGIBILITY FOR ADDITIONAL VACCINATION

Header Text: c4591001

Visit: Disposition - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 4444

Subject No: 44441161

Generated By: (b) (4)

Form: WITHDRAWAL OF CONSENT

Form Status: Not Started

Site Name: (4444) Hospital Militar Central Cirujano
Mayor Dr Cosme Argerich

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 17:38

Withdrawal Of Consent

1.	Withdrawal of Consent Date :	//
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Header Text: c4591001

Visit: Disposition - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 4444

Subject No: 44441161

Generated By: (b) (4)

Form: DEATH DETAILS CODED

Form Status: Not Started

Site Name: (4444) Hospital Militar Central Cirujano
Mayor Dr Cosme Argerich

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 17:38

Death Details

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

Cause of Death

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

Header Text: c4591001

Visit: Subject Status - Unscheduled

Form: SUBJECT STATUS

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Verified

Site No: 4444

Site Name: (4444) Hospital Militar Central Cirujano
Mayor Dr Cosme Argerich

Subject No: 44441161

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 17:38

[eCRF Audit Trail History](#)

Subject Status

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

Header Text: c4591001

Visit: Investigator Signature -
Unscheduled

Form: CASEBOOK SIGNATURE FORM

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Signed, Verified

Site No: 4444

Site Name: (4444) Hospital Militar Central Cirujano
Mayor Dr Cosme Argerich

Subject No: 44441161

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 17:38

[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: 4444

Site Name: (4444) Hospital Militar Central Cirujano
Mayor Dr Cosme Argerich

Subject No: 44441161

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 17:38

[Audit Trail](#)

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

- CRF_Sign

Name	Signature Meaning	Date	Type	Action
Yanina Rivera	Approved	Mar-10-2021 22:42:25 (UTC-03:00) City of Buenos Aires	BOOK	Signed

Affidavit:

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

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

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

090177e196ae2ede\Final\Final On: 01-Apr-2021 03:26 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 15-Sep-2020 21:53

Site No: 4444

Subject No: 44441161

Generated By: (b) (4)

Form: INCLUSION/EXCLUSION CRITERIA -
Comments

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (4444) Hospital Militar Central Cirujano
Mayor Dr Cosme Argerich

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 17:38

[Back to Form](#)

Item	Date	User	Comment
Form	Sep-22-2020 17:57:21 (UTC-03:00) City of Buenos Aires	Martina Davalli (b) (4)	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: 4444

Site Name: (4444) Hospital Militar Central Cirujano
Mayor Dr Cosme Argerich

Subject No: 44441161

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 17:38

[Back to Form](#)

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

- CRF_Sign

Name	Signature Meaning	Date	Type	Action
Yanina Rivera	Approved	Mar-10-2021 22:42:25 (UTC-03:00) City of Buenos Aires	BOOK	Signed

Affidavit:

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

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

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

(b) (6)	N/A	Feb-20-2021 16:08:50 (UTC-03:00) City of Buenos Aires		Edit - All signatures invalidated
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Affidavit:

N/A

(b) (6)	Approved	Feb-16-2021 13:07:19 (UTC-03:00) City of Buenos Aires	BOOK	Signed
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090177e196ae2ede\Final\Final On: 01-Apr-2021 03:26 (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: 4444

Site Name: (4444) Hospital Militar Central Cirujano
Mayor Dr Cosme Argerich

Subject No: 44441161

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 17:38

Affidavit:

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

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

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

(b) (6)	N/A	Feb-11-2021 12:53:46 (UTC-03:00) City of Buenos Aires		Edit - All signatures invalidated
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Affidavit:

N/A

(b) (6)	Approved	Feb-05-2021 12:30:22 (UTC-03:00) City of Buenos Aires	BOOK	Signed
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090177e196ae2ede\Final\Final On: 01-Apr-2021 03:26 (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: 4444

Site Name: (4444) Hospital Militar Central Cirujano
Mayor Dr Cosme Argerich

Subject No: 44441161

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 17:38

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-29-2021 12:10:30 (UTC-03:00) City of Buenos Aires		Edit - All signatures invalidated
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Affidavit:

N/A

Tatiana Estrada	Approved	Jan-25-2021 18:44:30 (UTC-03:00) City of Buenos Aires	BOOK	Signed
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090177e196ae2ede\Final\Final On: 01-Apr-2021 03:26 (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: 4444

Site Name: (4444) Hospital Militar Central Cirujano
Mayor Dr Cosme Argerich

Subject No: 44441161

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 17:38

Affidavit:

By my dated signature below, I, Tatiana Estrada, 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-24-2021 10:43:25 (UTC-03:00) City of Buenos Aires		Edit - All signatures invalidated
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Affidavit:

N/A

(b) (6)	Approved	Nov-13-2020 10:34:27 (UTC-03:00) City of Buenos Aires	BOOK	Signed
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090177e196ae2ede\Final\Final On: 01-Apr-2021 03:26 (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: 4444

Site Name: (4444) Hospital Militar Central Cirujano
Mayor Dr Cosme Argerich

Subject No: 44441161

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 17:38

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) [Redacted]	N/A	Nov-11-2020 19:52:09 (UTC-03:00) City of Buenos Aires		Edit - All signatures invalidated
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Affidavit:

N/A

Tatiana Estrada	Approved	Nov-10-2020 11:17:36 (UTC-03:00) City of Buenos Aires	BOOK	Signed
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090177e196ae2ede\Final\Final On: 01-Apr-2021 03:26 (GMT)

Header Text: c4591001

Visit: Investigator Signature -
Unscheduled

Form Version: 22-Apr-2020 21:04

Site No: 4444

Subject No: 44441161

Generated By: (b) (4)

Form: CASEBOOK SIGNATURE FORM - Signature
History

Form Status: Data Complete, Signed, Verified

Site Name: (4444) Hospital Militar Central Cirujano
Mayor Dr Cosme Argerich

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 17:38

Affidavit:

By my dated signature below, I, Tatiana Estrada, 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: 15-Sep-2020 21:55

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 4444

Site Name: (4444) Hospital Militar Central Cirujano Mayor Dr Cosme Argerich

Subject No: 44441161

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 17:38

[Back to Form](#)

1. Select appropriate response - Protocol version

Date	Location	User	Value	Reason
Sep-22-2020 17:56:43 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	Martina Davalli (b) (4)	Data Entry: 08 SEP 2020	Initial Entry

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

Date	Location	User	Value	Reason
Sep-22-2020 17:56:43 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	Martina Davalli (b) (4)	Data Entry: STAGE 3 COHORT S	Initial Entry

090177e196ae2ede\Final\Final On: 01-Apr-2021 03:26 (GMT)

Header Text: c4591001

Visit: COHORT_SELECTION

Form: MAIN INFORMED CONSENT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 4444

Site Name: (4444) Hospital Militar Central Cirujano Mayor Dr Cosme Argerich

Subject No: 44441161

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 17:38

[Back to Form](#)

1. Consent Was:

Date	Location	User	Value	Reason
Sep-22-2020 17:56:51 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	Martina Davalli (b) (4)	Data Entry: OBTAINED Date Written Conse nt Obtained Sep/21/2020	Initial Entry

090177e196ae2ede\Final\Final On: 01-Apr-2021 03:26 (GMT)

Header Text: c4591001

Visit: COHORT_SELECTION

Form Version: 15-Sep-2020 21:54

Site No: 4444

Subject No: 44441161

Generated By: (b) (4)

Form: DEMOGRAPHY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (4444) Hospital Militar Central Cirujano Mayor Dr Cosme Argerich

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 17:38

[Back to Form](#)

1. Subject ID

Date	Location	User	Value	Reason
Sep-21-2020 20:55:46 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 44441161	Item copied from previous form

2. Birth Date:

Date	Location	User	Value	Reason
Sep-21-2020 20:55:43 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: (b) (6) 1951	Enrollment Entry

3. Sex:

Date	Location	User	Value	Reason
Sep-22-2020 17:57:04 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	Martina Davalli (b) (4)	Data Entry: MALE	Initial Entry

4. Ethnicity:

Date	Location	User	Value	Reason
Sep-22-2020 17:57:04	ACV0PFEINFP6000	Martina Davalli	Data Entry: HISPANIC OR LAT	Initial Entry

090177e196ae2ede\Final\Final On: 01-Apr-2021 03:26 (GMT)

Header Text: c4591001

Visit: COHORT_SELECTION

Form: DEMOGRAPHY - eCRF Audit Trail History

Form Version: 15-Sep-2020 21:54

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 4444

Site Name: (4444) Hospital Militar Central Cirujano Mayor Dr Cosme Argerich

Subject No: 44441161

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 17:38

(UTC-03:00) City of Buenos Aires		(b) (4)	INO(A) OR OF SPANISH ORIGIN	
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5. Race: (Check X all that apply):

Date	Location	User	Value	Reason
Sep-22-2020 17:57:04 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	Martina Davalli (b) (4)	Data Entry: WHITE	Initial Entry

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:02

Site No: 4444

Subject No: 44441161

Generated By: (b) (4)

Form: DATE OF VISIT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (4444) Hospital Militar Central Cirujano
Mayor Dr Cosme Argerich

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 17:38

[Back to Form](#)

1. Date of Visit

Date	Location	User	Value	Reason
Sep-22-2020 17:57:12 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	Martina Davalli (b) (4)	Data Entry: Sep/21/2020	Initial Entry

090177e196ae2ede\Final\Final On: 01-Apr-2021 03:26 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 15-Sep-2020 21:52

Site No: 4444

Subject No: 44441161

Generated By: (b) (4)

Form: DISPOSITION - SCREENING - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (4444) Hospital Militar Central Cirujano Mayor Dr Cosme Argerich

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 17:38

[Back to Form](#)

1. Date of Completion/Discontinuation/Death

Date	Location	User	Value	Reason
Sep-22-2020 17:57:31 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	Martina Davalli (b) (4)	Data Entry: Sep/21/2020	Initial Entry

2. Phase of Disposition:

Date	Location	User	Value	Reason
Sep-22-2020 17:57:31 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SCREENING	Initial Entry

3. Status:

Date	Location	User	Value	Reason
Sep-22-2020 17:57:31 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	Martina Davalli (b) (4)	Data Entry: COMPLETED	Initial Entry

090177e196ae2ede\Final\Final On: 01-Apr-2021 03:26 (GMT)

Header Text: c4591001**Visit:** V1_DAY1_VAX1_L**Form Version:** 22-Apr-2020 21:03**Site No:** 4444**Subject No:** 44441161**Generated By:** (b) (4)**Form:** GENERAL MEDICAL HISTORY - eCRF Audit Trail History**Form Status:** Data Complete, Frozen, Verified**Site Name:** (4444) Hospital Militar Central Cirujano Mayor Dr Cosme Argerich**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 17:38[Back to Form](#)*1.a*

Date	Location	User	Value	Reason
Sep-22-2020 17:58:03 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH 1 Number: Medical Hi Arterial h story Term ypertensi : on Start Date: Sep/8/201 0 Ongoing: YES	Initial Entry

1.a Line/MH Number:

Date	Location	User	Value	Reason
Sep-22-2020 17:58:03 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 1	Initial Entry

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

Date	Location	User	Value	Reason
Sep-22-2020 17:58:03 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	Martina Davalli (b) (4)	Data Entry: Arterial hypertension	Initial Entry

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 4444

Site Name: (4444) Hospital Militar Central Cirujano Mayor Dr Cosme Argerich

Subject No: 44441161

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 17:38

1.a Start Date:

Date	Location	User	Value	Reason
Sep-22-2020 17:58:03 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	Martina Davalli (b) (4)	Data Entry: Sep/8/2010	Initial Entry

1.a Ongoing:

Date	Location	User	Value	Reason
Sep-22-2020 17:58:03 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	Martina Davalli (b) (4)	Data Entry: YES	Initial Entry

1.b

Date	Location	User	Value	Reason
Nov-12-2020 08:30:56 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 2 Medical History Term: Insomnia Start Date: Nov/1/2015 Ongoing: YES	Initial Entry

090177e196ae2ede\Final\Final On: 01-Apr-2021 03:26 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 4444

Site Name: (4444) Hospital Militar Central Cirujano Mayor Dr Cosme Argerich

Subject No: 44441161

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 17:38

1.b Line/MH Number:

Date	Location	User	Value	Reason
Nov-12-2020 08:30:56 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 2	Initial Entry

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

Date	Location	User	Value	Reason
Nov-12-2020 08:30:56 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Insomnia	Initial Entry

1.b Start Date:

Date	Location	User	Value	Reason
Nov-12-2020 08:30:56 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Nov/1/2015	Initial Entry

1.b Ongoing:

Date	Location	User	Value	Reason
Nov-12-2020 08:30:56 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

090177e196ae2ede\Final\Final On: 01-Apr-2021 03:26 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 4444

Site Name: (4444) Hospital Militar Central Cirujano Mayor Dr Cosme Argerich

Subject No: 44441161

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 17:38

I.c

Date	Location	User	Value	Reason
Jan-24-2021 10:43:25 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH N 3 umber: Medical His Obesity tory Term: Start Date: UNK/U NK/201 5 Ongoing: YES	Initial Entry

090177e196ae2ede\Final\Final On: 01-Apr-2021 03:26 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 4444

Site Name: (4444) Hospital Militar Central Cirujano Mayor Dr Cosme Argerich

Subject No: 44441161

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 17:38

I.c Line/MH Number:

Date	Location	User	Value	Reason
Jan-24-2021 10:43:25 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 3	Initial Entry

I.c Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:

Date	Location	User	Value	Reason
Jan-24-2021 10:43:25 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Obesity	Initial Entry

I.c Start Date:

Date	Location	User	Value	Reason
Jan-24-2021 10:43:25 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: UNK/UNK/2015	Initial Entry

I.c Ongoing:

Date	Location	User	Value	Reason
Jan-24-2021 10:43:25 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

090177e196ae2ede\Final\Final On: 01-Apr-2021 03:26 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 4444

Site Name: (4444) Hospital Militar Central Cirujano Mayor Dr Cosme Argerich

Subject No: 44441161

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 17:38

1.d

Date	Location	User	Value	Reason
Jan-24-2021 10:44:52 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH N 4 umber: Medical Hi Alcoholic story Term c cirrhosi : s Start Date: UNK/UN K/2013 Ongoing: YES	Initial Entry

090177e196ae2ede\Final\Final On: 01-Apr-2021 03:26 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 4444

Site Name: (4444) Hospital Militar Central Cirujano Mayor Dr Cosme Argerich

Subject No: 44441161

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 17:38

1.d Line/MH Number:

Date	Location	User	Value	Reason
Jan-24-2021 10:44:52 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 4	Initial Entry

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

Date	Location	User	Value	Reason
Jan-24-2021 10:44:52 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Alcoholic cirrhosis	Initial Entry

1.d Start Date:

Date	Location	User	Value	Reason
Jan-24-2021 10:44:52 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: UNK/UNK/2013	Initial Entry

1.d Ongoing:

Date	Location	User	Value	Reason
Jan-24-2021 10:44:52 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

090177e196ae2ede\Final\Final On: 01-Apr-2021 03:26 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 4444

Site Name: (4444) Hospital Militar Central Cirujano Mayor Dr Cosme Argerich

Subject No: 44441161

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 17:38

I.e

Date	Location	User	Value	Reason
Feb-01-2021 12:29:56 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Line/M 5 H Num ber: Medical History Benign p rostatic h Term: yperplasi a Start Date: UNK/UN K/2018 Ongoing: YES	Transcription Error
Jan-29-2021 12:10:30 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/M 5 H Num ber: Medical History Benign p rostatic h Term: yperplasi a Start Date: UNK/UN K/2019 Ongoing: YES	Initial Entry

090177e196ae2ede\Final\Final On: 01-Apr-2021 03:26 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 4444

Site Name: (4444) Hospital Militar Central Cirujano Mayor Dr Cosme Argerich

Subject No: 44441161

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 17:38

I.e Line/MH Number:

Date	Location	User	Value	Reason
Jan-29-2021 12:10:30 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 5	Initial Entry

I.e Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:

Date	Location	User	Value	Reason
Jan-29-2021 12:10:30 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Benign prostatic hyp erplasia	Initial Entry

I.e Start Date:

Date	Location	User	Value	Reason
Feb-01-2021 12:29:56 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: UNK/UNK/2018	Transcription Error
Jan-29-2021 12:10:30 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: UNK/UNK/2019	Initial Entry

I.e Ongoing:

Date	Location	User	Value	Reason
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090177e196ae2ede\Final\Final On: 01-Apr-2021 03:26 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 4444

Site Name: (4444) Hospital Militar Central Cirujano Mayor Dr Cosme Argerich

Subject No: 44441161

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 17:38

Jan-29-2021 12:10:30 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry
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If

Date	Location	User	Value	Reason
Jan-29-2021 12:21:43 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH N 6 umber: Medical His smoking tory Term: Start Date: UNK/U NK/199 6 Ongoing: YES	Initial Entry

090177e196ae2ede\Final\Final On: 01-Apr-2021 03:26 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 4444

Site Name: (4444) Hospital Militar Central Cirujano Mayor Dr Cosme Argerich

Subject No: 44441161

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 17:38

1.f Line/MH Number:

Date	Location	User	Value	Reason
Jan-29-2021 12:21:43 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 6	Initial Entry

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

Date	Location	User	Value	Reason
Jan-29-2021 12:21:43 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: smoking	Initial Entry

1.f Start Date:

Date	Location	User	Value	Reason
Jan-29-2021 12:21:43 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: UNK/UNK/1996	Initial Entry

1.f Ongoing:

Date	Location	User	Value	Reason
Jan-29-2021 12:21:43	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

090177e196ae2ede\Final\Final On: 01-Apr-2021 03:26 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 4444

Site Name: (4444) Hospital Militar Central Cirujano Mayor Dr Cosme Argerich

Subject No: 44441161

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 17:38

(UTC-03:00)
City of Buenos
Aires

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

I.g

Date	Location	User	Value	Reason
Feb-01-2021 18:50:16 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	Santiago Corradetti (b) (4)	Data Entry: Line/MH 7 Number: Medical H COPD istory Ter m: Start Date May/2 : 0/2013 Ongoing: YES	Initial Entry
Jan-29-2021 12:23:09 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Nu 7 mber: Medical Hist CO ory Term: PD Start Date: Ongoing: YE S	Initial Entry

090177e196ae2ede\Final\Final On: 01-Apr-2021 03:26 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 4444

Site Name: (4444) Hospital Militar Central Cirujano Mayor Dr Cosme Argerich

Subject No: 44441161

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 17:38

1.g Line/MH Number:

Date	Location	User	Value	Reason
Jan-29-2021 12:23:09 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 7	Initial Entry

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

Date	Location	User	Value	Reason
Jan-29-2021 12:23:09 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: COPD	Initial Entry

1.g Start Date:

Date	Location	User	Value	Reason
Feb-01-2021 18:50:16 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	Santiago Corradetti (b) (4)	Data Entry: May/20/2013	Initial Entry

1.g Ongoing:

Date	Location	User	Value	Reason
Jan-29-2021 12:23:09 (UTC-03:00)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

090177e196ae2ede\Final\Final On: 01-Apr-2021 03:26 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 4444

Site Name: (4444) Hospital Militar Central Cirujano Mayor Dr Cosme Argerich

Subject No: 44441161

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 17:38

City of Buenos Aires

I.h

Date	Location	User	Value	Reason
Feb-01-2021 18:50:16 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	Santiago Corradetti (b) (4)	Data Entry: Line/MH 8 Number: Medical portal h History T yper erm: sion Start Dat May/10 e: /2014 Ongoing: YES	Initial Entry
Jan-29-2021 12:24:57 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH 8 Number: Medical portal h History T yper erm: sion Start Dat e: Ongoing: YES	Initial Entry

090177e196ae2ede\Final\Final On: 01-Apr-2021 03:26 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 4444

Site Name: (4444) Hospital Militar Central Cirujano Mayor Dr Cosme Argerich

Subject No: 44441161

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 17:38

1.h Line/MH Number:

Date	Location	User	Value	Reason
Jan-29-2021 12:24:57 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 8	Initial Entry

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

Date	Location	User	Value	Reason
Jan-29-2021 12:24:57 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: portal hypertension	Initial Entry

1.h Start Date:

Date	Location	User	Value	Reason
Feb-01-2021 18:50:16 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	Santiago Corradetti (b) (4)	Data Entry: May/10/2014	Initial Entry

1.h Ongoing:

Date	Location	User	Value	Reason
Jan-29-2021 12:24:57 (UTC-03:00)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

090177e196ae2ede\Final\Final On: 01-Apr-2021 03:26 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 4444

Site Name: (4444) Hospital Militar Central Cirujano Mayor Dr Cosme Argerich

Subject No: 44441161

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 17:38

City of Buenos Aires

Li

Date	Location	User	Value	Reason
Feb-01-2021 18:50:16 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	Santiago Corradetti (b) (4)	Data Entry: Line/MH 9 Number: Medical History Term: esophag T real vari ces Start Date: May/10 /2014 Ongoing: YES	Initial Entry
Jan-29-2021 12:25:32 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH 9 Number: Medical History Term: esopha T geal var ices Start Date: Ongoing: YES	Initial Entry

090177e196ae2ede\Final\Final On: 01-Apr-2021 03:26 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 4444

Site Name: (4444) Hospital Militar Central Cirujano Mayor Dr Cosme Argerich

Subject No: 44441161

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 17:38

1.i Line/MH Number:

Date	Location	User	Value	Reason
Jan-29-2021 12:25:32 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 9	Initial Entry

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

Date	Location	User	Value	Reason
Jan-29-2021 12:25:32 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: esophageal varices	Initial Entry

1.i Start Date:

Date	Location	User	Value	Reason
Feb-01-2021 18:50:16 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	Santiago Corradetti (b) (4)	Data Entry: May/10/2014	Initial Entry

1.i Ongoing:

Date	Location	User	Value	Reason
Jan-29-2021 12:25:32 (UTC-03:00)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

090177e196ae2ede\Final\Final On: 01-Apr-2021 03:26 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 4444

Site Name: (4444) Hospital Militar Central Cirujano Mayor Dr Cosme Argerich

Subject No: 44441161

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 17:38

City of Buenos Aires				
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Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 15-Sep-2020 21:57

Site No: 4444

Subject No: 44441161

Generated By: (b) (4)

Form: HIV STATUS - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (4444) Hospital Militar Central Cirujano Mayor Dr Cosme Argerich

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 17:38

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1. Select appropriate response - What is the subject HIV status?

Date	Location	User	Value	Reason
Sep-22-2020 17:58:18 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	Martina Davalli (b) (4)	Data Entry: The subject is NOT known to be HIV PO SITIVE	Initial Entry

090177e196ae2ede\Final\Final On: 01-Apr-2021 03:26 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: VITAL SIGNS - BASELINE - eCRF Audit Trail History

Form Version: 15-Sep-2020 21:56

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 4444

Site Name: (4444) Hospital Militar Central Cirujano Mayor Dr Cosme Argerich

Subject No: 44441161

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 17:38

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1. Date:

Date	Location	User	Value	Reason
Sep-22-2020 17:58:40 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	Martina Davalli (b) (4)	Data Entry: Sep/21/2020	Initial Entry

2. Weight:

Date	Location	User	Value	Reason
Sep-22-2020 17:58:40 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	Martina Davalli (b) (4)	Data Entry: 117.0	Initial Entry

3. Unit:

Date	Location	User	Value	Reason
Sep-22-2020 17:58:40 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	Martina Davalli (b) (4)	Data Entry: kg	Initial Entry

4. Height:

Date	Location	User	Value	Reason
Sep-22-2020	ACV0PFEINFP6000	Martina	Data Entry:	Initial Entry

090177e196ae2ede\Final\Final On: 01-Apr-2021 03:26 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: VITAL SIGNS - BASELINE - eCRF Audit Trail History

Form Version: 15-Sep-2020 21:56

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 4444

Site Name: (4444) Hospital Militar Central Cirujano Mayor Dr Cosme Argerich

Subject No: 44441161

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 17:38

17:58:40
(UTC-03:00) City
of Buenos Aires

Davalli
(b) (4)

172.0

5. Unit:

Date	Location	User	Value	Reason
Sep-22-2020 17:58:40 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	Martina Davalli (b) (4)	Data Entry: cm	Initial Entry

6. Body Mass Index:

Date	Location	User	Value	Reason
Sep-22-2020 17:58:40 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 39.5	Initial Entry

7.a

Date	Location	User	Value	Reason
Sep-22-2020 17:58:40 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	Martina Davalli (b) (4)	Data Entry: Record Identifier: Temperature: Temperature Unit:	Initial Entry

090177e196ae2ede\Final\Final On: 01-Apr-2021 03:26 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: VITAL SIGNS - BASELINE - eCRF Audit Trail History

Form Version: 15-Sep-2020 21:56

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 4444

Site Name: (4444) Hospital Militar Central Cirujano Mayor Dr Cosme Argerich

Subject No: 44441161

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 17:38

			Temperatu re Locatio n::	ORAL CAVIT Y
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7.a Record Identifier:

Date	Location	User	Value	Reason
Sep-22-2020 17:58:40 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	Martina Davalli (b) (4)	Data Entry: 1	Initial Entry

7.a Temperature:

Date	Location	User	Value	Reason
Sep-22-2020 17:58:40 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	Martina Davalli (b) (4)	Data Entry: 36.5	Initial Entry

7.a Unit:

Date	Location	User	Value	Reason
Sep-22-2020 17:58:40 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	Martina Davalli (b) (4)	Data Entry: C	Initial Entry

7.a Temperature Location:

Date	Location	User	Value	Reason
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090177e196ae2ede\Final\Final On: 01-Apr-2021 03:26 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: VITAL SIGNS - BASELINE - eCRF Audit Trail History

Form Version: 15-Sep-2020 21:56

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 4444

Site Name: (4444) Hospital Militar Central Cirujano Mayor Dr Cosme Argerich

Subject No: 44441161

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 17:38

Sep-22-2020 17:58:40 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	Martina Davalli (b) (4)	Data Entry: ORAL CAVITY	Initial Entry
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090177e196ae2ede\Final\Final On: 01-Apr-2021 03:26 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 4444

Subject No: 44441161

Generated By: (b) (4)

Form: RANDOMIZATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (4444) Hospital Militar Central Cirujano Mayor Dr Cosme Argerich

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 17:38

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1. Randomization Date :

Date	Location	User	Value	Reason
Sep-22-2020 17:58:55 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	Martina Davalli (b) (4)	Data Entry: Sep/21/2020	Initial Entry

2. Randomization Number:

Date	Location	User	Value	Reason
Sep-22-2020 17:58:55 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	Martina Davalli (b) (4)	Data Entry: 262992	Initial Entry

090177e196ae2ede\Final\Final On: 01-Apr-2021 03:26 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 4444

Subject No: 44441161

Generated By: (b) (4)

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

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (4444) Hospital Militar Central Cirujano Mayor Dr Cosme Argerich

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 17:38

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1. Data Origin

Date	Location	User	Value	Reason
Sep-22-2020 17:59:00 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Sep-22-2020 17:59:00 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SERUM	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Sep-23-2020 09:17:20 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Sep-23-2020 03:31:13 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	'Sample Collected?' is Yes, however no barcodes are entered.

090177e196ae2ede\Final\Final On: 01-Apr-2021 03:26 (GMT)

Header Text: c4591001**Visit:** V1_DAY1_VAX1_L**Form Version:** 22-Apr-2020 21:03**Site No:** 4444**Subject No:** 44441161**Generated By:** (b) (4)**Form:** ELECTRONIC SAMPLE TRACKING -
IMMUNOGENICITY - eCRF Audit Trail History**Form Status:** Data Complete, Locked, Frozen, Verified**Site Name:** (4444) Hospital Militar Central Cirujano
Mayor Dr Cosme Argerich**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 17:38

				Please review and correct as appropriate.
Sep-22-2020 17:59:00 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Sep-22-2020 17:59:00 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	Martina Davalli (b) (4)	Data Entry: YES Date of Collection : Sep/21/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Sep-23-2020 09:17:20 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample I BRXSV D: X	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Sep-23-2020 09:17:20	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BRXSVX	Initial Entry

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 4444

Site Name: (4444) Hospital Militar Central Cirujano Mayor Dr Cosme Argerich

Subject No: 44441161

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 17:38

(UTC-03:00) City of Buenos Aires

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

5.b

Date	Location	User	Value	Reason
Sep-23-2020 10:32:14 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample I BRXSW D: 7	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Sep-23-2020 10:32:14 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BRXSW7	Initial Entry

5.c

Date	Location	User	Value	Reason
Sep-23-2020 10:41:56 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample I BHXG0 D: M	Initial Entry

090177e196ae2ede\Final\Final On: 01-Apr-2021 03:26 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 4444

Subject No: 44441161

Generated By: (b) (4)

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

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (4444) Hospital Militar Central Cirujano Mayor Dr Cosme Argerich

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 17:38

5.c Sample ID

Date	Location	User	Value	Reason
Sep-23-2020 10:41:56 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Data Entry: BHXGOM	Initial Entry

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 4444

Subject No: 44441161

Generated By: (b) (4)

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

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (4444) Hospital Militar Central Cirujano Mayor Dr Cosme Argerich

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 17:38

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1. Data Origin

Date	Location	User	Value	Reason
Sep-22-2020 17:59:06 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Sep-22-2020 17:59:06 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: NASAL_SWAB	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Sep-23-2020 09:38:03 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Sep-23-2020 03:31:13 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	'Sample Collected?' is Yes, however no barcodes are entered.

090177e196ae2ede\Final\Final On: 01-Apr-2021 03:26 (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:** 4444**Site Name:** (4444) Hospital Militar Central Cirujano Mayor Dr Cosme Argerich**Subject No:** 44441161**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 17:38

				Please review and correct as appropriate.
Sep-22-2020 17:59:06 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Sep-22-2020 17:59:06 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	Martina Davalli (b) (4)	Data Entry: YES Date of Collection : Sep/21/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Sep-23-2020 09:38:03 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	Romina Barrera (b) (4)	Data Entry: Sample I BPWT4 D: K	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Sep-23-2020 09:38:03	ACV0PFEINFP6000	Romina Barrera	Data Entry: BPWT4K	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: 4444

Site Name: (4444) Hospital Militar Central Cirujano Mayor Dr Cosme Argerich

Subject No: 44441161

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 17:38

(UTC-03:00) City of Buenos Aires		(b) (4)		
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Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:04

Site No: 4444

Subject No: 44441161

Generated By: (b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (4444) Hospital Militar Central Cirujano Mayor Dr Cosme Argerich

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 17:38

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1. Was there a temporary delay of vaccination?

Date	Location	User	Value	Reason
Sep-22-2020 17:59:22 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	Martina Davalli (b) (4)	Data Entry: NO	Initial Entry

2. Treatment Name

Date	Location	User	Value	Reason
Sep-22-2020 17:59:22 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: BLINDED THERAPY	Initial Entry

3. Formulation:

Date	Location	User	Value	Reason
Sep-22-2020 17:59:22 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: INJECTION	Initial Entry

4. Dose Date Time:

Date	Location	User	Value	Reason
Sep-22-2020 17:59:22	ACV0PFEINFP6000	Martina Davalli	Data Entry: Sep/21/2020 18:10	Initial Entry

090177e196ae2ede\Final\Final On: 01-Apr-2021 03:26 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:04

Site No: 4444

Subject No: 44441161

Generated By: (b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (4444) Hospital Militar Central Cirujano Mayor Dr Cosme Argerich

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 17:38

(UTC-03:00) City of Buenos Aires		(b) (4)		
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5. Anatomical Location:

Date	Location	User	Value	Reason
Sep-22-2020 17:59:22 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: DELTOID MUSCLE	Initial Entry

6. Body Side:

Date	Location	User	Value	Reason
Sep-22-2020 17:59:22 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	Martina Davalli (b) (4)	Data Entry: LEFT	Initial Entry

7. Route:

Date	Location	User	Value	Reason
Sep-22-2020 17:59:22 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: INTRAMUSCULAR	Initial Entry

10. Timeframe Subject Was Observed

Date	Location	User	Value	Reason
Sep-22-2020 17:59:22	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: THE PROTOCOL SPE	Initial Entry

090177e196ae2ede\Final\Final On: 01-Apr-2021 03:26 (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: 4444

Site Name: (4444) Hospital Militar Central Cirujano Mayor Dr Cosme Argerich

Subject No: 44441161

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 17:38

(UTC-03:00) City of Buenos Aires			CIFIED OBSERVATIO N PERIOD	
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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-22-2020 17:59:22 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	Martina Davalli (b) (4)	Data Entry: YES	Initial Entry

090177e196ae2ede\Final\Final On: 01-Apr-2021 03:26 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 06-Jul-2020 21:53

Site No: 4444

Subject No: 44441161

Generated By: (b) (4)

Form: REACTOGENICITY DIARY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (4444) Hospital Militar Central Cirujano Mayor Dr Cosme Argerich

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 17:38

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1. Select appropriate response - Reactogenicity diary collection

Date	Location	User	Value	Reason
Sep-22-2020 17:59:26 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	Martina Davalli (b) (4)	Data Entry: NO - REACTOGEN ICITY E-DIARY N OT COLLECTED F OR THIS SUBJECT	Initial Entry

090177e196ae2ede\Final\Final On: 01-Apr-2021 03:26 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:02

Site No: 4444

Subject No: 44441161

Generated By: (b) (4)

Form: DATE OF VISIT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (4444) Hospital Militar Central Cirujano
Mayor Dr Cosme Argerich

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 17:38

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1. Date of Visit

Date	Location	User	Value	Reason
Oct-13-2020 19:06:26 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6) [Redacted] [Redacted]	Data Entry: Oct/13/2020	Initial Entry

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 10-Oct-2020 16:01

Site No: 4444

Subject No: 44441161

Generated By: (b) (4)

Form: VITAL SIGNS - TEMP - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (4444) Hospital Militar Central Cirujano Mayor Dr Cosme Argerich

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 17:38

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1. Date:

Date	Location	User	Value	Reason
Oct-13-2020 19:06:56 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Oct/13/2020	Initial Entry

2.a

Date	Location	User	Value	Reason
Oct-13-2020 19:06:56 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Record Identifier:: Temperature: 36.8 Temperature Unit: C Temperature Location: ORAL CAVIT :: Y	Initial Entry

2.a Record Identifier:

Date	Location	User	Value	Reason
Oct-13-2020 19:06:56 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 1	Initial Entry

090177e196ae2ede\Final\Final On: 01-Apr-2021 03:26 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form: VITAL SIGNS - TEMP - eCRF Audit Trail History

Form Version: 10-Oct-2020 16:01

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 4444

Site Name: (4444) Hospital Militar Central Cirujano Mayor Dr Cosme Argerich

Subject No: 44441161

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 17:38

2.a Temperature:

Date	Location	User	Value	Reason
Oct-13-2020 19:06:56 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 36.8	Initial Entry

2.a Unit:

Date	Location	User	Value	Reason
Oct-13-2020 19:06:56 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: C	Initial Entry

2.a Temperature Location:

Date	Location	User	Value	Reason
Oct-13-2020 19:06:56 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: ORAL CAVITY	Initial Entry

090177e196ae2ede\Final\Final On: 01-Apr-2021 03:26 (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: 4444

Site Name: (4444) Hospital Militar Central Cirujano Mayor Dr Cosme Argerich

Subject No: 44441161

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 17:38

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1. Data Origin

Date	Location	User	Value	Reason
Oct-13-2020 19:07:21 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Oct-13-2020 19:07:21 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: NASAL_SWAB	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Oct-13-2020 19:08:12 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Oct-13-2020 19:07:21 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered.

090177e196ae2ede\Final\Final On: 01-Apr-2021 03:26 (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: 4444

Site Name: (4444) Hospital Militar Central Cirujano Mayor Dr Cosme Argerich

Subject No: 44441161

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 17:38

				Please review and correct as appropriate.
Oct-13-2020 19:07:21 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Date of Collection: Oct/13/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Oct-13-2020 19:08:12 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	Alan Colombo (b) (4)	Data Entry: Sample I BP1VC D: 1	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Oct-13-2020 19:08:12 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	Alan Colombo (b) (4)	Data Entry: BP1VC1	Initial Entry

090177e196ae2ede\Final\Final On: 01-Apr-2021 03:26 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:04

Site No: 4444

Subject No: 44441161

Generated By: (b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (4444) Hospital Militar Central Cirujano Mayor Dr Cosme Argerich

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 17:38

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1. Was there a temporary delay of vaccination?

Date	Location	User	Value	Reason
Oct-13-2020 19:09:01 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2. Treatment Name

Date	Location	User	Value	Reason
Oct-13-2020 19:08:39 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: BLINDED THERAPY	Initial Entry

3. Formulation:

Date	Location	User	Value	Reason
Oct-13-2020 19:08:39 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: INJECTION	Initial Entry

4. Dose Date Time:

Date	Location	User	Value	Reason
Oct-13-2020 19:08:39	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Oct/13/2020 17:00	Initial Entry

090177e196ae2ede\Final\Final On: 01-Apr-2021 03:26 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:04

Site No: 4444

Subject No: 44441161

Generated By: (b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (4444) Hospital Militar Central Cirujano Mayor Dr Cosme Argerich

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 17:38

(UTC-03:00) City of Buenos Aires

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

5. Anatomical Location:

Date	Location	User	Value	Reason
Oct-13-2020 19:08:39 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: DELTOID MUSCLE	Initial Entry

6. Body Side:

Date	Location	User	Value	Reason
Oct-13-2020 19:08:39 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: LEFT	Initial Entry

7. Route:

Date	Location	User	Value	Reason
Oct-13-2020 19:08:39 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: INTRAMUSCULAR	Initial Entry

10. Timeframe Subject Was Observed

Date	Location	User	Value	Reason
Oct-13-2020 19:08:39	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: THE PROTOCOL SPE	Initial Entry

090177e196ae2ede\Final\Final On: 01-Apr-2021 03:26 (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: 4444

Site Name: (4444) Hospital Militar Central Cirujano Mayor Dr Cosme Argerich

Subject No: 44441161

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 17:38

(UTC-03:00) City of Buenos Aires			CIFIED OBSERVATIO N PERIOD	
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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
Oct-13-2020 19:08:39 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

090177e196ae2ede\Final\Final On: 01-Apr-2021 03:26 (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: 4444

Site Name: (4444) Hospital Militar Central Cirujano
Mayor Dr Cosme Argerich

Subject No: 44441161

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 17:38

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1. Date of Visit

Date	Location	User	Value	Reason
Nov-12-2020 15:31:31 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Nov-12-2020 11:07:52 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Data has been updated. Thank you
Nov-12-2020 09:28:46 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	DM: The treatment period is defined as 1st vaccination visit through the 1-month post vaccination visit after the 2nd vaccination. Please complete treatment disposition CRF and

090177e196ae2ede\Final\Final On: 01-Apr-2021 03:26 (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: 4444 **Site Name:** (4444) Hospital Militar Central Cirujano
Mayor Dr Cosme Argerich

Subject No: 44441161 **Subject Initials:** ---

Generated By: (b) (4) **Generated Time (GMT):** 29-Mar-2021 17:38

				update date of EOT to match date of visit at visit 3.
Nov-11-2020 19:52:09 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Nov/11/2020	Initial Entry

090177e196ae2ede\Final\Final On: 01-Apr-2021 03:26 (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: 4444 **Site Name:** (4444) Hospital Militar Central Cirujano Mayor Dr Cosme Argerich

Subject No: 44441161 **Subject Initials:** ---

Generated By: (b) (4) **Generated Time (GMT):** 29-Mar-2021 17:38

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1. Data Origin

Date	Location	User	Value	Reason
Nov-11-2020 19:52:17 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Nov-11-2020 19:52:17 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SERUM	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Nov-12-2020 13:19:20 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Nov-11-2020 22:41:14 (UTC-03:00) City of Buenos	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	Sample Collected?' is Yes, however no barcodes

090177e196ae2ede\Final\Final On: 01-Apr-2021 03:26 (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:** 4444**Site Name:** (4444) Hospital Militar Central Cirujano Mayor Dr Cosme Argerich**Subject No:** 44441161**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 17:38

Aires				are entered. Please review and correct as appropriate.
Nov-11-2020 19:52:17 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Nov-11-2020 19:52:17 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Date of Collection: Nov/11/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Nov-12-2020 13:19:20 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID BP1PB : Z	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
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Header Text: c4591001

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

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

Site No: 4444 **Site Name:** (4444) Hospital Militar Central Cirujano Mayor Dr Cosme Argerich

Subject No: 44441161 **Subject Initials:** ---

Generated By: (b) (4) **Generated Time (GMT):** 29-Mar-2021 17:38

Nov-12-2020 13:19:20 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BP1PBZ	Initial Entry
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5.b

Date	Location	User	Value	Reason
Nov-12-2020 13:47:53 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID BJ4F4 : X	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Nov-12-2020 13:47:53 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BJ4F4X	Initial Entry

5.c

Date	Location	User	Value	Reason
Nov-12-2020 15:23:03 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BJ4F3L	Initial Entry

090177e196ae2ede\Final\Final On: 01-Apr-2021 03:26 (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: 4444 **Site Name:** (4444) Hospital Militar Central Cirujano Mayor Dr Cosme Argerich

Subject No: 44441161 **Subject Initials:** ---

Generated By: (b) (4) **Generated Time (GMT):** 29-Mar-2021 17:38

5.c Sample ID

Date	Location	User	Value	Reason
Nov-12-2020 15:23:03 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Data Entry: BJ4F3L	Initial Entry

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 4444

Subject No: 44441161

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - Audit Trail

Form Status:

Site Name: (4444) Hospital Militar Central Cirujano
Mayor Dr Cosme Argerich

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 17:38

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Date	Location	User	Value	Reason
Feb-04-2021 13:45:35 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Created	

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, Frozen

Site No: 4444

Site Name: (4444) Hospital Militar Central Cirujano Mayor Dr Cosme Argerich

Subject No: 44441161

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 17:38

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1. Category:

Date	Location	User	Value	Reason
Feb-04-2021 13:45:35 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: ADVERSE EVENT	Initial Entry

2. AE ID:

Date	Location	User	Value	Reason
Feb-04-2021 13:45:35 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 1	Initial Entry

3. Adverse Event:

(If possible specify diagnosis, not individual symptoms)

Date	Location	User	Value	Reason
Feb-04-2021 13:45:35 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Coronary heart disease	Initial Entry

4. Start Date Time:

Date	Location	User	Value	Reason
Feb-04-2021	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Initial Entry

090177e196ae2ede\Final\Final On: 01-Apr-2021 03:26 (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, Frozen

Site No: 4444

Site Name: (4444) Hospital Militar Central Cirujano Mayor Dr Cosme Argerich

Subject No: 44441161

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 17:38

13:45:35
(UTC-03:00) City of Buenos Aires

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

Oct/1/2020 10:00

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Feb-20-2021 16:08:50 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO End Date Time: Feb/17/2021 10:00	New Information
Feb-04-2021 13:45:35 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

6. Toxicity Grade:

Date	Location	User	Value	Reason
Feb-04-2021 13:45:35 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 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

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Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen

Site No: 4444

Site Name: (4444) Hospital Militar Central Cirujano Mayor Dr Cosme Argerich

Subject No: 44441161

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 17:38

medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).

Date	Location	User	Value	Reason
Feb-16-2021 23:18:51 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Closed	Response satisfies query
Feb-09-2021 11:24:03 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Answered	I clarify that Covid testing was not performed because the AE is not related to COVID illness and the patient did not present any Covid symptoms. This information was sent in SAE initial form on 03FEB2021.
Feb-08-2021 15:49:36 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Opened	Clinical COVID test status (yes/no) during Hosp was not reported in the SAE. Please submit a

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Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

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Form Status: Data Complete, Frozen

Site No: 4444

Site Name: (4444) Hospital Militar Central Cirujano Mayor Dr Cosme Argerich

Subject No: 44441161

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 17:38

				follow-up SAE form [#2021115175] to document if COVID testing was performed in Hospital (YES/NO or info not available) and if yes, the date and results.
Feb-05-2021 11:09:43 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Feb-04-2021 13:45:35 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	For AE Coronary heart disease: Response to "Is the adverse event serious?" is 'Yes' but "Serious Adverse Event Number" is blank.
Feb-04-2021 13:45:35 (UTC-03:00)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Is this serious ev	Initial Entry

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Header Text: c4591001

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Form Status: Data Complete, Frozen

Site No: 4444

Site Name: (4444) Hospital Militar Central Cirujano Mayor Dr Cosme Argerich

Subject No: 44441161

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 17:38

City of Buenos Aires

ent associated with congenital anomaly or birth defect?

NO

Did this serious event result in death?

NO

Did this serious event require or prolong hospitalization?

YES

Did this serious event result in persistent or significant disability/in capacity?

NO

Is this serious event life threatening?

NO

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Header Text: c4591001

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Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

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Form Status: Data Complete, Frozen

Site No: 4444

Site Name: (4444) Hospital Militar Central Cirujano Mayor Dr Cosme Argerich

Subject No: 44441161

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 17:38

			Other medically important serious event	
			YES	

8. Is this adverse event the result of a study Medication Error?
If Yes, record the type of medication error on the Medication Error Log.

Date	Location	User	Value	Reason
Feb-04-2021 13:45:35 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

9. Is this event related to study treatment:

Date	Location	User	Value	Reason
Feb-04-2021 13:45:35 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NOT RELATED If Not Related to study treatment(s), this event is due to: OTHER <i>If Other, specify:</i> Cardiovascular risk factors (hypertension, smoker,	Initial Entry

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Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

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Form Status: Data Complete, Frozen

Site No: 4444

Site Name: (4444) Hospital Militar Central Cirujano Mayor Dr Cosme Argerich

Subject No: 44441161

Subject Initials: ---

Generated By: (b) (4)

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			obesity, sex and age)	
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10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Feb-04-2021 13:45:35 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NOT APPLICABLE	Initial Entry

11. Was a Concomitant Medication given?

Date	Location	User	Value	Reason
Feb-04-2021 13:45:35 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Feb-04-2021 13:45:35 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

13. What was the outcome of this adverse event?:

Date	Location	User	Value	Reason
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Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

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Form Status: Data Complete, Frozen

Site No: 4444

Site Name: (4444) Hospital Militar Central Cirujano Mayor Dr Cosme Argerich

Subject No: 44441161

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 17:38

Feb-20-2021 16:09:05 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Feb-20-2021 16:09:05 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: RECOVERED/ RESOLVED	New Information
Feb-20-2021 16:08:50 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	For AE Coronary heart disease: Response to "What was the outcome of this adverse event?" is 'Recovering/Resolving' but AE End Date/Time is present.
Feb-04-2021 13:45:35 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: RECOVERING /RESOLVING	Initial Entry

14. Did the adverse event cause the subject to be discontinued from the study?

Date	Location	User	Value	Reason
Feb-04-2021 13:45:35 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

090177e196ae2ede\Final\Final On: 01-Apr-2021 03:26 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

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Form Status: Data Complete, Frozen

Site No: 4444

Site Name: (4444) Hospital Militar Central Cirujano Mayor Dr Cosme Argerich

Subject No: 44441161

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 17:38

15. Serious Adverse Event Number: For Pfizer Use Only

Date	Location	User	Value	Reason
Feb-05-2021 11:09:43 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6) [Redacted]	Data Entry: 2021115175	Initial Entry

Header Text: c4591001**Visit:** End of Treatment - Unscheduled **Form:** DISPOSITION - TREATMENT - eCRF Audit Trail History**Form Version:** 15-Sep-2020 21:55**Form Status:** Data Complete, Locked, Frozen, Verified**Site No:** 4444**Site Name:** (4444) Hospital Militar Central Cirujano Mayor Dr Cosme Argerich**Subject No:** 44441161**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 17:38[Back to Form](#)**1. Date of Completion/Discontinuation/Death :**

Date	Location	User	Value	Reason
Nov-12-2020 13:13:59 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Nov-12-2020 13:13:59 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Nov/11/2020	Transcription Error
Nov-12-2020 11:07:14 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	Response to "Date of Completion/Discontinuation/Death" 11/Nov/2021 is a future date relative to when it was entered on 12/Nov/2020. Please correct.
Nov-12-2020 11:07:14 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Nov/11/2021	Initial Entry

2. Phase of Disposition:

Date	Location	User	Value	Reason
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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: 4444 **Site Name:** (4444) Hospital Militar Central Cirujano Mayor Dr Cosme Argerich

Subject No: 44441161 **Subject Initials:** ---

Generated By: (b) (4) **Generated Time (GMT):** 29-Mar-2021 17:38

Nov-12-2020 11:07:14 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: VACCINATION	Initial Entry
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3. Status:

Date	Location	User	Value	Reason
Nov-12-2020 11:07:14 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: COMPLETED	Initial Entry

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Header Text: c4591001

Visit: Potential ReVax Initial Contact - **Form:** DATE OF VISIT - eCRF Audit Trail History
Unscheduled

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

Site No: 4444 **Site Name:** (4444) Hospital Militar Central Cirujano
Mayor Dr Cosme Argerich

Subject No: 44441161 **Subject Initials:** ---

Generated By: (b) (4) **Generated Time (GMT):** 29-Mar-2021 17:38

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1. Date of Visit

Date	Location	User	Value	Reason
Feb-11-2021 12:53:46 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Feb/11/2021	Initial Entry

Header Text: c4591001

Visit: Potential ReVax Initial Contact - **Form:** FURTHER VACCINATION CONFIRMATION -
Unscheduled eCRF Audit Trail History

Form Version: 10-Dec-2020 02:25 **Form Status:** Data Complete, Frozen

Site No: 4444 **Site Name:** (4444) Hospital Militar Central Cirujano
Mayor Dr Cosme Argerich

Subject No: 44441161 **Subject Initials:** ---

Generated By: (b) (4) **Generated Time (GMT):** 29-Mar-2021 17:38

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

Date	Location	User	Value	Reason
Feb-11-2021 12:54:41 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Feb-11-2021 12:54:00 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	The response indicates participant was unblinded, however the TREATMENT UNBLINDED date is missing in the DISP visit. Please complete this date.
Feb-11-2021 12:54:00 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Participant is willin g to return for Vacc ination 3 Participant is: eligible and NO T confirmed to h ave received onl y placebo at Vac	Initial Entry

090177e196ae2ede\Final\Final On: 01-Apr-2021 03:26 (GMT)

Header Text: c4591001

Visit: Disposition - Unscheduled

Form: TREATMENT UNBLINDED - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 4444

Site Name: (4444) Hospital Militar Central Cirujano Mayor Dr Cosme Argerich

Subject No: 44441161

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 17:38

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1. Date Treatment Unblinded :

Date	Location	User	Value	Reason
Feb-11-2021 12:54:41 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Feb/11/2021	Initial Entry

2. Primary Reason for Unblinding:

Date	Location	User	Value	Reason
Feb-11-2021 12:54:41 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: ASSESS ELIGIBILI TY FOR ADDITION AL VACCINATION	Initial Entry

090177e196ae2ede\Final\Final On: 01-Apr-2021 03:26 (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: 4444

Site Name: (4444) Hospital Militar Central Cirujano Mayor Dr Cosme Argerich

Subject No: 44441161

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 17:38

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1. Subject Status

Date	Location	User	Value	Reason
Nov-12-2020 11:07:14 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: FOLLOW-UP	Initial Entry
Sep-22-2020 17:58:55 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: ENROLLED/RANDOMIZED	Initial Entry
Sep-22-2020 17:57:31 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SCREENED	Initial Entry

2. Subject Status Date

Date	Location	User	Value	Reason
Jan-25-2021 03:49:23 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	deemed erroneous
Jan-24-2021 12:25:00 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	Santiago Corradetti (b) (4)	Query 1: Answered	E-diary record was deemed erroneous. Thank you.

090177e196ae2ede\Final\Final On: 01-Apr-2021 03:26 (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: 4444

Site Name: (4444) Hospital Militar Central Cirujano
Mayor Dr Cosme Argerich

Subject No: 44441161

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 17:38

Aires				
Jan-24-2021 08:51:41 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	Illness eDiary: Subject reported "Yes" for the question "Have you experienced any of the following?" for the COVID-19 symptoms or diagnosis on 18JAN2021. But there is no COVID Illness visit reported in the database. Please clarify.
Nov-12-2020 13:13:59 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Nov/11/2020	Transcription Error
Nov-12-2020 11:07:14 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Nov/11/2021	Initial Entry
Sep-22-2020 17:58:55	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sep/21/2020	Initial Entry

090177e196ae2ede\Final\Final On: 01-Apr-2021 03:26 (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: 4444

Site Name: (4444) Hospital Militar Central Cirujano
Mayor Dr Cosme Argerich

Subject No: 44441161

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 17:38

(UTC-03:00) City of Buenos Aires				
Sep-22-2020 17:57:31 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sep/21/2020	Initial Entry

Header Text: c4591001

Visit: Investigator Signature -
Unscheduled

Form Version: 22-Apr-2020 21:04

Site No: 4444

Subject No: 44441161

Generated By: (b) (4)

Form: CASEBOOK SIGNATURE FORM - eCRF Audit
Trail History

Form Status: Data Complete, Signed, Verified

Site Name: (4444) Hospital Militar Central Cirujano
Mayor Dr Cosme Argerich

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 17:38

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1. Casebook Signature

Date	Location	User	Value	Reason
Nov-10-2020 11:17:23 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	Tatiana Estrada (b) (4)	Data Entry: Click Here to Enable	Initial Entry

090177e196ae2ede\Final\Final On: 01-Apr-2021 03:26 (GMT)