

Header Text: C4591001

Visit: COHORT_SELECTION

Form: COHORT_SELECTION

Form Version: 30-Jul-2020 21:29

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1231

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

Subject No: 12311379

Subject Initials: ---

Generated By:

Generated Time (GMT): 29-Mar-2021 16:45

(b) (4)

[eCRF Audit Trail History](#)

Cohort Selection

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

1.	Select appropriate response - Protocol version	30 JUN 2020
2.	Select appropriate response - What cohort does the subject belong to?	STAGE 3 COHORTS

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Header Text: C4591001

Visit: COHORT_SELECTION

Form Version: 22-Apr-2020 21:02

Site No: 1231

Subject No: 12311379

Generated By:

(b) (4)

Form: MAIN INFORMED CONSENT

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 16:45

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Informed Consent

1.	Consent Was:	OBTAINED Date Written Consent Obtained Aug/15/2020
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Form Version: 06-Jul-2020 21:55

Site No: 1231

Subject No: 12311379

Generated By:

(b) (4)

Form: DEMOGRAPHY

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 16:45

[eCRF Audit Trail History](#)

Demography

1.	Subject ID	[12311379]
2.	Birth Date:	(b) (6)/1948
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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Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:02

Site No: 1231

Subject No: 12311379

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(b) (4)

Form: DATE OF VISIT

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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Date of Visit

1.	Date of Visit	Aug/15/2020
2.	Erroneous Visit	

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Visit: V1_DAY1_VAX1_L

Form Version: 30-Jul-2020 21:27

Site No: 1231

Subject No: 12311379

Generated By:

(b) (4)

Form: INCLUSION/EXCLUSION CRITERIA

Form Status: Data Complete, Locked, Frozen, Verified

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

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[eCRF Audit Trail History](#)

Study eligibility requires subjects to meet all inclusion criteria (YES) and Not meet exclusion criteria (NO).

Inclusion Criteria

1.a	Inclusion Number:	1
	Criterion Description:	Male or female participants between the ages of 18 and 55 years, inclusive, 65 and 85 years, inclusive, or 18 and 85 years, inclusive, at randomization (dependent upon study stage)
	Criterion met?	YES
	Criterion ID: (For Pfizer use only)	IN01A00
1.b	Inclusion Number:	2
	Criterion Description:	Participants who are willing and able to comply with all scheduled visits, vaccination plan, laboratory tests, lifestyle considerations, and other study procedures
	Criterion met?	YES
	Criterion ID: (For Pfizer use only)	IN02A00

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Form: INCLUSION/EXCLUSION CRITERIA

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1.c	Inclusion Number:	3
	Criterion Description:	Healthy participants who are determined by medical history, physical examination, and clinical judgment of the investigator to be eligible for inclusion in the study
	Criterion met?	YES
	Criterion ID: (For Pfizer use only)	IN03A00

1.d	Inclusion Number:	4
	Criterion Description:	Capable of giving personal signed informed consent, which includes compliance with the requirements and restrictions listed in the ICD and in this protocol
	Criterion met?	YES
	Criterion ID: (For Pfizer use only)	IN04A00

Exclusion Criteria

2.a	Exclusion Number:	1
	Criterion Description:	Other medical or psychiatric condition incl. recent (within past year) or active suicidal ideation/behavior/lab abnormality that may increase the risk of study participation
	Criterion met?	NO
	Criterion ID: (For Pfizer use only)	EX01A00

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Form: INCLUSION/EXCLUSION CRITERIA

Form Status: Data Complete, Locked, Frozen, Verified

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2.b	Exclusion Number:	2
	Criterion Description:	Known infection with human immunodeficiency virus (HIV), hepatitis C virus (HCV), or hepatitis B virus (HBV)
	Criterion met?	NO
	Criterion ID: (For Pfizer use only)	EX02A00
2.c	Exclusion Number:	3
	Criterion Description:	History of severe adverse reaction associated with a vaccine and/or severe allergic reaction (eg, anaphylaxis) to any component of the study intervention(s)
	Criterion met?	NO
	Criterion ID: (For Pfizer use only)	EX03A00
2.d	Exclusion Number:	4
	Criterion Description:	Receipt of medications intended to prevent COVID-19
	Criterion met?	NO
	Criterion ID: (For Pfizer use only)	EX04A00

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Form: INCLUSION/EXCLUSION CRITERIA

Form Status: Data Complete, Locked, Frozen, Verified

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

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2.e	Exclusion Number:	8
	Criterion Description:	Immunocompromised individuals with known or suspected immunodeficiency, as determined by history and/or laboratory/physical examination
	Criterion met?	NO
	Criterion ID: (For Pfizer use only)	EX08A00
2.f	Exclusion Number:	10
	Criterion Description:	Bleeding diathesis or condition associated with prolonged bleeding that would, in the opinion of the investigator, contraindicate intramuscular injection
	Criterion met?	NO
	Criterion ID: (For Pfizer use only)	EX10A00
2.g	Exclusion Number:	11
	Criterion Description:	Women who are pregnant or breastfeeding
	Criterion met?	NO
	Criterion ID: (For Pfizer use only)	EX11A00

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Form: INCLUSION/EXCLUSION CRITERIA

Form Status: Data Complete, Locked, Frozen, Verified

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2.h	Exclusion Number:	12
	Criterion Description:	Previous vaccination with any coronavirus vaccine
	Criterion met?	NO
	Criterion ID: (For Pfizer use only)	EX12A00
2.i	Exclusion Number:	13
	Criterion Description:	Subjects who receive immunosuppressive therapy, such as cytotoxic agents or systemic corticosteroids
	Criterion met?	NO
	Criterion ID: (For Pfizer use only)	EX13A01
2.j	Exclusion Number:	15
	Criterion Description:	Receipt of blood/plasma products or immunoglobulin, from 60 days before study intervention administration or planned receipt throughout the study
	Criterion met?	NO
	Criterion ID: (For Pfizer use only)	EX14A01

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Form: INCLUSION/EXCLUSION CRITERIA

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1231) Hospital Militar Central Cirujano
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Subject Initials: ---

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2.k	Exclusion Number:	16
	Criterion Description:	Participation in other studies involving study intervention within 28 days prior to study entry and/or during study participation
	Criterion met?	NO
	Criterion ID: (For Pfizer use only)	EX15A01
2.1	Exclusion Number:	17
	Criterion Description:	Previous participation in other studies involving study intervention containing lipid nanoparticles
	Criterion met?	NO
	Criterion ID: (For Pfizer use only)	EX16A01
2.m	Exclusion Number:	22
	Criterion Description:	Investigator site staff or Pfizer employees directly involved in the conduct of the study, site staff otherwise supervised by the investigator, and their respective family members
	Criterion met?	NO
	Criterion ID: (For Pfizer use only)	EX21A01

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Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1231

Subject No: 12311379

Generated By:

(b) (4)

Form: DISPOSITION - SCREENING

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 16:45

[eCRF Audit Trail History](#)

Disposition - Screening

1.	Date of Completion/Discontinuation /Death	Aug/15/2020
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: 1231

Subject No: 12311379

Generated By:

(b) (4)

Form: GENERAL MEDICAL HISTORY

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 16:45

[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:	Jan/1/2005
	Ongoing:	YES
1.b	Line/MH Number:	[2]
	Disease/Syndrome /Surgery/Non-Drug Allergies/Drug Allergies:	[PSA elevation]
	Start Date:	Aug/12/2018
	Ongoing:	YES

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Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 30-Jul-2020 21:28

Site No: 1231

Subject No: 12311379

Generated By:

(b) (4)

Form: VITAL SIGNS - BASELINE

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 16:45

[eCRF Audit Trail History](#)

Vital Signs

1.	Date:	Aug/15/2020
2.	Weight:	[91.6]
3.	Unit:	kg
4.	Height:	[174.0]
5.	Unit:	cm
6.	Body Mass Index:	[30.3]

Vital Signs Details

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

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Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1231

Subject No: 12311379

Generated By:

(b) (4)

Form: RANDOMIZATION

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 16:45

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Disposition

1.	Randomization Date :	Aug/15/2020
2.	Randomization Number:	[229565]
3.	Randomization Group:	[]

Header Text: C4591001**Visit:** V1_DAY1_VAX1_L**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY**Form Version:** 22-Apr-2020 21:03**Form Status:** Data Complete, Locked, Frozen, Verified**Site No:** 1231**Site Name:** (1231) Hospital Militar Central Cirujano Mayor Dr. Cosme Argerich**Subject No:** 12311379**Subject Initials:** ---**Generated By:****Generated Time (GMT):** 29-Mar-2021 16:45

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

1.	Data Origin	SITE
2.	Sample Type	SERUM
3.	Sample Collected?	YES Date of Collection: Aug/15/2020
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[]

Aliquot

Please enter barcode for each aliquot.

5.a	Sample ID	[BLCVNV]
5.b	Sample ID	[BLCVNT]
5.c	Sample ID	[BM83XC]
5.d	Sample ID	[BM83XB]
5.e	Sample ID	[BM840B]

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1231

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

Subject No: 12311379

Subject Initials: ---

Generated By:

Generated Time (GMT): 29-Mar-2021 16:45

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[eCRF Audit Trail History](#)

Electronic Sample Tracking

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB
3.	Sample Collected?	YES Date of Collection: Aug/15/2020
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[]

Aliquot

Please enter barcode for each aliquot.

5.a	Sample ID	[BM8449]
5.b	Sample ID	[BM83XC]
5.c	Sample ID	[BM83XB]
5.d	Sample ID	[BM840B]

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Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:04

Site No: 1231

Subject No: 12311379

Generated By:

(b) (4)

Form: VACCINATION

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 16:45

[eCRF Audit Trail History](#)

Vaccination

1.	Was there a temporary delay of vaccination?	NO
2.	Treatment Name	[BLINDED THERAPY]
3.	Formulation:	INJECTION
4.	Dose Date Time:	Aug/15/2020 15:35
5.	Anatomical Location:	DELTOID MUSCLE
6.	Body Side:	LEFT
7.	Route:	INTRAMUSCULAR
8.	Actual Dose:	[]
9.	Unit:	
10.	Timeframe Subject Was Observed	THE PROTOCOL SPECIFIED OBSERVATION PERIOD
11.	Was the subject observed for at least the protocol specified observation period after investigational product administration?	YES

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Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 06-Jul-2020 21:53

Site No: 1231

Subject No: 12311379

Generated By:

(b) (4)

Form: REACTOGENICITY DIARY

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 16:45

[eCRF Audit Trail History](#)

Reactogenicity Diary

1.	Select appropriate response - Reactogenicity diary collection	YES - REACTOGENICITY E-DIARY COLLECTED FOR THIS SUBJECT
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Header Text: C4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:02

Site No: 1231

Subject No: 12311379

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(b) (4)

Form: DATE OF VISIT

Form Status: Data Complete, Locked, Frozen, Verified

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

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Date of Visit

1.	Date of Visit	Sep/7/2020
2.	Erroneous Visit	

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Visit: V2_VAX2_L

Form Version: 30-Jul-2020 21:30

Site No: 1231

Subject No: 12311379

Generated By:

(b) (4)

Form: VACCINATION SYMPTOMS DIARY -
SYMPTOM RESOLVED DATES

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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[eCRF Audit Trail History](#)

Vaccination Symptoms Diary - Symptom Resolved Dates

1.	Were medications to treat fever/pain given on the last day the Subject Diary was completed?	NO
2.a	Symptom:	FEVER
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO
2.b	Symptom:	FATIGUE
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO
2.c	Symptom:	HEADACHE
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO

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Header Text: C4591001

Visit: V2_VAX2_L

Form: VACCINATION SYMPTOMS DIARY -
SYMPTOM RESOLVED DATES

Form Version: 30-Jul-2020 21:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1231

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

Subject No: 12311379

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2.d	Symptom:	CHILLS
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO
2.e	Symptom:	VOMITING
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO
2.f	Symptom:	DIARRHEA
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO
2.g	Symptom:	NEW OR WORSENERED MUSCLE PAIN
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO
2.h	Symptom:	NEW OR WORSENERED JOINT PAIN
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO

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Visit: V2_VAX2_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES

Form Version: 30-Jul-2020 21:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1231

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

Subject No: 12311379

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3.	Injection Site Location:	DELTOID MUSCLE
4.	Injection Site Body Side:	LEFT
5.a	Injection Site Reaction:	REDNESS
	Were injection site reactions present on the last day the Subject Diary was completed?	NO
5.b	Injection Site Reaction:	SWELLING
	Were injection site reactions present on the last day the Subject Diary was completed?	NO
5.c	Injection Site Reaction:	PAIN AT INJECTION SITE
	Were injection site reactions present on the last day the Subject Diary was completed?	NO

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Header Text: C4591001

Visit: V2_VAX2_L

Form Version: 21-Aug-2020 02:51

Site No: 1231

Subject No: 12311379

Generated By:

(b) (4)

Form: VITAL SIGNS - TEMP

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 16:45

[eCRF Audit Trail History](#)

Vital Signs

1.	Date:	Sep/7/2020
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Vital Signs Details

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

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Header Text: C4591001

Visit: V2_VAX2_L

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1231

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

Subject No: 12311379

Subject Initials: ---

Generated By:

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[eCRF Audit Trail History](#)

Electronic Sample Tracking

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB
3.	Sample Collected?	YES Date of Collection: Sep/7/2020
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	[BP1TM8]
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Header Text: C4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:04

Site No: 1231

Subject No: 12311379

Generated By:

(b) (4)

Form: VACCINATION

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 16:45

[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/7/2020 18:40
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: V3_MONTH1_POSTVAX2_L **Form:** DATE OF VISIT

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

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

Subject No: 12311379 **Subject Initials:** ---

Generated By: (b) (4) **Generated Time (GMT):** 29-Mar-2021 16:45

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Date of Visit

1.	Date of Visit	Oct/7/2020
2.	Erroneous Visit	

Header Text: C4591001

Visit: V3_MONTH1_POSTVAX2_L **Form:** VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES

Form Version: 30-Jul-2020 21:30 **Form Status:** Data Complete, Locked, Frozen, Verified

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

Subject No: 12311379 **Subject Initials:** ---

Generated By: (b) (4) **Generated Time (GMT):** 29-Mar-2021 16:45

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Vaccination Symptoms Diary - Symptom Resolved Dates

1.	Were medications to treat fever/pain given on the last day the Subject Diary was completed?	NO
2.a	Symptom:	FEVER
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO
2.b	Symptom:	FATIGUE
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO
2.c	Symptom:	HEADACHE
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO

090177e196ae2e95\Final\Final On: 01-Apr-2021 03:17 (GMT)

Header Text: C4591001

Visit: V3_MONTH1_POSTVAX2_L **Form:** VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES

Form Version: 30-Jul-2020 21:30 **Form Status:** Data Complete, Locked, Frozen, Verified

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

Subject No: 12311379 **Subject Initials:** ---

Generated By: (b) (4) **Generated Time (GMT):** 29-Mar-2021 16:45

2.d	Symptom:	CHILLS
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO
2.e	Symptom:	VOMITING
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO
2.f	Symptom:	DIARRHEA
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO
2.g	Symptom:	NEW OR WORSENERD MUSCLE PAIN
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO
2.h	Symptom:	NEW OR WORSENERD JOINT PAIN
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO

090177e196ae2e95\Final\Final On: 01-Apr-2021 03:17 (GMT)

Header Text: C4591001

Visit: V3_MONTH1_POSTVAX2_L **Form:** VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES

Form Version: 30-Jul-2020 21:30 **Form Status:** Data Complete, Locked, Frozen, Verified

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

Subject No: 12311379 **Subject Initials:** ---

Generated By: (b) (4) **Generated Time (GMT):** 29-Mar-2021 16:45

3.	Injection Site Location:	DELTOID MUSCLE
4.	Injection Site Body Side:	LEFT
5.a	Injection Site Reaction:	REDNESS
	Were injection site reactions present on the last day the Subject Diary was completed?	NO
5.b	Injection Site Reaction:	SWELLING
	Were injection site reactions present on the last day the Subject Diary was completed?	NO
5.c	Injection Site Reaction:	PAIN AT INJECTION SITE
	Were injection site reactions present on the last day the Subject Diary was completed?	NO

090177e196ae2e95\Final\Final On: 01-Apr-2021 03:17 (GMT)

Header Text: C4591001**Visit:** V3_MONTH1_POSTVAX2_L **Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY**Form Version:** 22-Apr-2020 21:03 **Form Status:** Data Complete, Locked, Frozen, Verified**Site No:** 1231**Site Name:** (1231) Hospital Militar Central Cirujano Mayor Dr. Cosme Argerich**Subject No:** 12311379**Subject Initials:** ---**Generated By:****Generated Time (GMT):** 29-Mar-2021 16:45

(b) (4)

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

1.	Data Origin	SITE
2.	Sample Type	SERUM
3.	Sample Collected?	YES Date of Collection: Oct/7/2020
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	[BNVB26]
5.b	Sample ID	[BNV331]
5.c	Sample ID	[BPW759]

Header Text: C4591001

Visit: V4_MONTH6_L

Form Version: 22-Apr-2020 21:02

Site No: 1231

Subject No: 12311379

Generated By:

(b) (4)

Form: DATE OF VISIT

Form Status: Not Started

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

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 16:45

Date of Visit

1.	Date of Visit	//
2.	Erroneous Visit	

Header Text: C4591001

Visit: V4_MONTH6_L

Form Version: 22-Apr-2020 21:03

Site No: 1231

Subject No: 12311379

Generated By:

(b) (4)

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Status: Not Started

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

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 16:45

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: V5_MONTH12_L

Form Version: 22-Apr-2020 21:02

Site No: 1231

Subject No: 12311379

Generated By:

(b) (4)

Form: DATE OF VISIT

Form Status: Not Started

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

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 16:45

Date of Visit

1.	Date of Visit	//
2.	Erroneous Visit	

Header Text: C4591001

Visit: V5_MONTH12_L

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1231

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

Subject No: 12311379

Subject Initials: ---

Generated By:

Generated Time (GMT): 29-Mar-2021 16:45

(b) (4)

Electronic Sample Tracking

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

Aliquot

Please enter barcode for each aliquot.

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

090177e196ae2e95\Final\Final On: 01-Apr-2021 03:17 (GMT)

Header Text: C4591001

Visit: V6_MONTH24_L

Form Version: 22-Apr-2020 21:02

Site No: 1231

Subject No: 12311379

Generated By:

(b) (4)

Form: DATE OF VISIT

Form Status: Not Started

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

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 16:45

Date of Visit

1.	Date of Visit	//
2.	Erroneous Visit	

Header Text: C4591001**Visit:** V6_MONTH24_L**Form Version:** 22-Apr-2020 21:03**Site No:** 1231**Subject No:** 12311379**Generated By:**

(b) (4)

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY**Form Status:** Not Started**Site Name:** (1231) Hospital Militar Central Cirujano Mayor Dr. Cosme Argerich**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 16:45**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_ILL - New
Unscheduled Visit

Form: DATE OF VISIT - ILLNESS ONSET

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1231

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

Subject No: 12311379

Subject Initials: ---

Generated By:

Generated Time (GMT): 29-Mar-2021 16:45

(b) (4)

Date of Visit

1.	Date of Visit	//
2.	Erroneous Visit	

COVID-19 Illness Visit

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

090177e196ae2e95\Final\Final On: 01-Apr-2021 03:17 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL - New
Unscheduled Visit

Form Version: 28-Mar-2021 02:35

Site No: 1231

Subject No: 12311379

Generated By:

(b) (4)

Form: SIGNS AND SYMPTOMS OF POTENTIAL
COVID-19

Form Status: Not Started

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

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 16:45

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:	[]
----	------------------------	-----

090177e196ae2e95\Final\Final On: 01-Apr-2021 03:17 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL - New
Unscheduled Visit

Form Version: 22-Apr-2020 21:03

Site No: 1231

Subject No: 12311379

Generated By:

(b) (4)

Form: ELECTRONIC SAMPLE TRACKING - NASAL
SWAB SELF

Form Status: Not Started

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

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 16:45

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

090177e196ae2e95\Final\Final On: 01-Apr-2021 03:17 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL - New
Unscheduled Visit

Form Version: 22-Apr-2020 21:03

Site No: 1231

Subject No: 12311379

Generated By:

(b) (4)

Form: ELECTRONIC SAMPLE TRACKING - NASAL
SWAB

Form Status: Not Started

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

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 16:45

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

090177e196ae2e95\Final\Final On: 01-Apr-2021 03:17 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL - New
Unscheduled Visit

Form Version: 28-Mar-2021 02:23

Site No: 1231

Subject No: 12311379

Generated By:

(b) (4)

Form: HEALTH CARE UTILIZATION

Form Status: Not Started

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

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 16:45

Health Care Utilization

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

Health Care Utilization Other

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

Health Care Utilization

3.	Has the subject been hospitalized due to potential COVID-19 illness?	
----	--	--

090177e196ae2e95\Final\Final On: 01-Apr-2021 03:17 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL - New
Unscheduled Visit

Form Version: 06-Jul-2020 21:52

Site No: 1231

Subject No: 12311379

Generated By:

(b) (4)

Form: ILLNESS DETAILS

Form Status: Not Started

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

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 16:45

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: 1231

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

Subject No: 12311379

Subject Initials: ---

Generated By:

Generated Time (GMT): 29-Mar-2021 16:45

(b) (4)

Date of Visit

1.	Date of Visit	//
2.	Erroneous Visit	

COVID-19 Illness Visit

3.	COVID-19 Illness Visit:	
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090177e196ae2e95\Final\Final On: 01-Apr-2021 03:17 (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:** 1231**Site Name:** (1231) Hospital Militar Central Cirujano
Mayor Dr. Cosme Argerich**Subject No:** 12311379**Subject Initials:** ---**Generated By:****Generated Time (GMT):** 29-Mar-2021 16:45

(b) (4)

Electronic Sample Tracking

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

Aliquot

Please enter barcode for each aliquot.

5.	Sample ID	[]
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Header Text: C4591001

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

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

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

Subject No: 12311379 **Subject Initials:** ---

Generated By: (b) (4) **Generated Time (GMT):** 29-Mar-2021 16:45

Date of Visit

1.	Date of Visit	//
2.	Erroneous Visit	

090177e196ae2e95\Final\Final On: 01-Apr-2021 03:17 (GMT)

Header Text: C4591001

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

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

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

Subject No: 12311379 **Subject Initials:** ---

Generated By: (b) (4) **Generated Time (GMT):** 29-Mar-2021 16:45

Unplanned Assessments

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

Header Text: C4591001

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

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

Site No: 1231

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

Subject No: 12311379

Subject Initials: ---

Generated By:

Generated Time (GMT): 29-Mar-2021 16:45

(b) (4)

[eCRF Audit Trail History](#)

Disposition - Treatment

1.	Date of Completion/Discontinuation/Death :	Oct/7/2020
2.	Phase of Disposition:	VACCINATION
3.	Status:	COMPLETED
4.	Specify Status:	[]

090177e196ae2e95\Final\Final On: 01-Apr-2021 03:17 (GMT)

Header Text: C4591001

Visit: Follow-Up - Unscheduled

Form Version: 15-Sep-2020 21:53

Site No: 1231

Subject No: 12311379

Generated By:

(b) (4)

Form: DISPOSITION - FOLLOW-UP

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 16:45

[eCRF Audit Trail History](#)

Disposition - Follow-Up

1.	Date of Completion/Discontinuation/Death :	Feb/24/2021
2.	Phase of Disposition:	FOLLOW-UP
3.	Status:	PROTOCOL DEVIATION
4.	Specify Status:	[The volunteer was given a vaccine not related to the study]

090177e196ae2e95\Final\Final On: 01-Apr-2021 03:17 (GMT)

Header Text: C4591001

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

Form Version: 10-Oct-2020 15:57

Form Status: Not Started

Site No: 1231

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

Subject No: 12311379

Subject Initials: ---

Generated By:

Generated Time (GMT): 29-Mar-2021 16:45

(b) (4)

Date of Visit

1.	Date of Visit	//
2.	Erroneous Visit	

COVID-19 Repeat Swab

3.	COVID-19 Repeat Swab:	
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090177e196ae2e95\Final\Final On: 01-Apr-2021 03:17 (GMT)

Header Text: C4591001**Visit:** POT_COVID_REPEAT_SWAB - New Unscheduled Visit **Form:** ELECTRONIC SAMPLE TRACKING - REPEAT SWAB**Form Version:** 10-Oct-2020 15:57 **Form Status:** Not Started**Site No:** 1231**Site Name:** (1231) Hospital Militar Central Cirujano Mayor Dr. Cosme Argerich**Subject No:** 12311379**Subject Initials:** ---**Generated By:****Generated Time (GMT):** 29-Mar-2021 16:45

(b) (4)

Electronic Sample Tracking

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

Aliquot

Please enter barcode for each aliquot.

5.	Sample ID	[]
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Header Text: C4591001

Visit: Unplanned Vaccination -
Unscheduled

Form: DATE OF VISIT

Form Version: 22-Apr-2020 21:02

Form Status: Not Started

Site No: 1231

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

Subject No: 12311379

Subject Initials: ---

Generated By:

Generated Time (GMT): 29-Mar-2021 16:45

(b) (4)

Date of Visit

1.	Date of Visit	//
2.	Erroneous Visit	

Header Text: C4591001

Visit: Unplanned Vaccination -
Unscheduled

Form: VITAL SIGNS - TEMP

Form Version: 28-Mar-2021 02:28

Form Status: Not Started

Site No: 1231

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

Subject No: 12311379

Subject Initials: ---

Generated By:

Generated Time (GMT): 29-Mar-2021 16:45

(b) (4)

Vital Signs

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

Vital Signs Details

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

090177e196ae2e95\Final\Final On: 01-Apr-2021 03:17 (GMT)

Header Text: C4591001

Visit: Unplanned Vaccination -
Unscheduled

Form: VACCINATION

Form Version: 10-Dec-2020 02:26

Form Status: Not Started

Site No: 1231

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

Subject No: 12311379

Subject Initials: ---

Generated By:

Generated Time (GMT): 29-Mar-2021 16:45

(b) (4)

Vaccination

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

090177e196ae2e95\Final\Final On: 01-Apr-2021 03:17 (GMT)

Header Text: C4591001

Visit: Unplanned Vaccination -
Unscheduled

Form Version: 10-Oct-2020 15:57

Site No: 1231

Subject No: 12311379

Generated By:

(b) (4)

Form: CONTACT OUTCOME - MONTH 1

Form Status: Not Started

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

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 16:45

Contact Outcome

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

Header Text: C4591001

Visit: Unplanned Vaccination -
Unscheduled

Form Version: 10-Oct-2020 16:01

Site No: 1231

Subject No: 12311379

Generated By:

(b) (4)

Form: CONTACT OUTCOME - MONTH 6

Form Status: Not Started

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

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 16:45

Contact Outcome

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

Header Text: C4591001

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

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

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

Subject No: 12311379 **Subject Initials:** ---

Generated By: (b) (4) **Generated Time (GMT):** 29-Mar-2021 16:45

Date of Visit

1.	Date of Visit	//
2.	Erroneous Visit	

Header Text: C4591001

Visit: V201_SURVEIL_CONSENT -
Unscheduled

Form: INFORMED CONSENT - ASYMPTOMATIC
SURVEILLANCE

Form Version: 14-Jan-2021 02:29

Form Status: Not Started

Site No: 1231

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

Subject No: 12311379

Subject Initials: ---

Generated By:

Generated Time (GMT): 29-Mar-2021 16:45

(b) (4)

Informed Consent - Asymptomatic Surveillance

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

Header Text: C4591001**Visit:** V201_SURVEIL_CONSENT -
Unscheduled**Form:** ELECTRONIC SAMPLE TRACKING -
IMMUNOGENICITY**Form Version:** 22-Apr-2020 21:03**Form Status:** Not Started**Site No:** 1231**Site Name:** (1231) Hospital Militar Central Cirujano
Mayor Dr. Cosme Argerich**Subject No:** 12311379**Subject Initials:** ---**Generated By:****Generated Time (GMT):** 29-Mar-2021 16:45

(b) (4)

Electronic Sample Tracking

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

Aliquot

Please enter barcode for each aliquot.

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

Header Text: C4591001**Visit:** V201_SURVEIL_CONSENT -
Unscheduled**Form:** ELECTRONIC SAMPLE TRACKING - NASAL
SWAB**Form Version:** 22-Apr-2020 21:03**Form Status:** Not Started**Site No:** 1231**Site Name:** (1231) Hospital Militar Central Cirujano
Mayor Dr. Cosme Argerich**Subject No:** 12311379**Subject Initials:** ---**Generated By:****Generated Time (GMT):** 29-Mar-2021 16:45

(b) (4)

Electronic Sample Tracking

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

Aliquot

Please enter barcode for each aliquot.

5.	Sample ID	[]
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Header Text: C4591001

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

Unscheduled

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1231

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

Subject No: 12311379

Subject Initials: ---

Generated By:

Generated Time (GMT): 29-Mar-2021 16:45

(b) (4)

[eCRF Audit Trail History](#)

Date of Visit

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

Header Text: C4591001

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

Form Version: 10-Dec-2020 02:25

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1231

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

Subject No: 12311379

Subject Initials: ---

Generated By:

Generated Time (GMT): 29-Mar-2021 16:45

(b) (4)

[eCRF Audit Trail History](#)

Further Vaccination Confirmation

1.	Select appropriate response - Is participant willing to return for Vaccination 3?	Participant is NOT willing to return for Vaccination 3 OR otherwise not eligible
----	---	---

Header Text: C4591001

Visit: Logs

Form: ADVERSE EVENT REPORT

Form Version: 22-Apr-2020 21:02

Site No: 1231

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

Subject No: 12311379

Subject Initials: ---

Generated By:

Generated Time (GMT): 29-Mar-2021 16:45

(b) (4)

#	Category	AE Identifier	Adverse Event	Start Date	Is the Adverse Event Still Ongoing	Form Instance
1.	ADVERSE EVENT	1	Prostate adeno carcinoma.	Nov/20/2020 12:00	YES	Repeating Pages

Header Text: C4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Verified

Site No: 1231

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

Subject No: 12311379

Subject Initials: ---

Generated By:

Generated Time (GMT): 29-Mar-2021 16:45

(b) (4)

[Back to Form](#)

[eCRF Audit Trail History](#)

[Form Audit Trail](#)

Adverse Event Report

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

090177e196ae2e95\Final\Final On: 01-Apr-2021 03:17 (GMT)

Header Text: C4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1231

Subject No: 12311379

Generated By:

(b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Verified

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

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 16:45

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

090177e196ae2e95\Final\Final On: 01-Apr-2021 03:17 (GMT)

Header Text: C4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1231

Subject No: 12311379

Generated By:

(b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Verified

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

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 16:45

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?:	NOT RECOVERED/NOT RESOLVED
14.	Did the adverse event cause the subject to be discontinued from the study?	NO
15.	Serious Adverse Event Number: For Pfizer Use Only	[2021028480]

090177e196ae2e95\Final\Final On: 01-Apr-2021 03:17 (GMT)

Header Text: C4591001

Visit: Logs

Form: MEDICATION ERROR

Form Version: 17-Jul-2020 21:54

Site No: 1231

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

Subject No: 12311379

Subject Initials: ---

Generated By:

Generated Time (GMT): 29-Mar-2021 16:45

(b) (4)

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

Header Text: C4591001

Visit: Logs - Unscheduled

Form: MEDICATION ERROR

Form Version: 17-Jul-2020 21:54

Form Status: Not Started

Site No: 1231

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

Subject No: 12311379

Subject Initials: ---

Generated By:

Generated Time (GMT): 29-Mar-2021 16:45

(b) (4)

[Back to Form](#)

Medication Error

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

090177e196ae2e95\Final\Final On: 01-Apr-2021 03:17 (GMT)

Header Text: C4591001

Visit: Logs

Form: CONCOMITANT MEDICATIONS - NON STUDY VACCINATIONS

Form Version: 22-Apr-2020 21:03

Site No: 1231

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

Subject No: 12311379

Subject Initials: ---

Generated By:

Generated Time (GMT): 29-Mar-2021 16:45

(b) (4)

#	Sponsor-Defined Identifier	Category for Medication	Concomitant Medications Pre-specified	Name of Medication	Start Date	Form Instance
1.	1	VACCINATIONS	NO	Gam-COVID-Vac (trade name Sputnik V).	Feb/18/2021	Repeating Pages

Header Text: C4591001

Visit: Logs - Unscheduled

Form: CONCOMITANT MEDICATIONS - NON STUDY VACCINATIONS

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1231

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

Subject No: 12311379

Subject Initials: ---

Generated By:

Generated Time (GMT): 29-Mar-2021 16:45

(b) (4)

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[eCRF Audit Trail History](#)

[Form Audit Trail](#)

Concomitant Medications

1.	What is the medication identifier?	[1]
2.	Category:	VACCINATIONS
3.	Concomitant Medications Pre-specified:	NO
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).	[Gam-COVID-Vac (trade name Sputnik V).]
5.	Date:	Feb/18/2021

090177e196ae2e95\Final\Final On: 01-Apr-2021 03:17 (GMT)

Header Text: C4591001

Visit: Logs

Form: CONCOMITANT MEDICATIONS - PROHIBITED

Form Version: 22-Apr-2020 21:03

Site No: 1231

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

Subject No: 12311379

Subject Initials: ---

Generated By:

Generated Time (GMT): 29-Mar-2021 16:45

(b) (4)

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

090177e196ae2e95\Final\Final On: 01-Apr-2021 03:17 (GMT)

Header Text: C4591001

Visit: Logs - Unscheduled

Form: CONCOMITANT MEDICATIONS - PROHIBITED

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1231

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

Subject No: 12311379

Subject Initials: ---

Generated By:

Generated Time (GMT): 29-Mar-2021 16:45

(b) (4)

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Concomitant Medications

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

090177e196ae2e95\Final\Final On: 01-Apr-2021 03:17 (GMT)

Header Text: C4591001

Visit: Logs

Form: RADIATION TREATMENT

Form Version: 22-Apr-2020 21:02

Site No: 1231

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

Subject No: 12311379

Subject Initials: ---

Generated By:

Generated Time (GMT): 29-Mar-2021 16:45

(b) (4)

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

Header Text: C4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1231

Subject No: 12311379

Generated By:

(b) (4)

Form: RADIATION TREATMENT

Form Status: Not Started

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

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 16:45

[Back to Form](#)

Radiation Treatment

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

090177e196ae2e95\Final\Final On: 01-Apr-2021 03:17 (GMT)

Header Text: C4591001

Visit: Logs

Form: TRANSFUSIONS

Form Version: 22-Apr-2020 21:03

Site No: 1231

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

Subject No: 12311379

Subject Initials: ---

Generated By:

Generated Time (GMT): 29-Mar-2021 16:45

(b) (4)

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

Header Text: C4591001

Visit: Logs - Unscheduled

Form: TRANSFUSIONS

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1231

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

Subject No: 12311379

Subject Initials: ---

Generated By:

Generated Time (GMT): 29-Mar-2021 16:45

(b) (4)

[Back to Form](#)

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

Header Text: C4591001

Visit: UNPLANNED_BOOSTER_CONTACT
- Unscheduled

Form: DATE OF VISIT

Form Version: 22-Apr-2020 21:02

Form Status: Not Started

Site No: 1231

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

Subject No: 12311379

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 16:45

Date of Visit

1.	Date of Visit	//
2.	Erroneous Visit	

Header Text: C4591001

Visit:
UNPLANNED_BOOSTER_CONTACT
- Unscheduled

Form: BOOSTER DOSE TRIGGER FORM

Form Version: 20-Feb-2021 02:20

Form Status: Not Started

Site No: 1231

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

Subject No: 12311379

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 16:45

Booster Dose Trigger Form

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

Header Text: C4591001

Visit: Disposition - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1231

Subject No: 12311379

Generated By:

(b) (4)

Form: TREATMENT UNBLINDED

Form Status: Not Started

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

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 16:45

Treatment Unblinded

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

Header Text: C4591001

Visit: Disposition - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1231

Subject No: 12311379

Generated By:

(b) (4)

Form: WITHDRAWAL OF CONSENT

Form Status: Not Started

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

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 16:45

Withdrawal Of Consent

1.	Withdrawal of Consent Date :	//
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090177e196ae2e95\Final\Final On: 01-Apr-2021 03:17 (GMT)

Header Text: C4591001

Visit: Disposition - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1231

Subject No: 12311379

Generated By:

(b) (4)

Form: DEATH DETAILS CODED

Form Status: Not Started

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

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 16:45

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: 1231

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

Subject No: 12311379

Subject Initials: ---

Generated By:

Generated Time (GMT): 29-Mar-2021 16:45

(b) (4)

[eCRF Audit Trail History](#)

Subject Status

1.	Subject Status	DISCONTINUED
2.	Subject Status Date	Feb/24/2021

090177e196ae2e95\Final\Final On: 01-Apr-2021 03:17 (GMT)

Header Text: C4591001

Visit: Investigator Signature -
Unscheduled

Form Version: 22-Apr-2020 21:04

Site No: 1231

Subject No: 12311379

Generated By:

(b) (4)

Form: CASEBOOK SIGNATURE FORM

Form Status: Data Complete, Signed, Verified

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

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 16:45

[eCRF Audit Trail History](#)

Casebook Signature Form

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

Visit: Investigator Signature -
Unscheduled

Form: CASEBOOK SIGNATURE FORM

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Signed, Verified

Site No: 1231

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

Subject No: 12311379

Subject Initials: ---

Generated By:

Generated Time (GMT): 29-Mar-2021 16:45

(b) (4)

[Audit Trail](#)

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

- CRF_Sign

Name	Signature Meaning	Date	Type	Action
(b) (6)	Approved	Mar-05-2021 14:07:24 (UTC-03:00) City of Buenos Aires	BOOK	Signed

Affidavit:

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

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

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

090177e196ae2e95\Final\Final On: 01-Apr-2021 03:17 (GMT)

Header Text: C4591001

Visit: Investigator Signature -
Unscheduled

Form: CASEBOOK SIGNATURE FORM - Signature
History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Signed, Verified

Site No: 1231

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

Subject No: 12311379

Subject Initials: ---

Generated By:

Generated Time (GMT): 29-Mar-2021 16:45

(b) (4)

[Back to Form](#)

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

- CRF_Sign

Name	Signature Meaning	Date	Type	Action
(b) (6) [Redacted]	Approved	Mar-05-2021 14:07:24 (UTC-03:00) City of Buenos Aires	BOOK	Signed

Affidavit:

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

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

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

(b) (6) [Redacted]	N/A	Feb-25-2021 12:33:26 (UTC-03:00) City of Buenos Aires		Edit - All signatures invalidated
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Affidavit:

N/A

Gonzalo Perez Marc	Approved	Feb-01-2021 12:36:37 (UTC-03:00) City of Buenos Aires	BOOK	Signed
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090177e196ae2e95\Final\Final On: 01-Apr-2021 03:17 (GMT)

Header Text: C4591001

Visit: Investigator Signature -
Unscheduled

Form: CASEBOOK SIGNATURE FORM - Signature
History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Signed, Verified

Site No: 1231

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

Subject No: 12311379

Subject Initials: ---

Generated By:

Generated Time (GMT): 29-Mar-2021 16:45

(b) (4)

Affidavit:

By my dated signature below, I, GonzaloPerez, 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 08:36:10 (UTC-03:00) City of Buenos Aires		Edit - All signatures invalidated
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Affidavit:

N/A

(b) (6)	Approved	Jan-20-2021 20:34:35 (UTC-03:00) City of Buenos Aires	BOOK	Signed
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090177e196ae2e95\Final\Final On: 01-Apr-2021 03:17 (GMT)

Header Text: C4591001

Visit: Investigator Signature -
Unscheduled

Form: CASEBOOK SIGNATURE FORM - Signature
History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Signed, Verified

Site No: 1231

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

Subject No: 12311379

Subject Initials: ---

Generated By:

Generated Time (GMT): 29-Mar-2021 16:45

(b) (4)

Affidavit:

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

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

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

(b) (6)	N/A	Jan-12-2021 15:51:39 (UTC-03:00) City of Buenos Aires		Edit - All signatures invalidated
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Affidavit:

N/A

Fernando Polack	Approved	Oct-22-2020 14:02:20 (UTC-03:00) City of Buenos Aires	BOOK	Signed
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090177e196ae2e95\Final\Final On: 01-Apr-2021 03:17 (GMT)

Header Text: C4591001

Visit: Investigator Signature -
Unscheduled

Form Version: 22-Apr-2020 21:04

Site No: 1231

Subject No: 12311379

Generated By:

(b) (4)

Form: CASEBOOK SIGNATURE FORM - Signature
History

Form Status: Data Complete, Signed, Verified

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

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 16:45

Affidavit:

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

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

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

090177e196ae2e95\Final\Final On: 01-Apr-2021 03:17 (GMT)

Header Text: C4591001

Visit: COHORT_SELECTION

Form: COHORT SELECTION - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:29

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1231

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

Subject No: 12311379

Subject Initials: ---

Generated By:

Generated Time (GMT): 29-Mar-2021 16:45

(b) (4)

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1. Select appropriate response - Protocol version

Date	Location	User	Value	Reason
Aug-15-2020 18:29:41 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 30 JUN 2020	Initial Entry

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

Date	Location	User	Value	Reason
Aug-15-2020 18:29:41 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: STAGE 3 COHOR TS	Initial Entry

Header Text: C4591001

Visit: COHORT_SELECTION

Form Version: 22-Apr-2020 21:02

Site No: 1231

Subject No: 12311379

Generated By:

(b) (4)

Form: MAIN INFORMED CONSENT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 16:45

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1. Consent Was:

Date	Location	User	Value	Reason
Aug-15-2020 18:29:49 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: OBTAINED Date Written Con sent Obtained Aug/15/2020	Initial Entry

090177e196ae2e95\Final\Final On: 01-Apr-2021 03:17 (GMT)

Header Text: C4591001

Visit: COHORT_SELECTION

Form Version: 06-Jul-2020 21:55

Site No: 1231

Subject No: 12311379

Generated By:

(b) (4)

Form: DEMOGRAPHY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 16:45

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1. Subject ID

Date	Location	User	Value	Reason
Aug-15-2020 13:40:34 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 12311379	Item copied from previous form

2. Birth Date:

Date	Location	User	Value	Reason
Aug-15-2020 13:40:30 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: (b) (6)/1948	Enrollment Entry

3. Sex:

Date	Location	User	Value	Reason
Aug-15-2020 18:30:03 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: MALE	Initial Entry

4. Ethnicity:

Date	Location	User	Value	Reason
Aug-15-2020	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Initial Entry

090177e196ae2e95\Final\Final On: 01-Apr-2021 03:17 (GMT)

Header Text: C4591001

Visit: COHORT_SELECTION

Form: DEMOGRAPHY - eCRF Audit Trail History

Form Version: 06-Jul-2020 21:55

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1231

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

Subject No: 12311379

Subject Initials: ---

Generated By:

Generated Time (GMT): 29-Mar-2021 16:45

(b) (4)

18:30:03 (UTC-03:00) City of Buenos Aires		(b) (4), (b) (6)	HISPANIC OR LA TINO(A) OR OF S PANISH ORIGIN	
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5. Race: (Check X all that apply):

Date	Location	User	Value	Reason
Aug-15-2020 18:30:03 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: WHITE	Initial Entry

090177e196ae2e95\Final\Final On: 01-Apr-2021 03:17 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:02

Site No: 1231

Subject No: 12311379

Generated By:

(b) (4)

Form: DATE OF VISIT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 16:45

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1. Date of Visit

Date	Location	User	Value	Reason
Aug-15-2020 18:30:20 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Aug/15/2020	Initial Entry

090177e196ae2e95\Final\Final On: 01-Apr-2021 03:17 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form: INCLUSION/EXCLUSION CRITERIA - eCRF
Audit Trail History

Form Version: 30-Jul-2020 21:27

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1231

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

Subject No: 12311379

Subject Initials: ---

Generated By:

Generated Time (GMT): 29-Mar-2021 16:45

(b) (4)

[Back to Form](#)

I.a

Date	Location	User	Value	Reason
Aug-15-2020 18:30:37 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<p>Data Entry:</p> <p>Incl 1 usio n N um ber :</p> <p>Cri Male or fema teri le participant on s between th Des e ages of 18 cri p and 55 years, tion inclusive, 65 : and 85 years, inclusive, or 18 and 85 ye ars, inclusive , at randomiz ation (depen dent upon stu dy stage)</p> <p>Cri YES teri on met ?:</p>	Initial Entry

090177e196ae2e95\Final\Final On: 01-Apr-2021 03:17 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form: INCLUSION/EXCLUSION CRITERIA - eCRF
Audit Trail History

Form Version: 30-Jul-2020 21:27

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1231

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

Subject No: 12311379

Subject Initials: ---

Generated By:

Generated Time (GMT): 29-Mar-2021 16:45

(b) (4)

			Cri IN01A00 teri on I D: (For Pfiz er u se o nly) :	
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1.a Inclusion Number:

Date	Location	User	Value	Reason
Aug-15-2020 18:30:37 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6) [Redacted]	Data Entry: 1	Initial Entry

1.a Criterion Description:

Date	Location	User	Value	Reason
Aug-15-2020 18:30:37 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6) [Redacted]	Data Entry: Male or female par ticipants between t he ages of 18 and 5 5 years, inclusive, 65 and 85 years, in clusive, or 18 and 85 years, inclusive, at randomization (Initial Entry

090177e196ae2e95\Final\Final On: 01-Apr-2021 03:17 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form: INCLUSION/EXCLUSION CRITERIA - eCRF
Audit Trail History

Form Version: 30-Jul-2020 21:27

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1231

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

Subject No: 12311379

Subject Initials: ---

Generated By:

Generated Time (GMT): 29-Mar-2021 16:45

(b) (4)

			dependent upon study stage)	
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1.a Criterion met?

Date	Location	User	Value	Reason
Aug-15-2020 18:30:37 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

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

Date	Location	User	Value	Reason
Aug-15-2020 18:30:37 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: IN01A00	Initial Entry

1.b

Date	Location	User	Value	Reason
Aug-15-2020 18:30:37 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Incl 2 usio n N um ber:	Initial Entry

090177e196ae2e95\Final\Final On: 01-Apr-2021 03:17 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 30-Jul-2020 21:27

Site No: 1231

Subject No: 12311379

Generated By:

(b) (4)

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Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 16:45

			<p>Crit Participants erio who are willi n D ng and able t escr o comply wit ipti h all schedul on: ed visits, vac cination plan , laboratory t ests, lifestyle consideratio ns, and other study proced ures</p> <p>Crit YES erio n m et?:</p> <p>Crit IN02A00 erio n I D: (For Pfiz er u se o nly) :</p>	
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090177e196ae2e95\Final\Final On: 01-Apr-2021 03:17 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

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Mayor Dr. Cosme Argerich

Subject No: 12311379

Subject Initials: ---

Generated By:

Generated Time (GMT): 29-Mar-2021 16:45

(b) (4)

1.b Inclusion Number:

Date	Location	User	Value	Reason
Aug-15-2020 18:30:37 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 2	Initial Entry

1.b Criterion Description:

Date	Location	User	Value	Reason
Aug-15-2020 18:30:37 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Participants who are willing and able to comply with all scheduled visits, vaccination plan, laboratory tests, lifestyle considerations, and other study procedures	Initial Entry

1.b Criterion met?

Date	Location	User	Value	Reason
Aug-15-2020 18:30:37 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

090177e196ae2e95\Final\Final On: 01-Apr-2021 03:17 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form: INCLUSION/EXCLUSION CRITERIA - eCRF
Audit Trail History

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Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1231

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

Subject No: 12311379

Subject Initials: ---

Generated By:

Generated Time (GMT): 29-Mar-2021 16:45

(b) (4)

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

Date	Location	User	Value	Reason
Aug-15-2020 18:30:37 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: IN02A00	Initial Entry

1.c

Date	Location	User	Value	Reason
Aug-15-2020 18:30:37 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Incl 3 usio n N um ber: Crit Healthy parti erio cipants who n D are determin escr ed by medic ipti al history, ph on: ytical exami nation, and c linical judgm ent of the inv estigator to b e eligible for inclusion in t he study	Initial Entry

090177e196ae2e95\Final\Final On: 01-Apr-2021 03:17 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form: INCLUSION/EXCLUSION CRITERIA - eCRF
Audit Trail History

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Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1231

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

Subject No: 12311379

Subject Initials: ---

Generated By:

Generated Time (GMT): 29-Mar-2021 16:45

(b) (4)

			<p>Crit YES erio n m et?: Crit IN03A00 erio n I D: (For Pfizer er u se o nly) :</p>	
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090177e196ae2e95\Final\Final On: 01-Apr-2021 03:17 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

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Mayor Dr. Cosme Argerich

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Subject Initials: ---

Generated By:

Generated Time (GMT): 29-Mar-2021 16:45

(b) (4)

I.c Inclusion Number:

Date	Location	User	Value	Reason
Aug-15-2020 18:30:37 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 3	Initial Entry

I.c Criterion Description:

Date	Location	User	Value	Reason
Aug-15-2020 18:30:37 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Healthy participant s who are determin ed by medical hist ory, physical exam ination, and clinica l judgment of the i nvestigator to be el igible for inclusion in the study	Initial Entry

I.c Criterion met?

Date	Location	User	Value	Reason
Aug-15-2020 18:30:37 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

090177e196ae2e95\Final\Final On: 01-Apr-2021 03:17 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form: INCLUSION/EXCLUSION CRITERIA - eCRF
Audit Trail History

Form Version: 30-Jul-2020 21:27

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1231

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

Subject No: 12311379

Subject Initials: ---

Generated By:

Generated Time (GMT): 29-Mar-2021 16:45

(b) (4)

1.c Criterion ID: (For Pfizer use only)

Date	Location	User	Value	Reason
Aug-15-2020 18:30:37 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: IN03A00	Initial Entry

1.d

Date	Location	User	Value	Reason
Aug-15-2020 18:30:37 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Incl 4 usio n N um ber: Crit Capable of g erio iving person n D al signed inf escr ormed conse ipti nt, which inc on: ludes compli ance with th e requiremen ts and restric tions listed i n the ICD an d in this prot ocol	Initial Entry

090177e196ae2e95\Final\Final On: 01-Apr-2021 03:17 (GMT)

Header Text: C4591001

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Audit Trail History

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Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1231

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

Subject No: 12311379

Subject Initials: ---

Generated By:

Generated Time (GMT): 29-Mar-2021 16:45

(b) (4)

			<p>Crit YES</p> <p>erio</p> <p>n m</p> <p>et?:</p> <p>Crit IN04A00</p> <p>erio</p> <p>n I</p> <p>D: (</p> <p>For</p> <p>Pfizer</p> <p>er u</p> <p>se o</p> <p>nly)</p> <p>:</p>	
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Header Text: C4591001

Visit: V1_DAY1_VAX1_L

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Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1231

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

Subject No: 12311379

Subject Initials: ---

Generated By:

Generated Time (GMT): 29-Mar-2021 16:45

(b) (4)

1.d Inclusion Number:

Date	Location	User	Value	Reason
Aug-15-2020 18:30:37 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 4	Initial Entry

1.d Criterion Description:

Date	Location	User	Value	Reason
Aug-15-2020 18:30:37 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Capable of giving personal signed in- formed consent, wh ich includes compl iance with the requ irements and restri ctions listed in the ICD and in this pro tocol	Initial Entry

1.d Criterion met?

Date	Location	User	Value	Reason
Aug-15-2020 18:30:37 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

090177e196ae2e95\Final\Final On: 01-Apr-2021 03:17 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

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Mayor Dr. Cosme Argerich

Subject No: 12311379

Subject Initials: ---

Generated By:

Generated Time (GMT): 29-Mar-2021 16:45

(b) (4)

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

Date	Location	User	Value	Reason
Aug-15-2020 18:30:37 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: IN04A00	Initial Entry

2.a

Date	Location	User	Value	Reason
Aug-15-2020 18:30:37 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Exc 1 lusi on Nu mb er:	Initial Entry

090177e196ae2e95\Final\Final On: 01-Apr-2021 03:17 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

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Site No: 1231

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

Subject No: 12311379

Subject Initials: ---

Generated By:

Generated Time (GMT): 29-Mar-2021 16:45

(b) (4)

			<p>Crit Other medic erio al or psychia n D tric conditio escr n incl. recent ipti (within past on: year) or activ e suicidal ide ation/behavi or/lab abnor mality that m ay increase t he risk of stu dy participati on</p> <p>Crit NO erio n m et?:</p> <p>Crit EX01A00 erio n I D: (For Pfiz er u se o nly) :</p>	
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2.a Exclusion Number:

Date	Location	User	Value	Reason
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090177e196ae2e95\Final\Final On: 01-Apr-2021 03:17 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form: INCLUSION/EXCLUSION CRITERIA - eCRF
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Site No: 1231

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

Subject No: 12311379

Subject Initials: ---

Generated By:

Generated Time (GMT): 29-Mar-2021 16:45

(b) (4)

Aug-15-2020 18:30:37 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 1	Initial Entry
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2.a Criterion Description:

Date	Location	User	Value	Reason
Aug-15-2020 18:30:37 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Other medical or p sychiatric conditio n incl. recent (with in past year) or acti ve suicidal ideatio n/behavior/lab abn ormality that may i ncrease the risk of study participation	Initial Entry

2.a Criterion met?

Date	Location	User	Value	Reason
Aug-15-2020 18:30:37 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

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

Date	Location	User	Value	Reason
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090177e196ae2e95\Final\Final On: 01-Apr-2021 03:17 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form: INCLUSION/EXCLUSION CRITERIA - eCRF
Audit Trail History

Form Version: 30-Jul-2020 21:27

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1231

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

Subject No: 12311379

Subject Initials: ---

Generated By:

Generated Time (GMT): 29-Mar-2021 16:45

(b) (4)

Aug-15-2020 18:30:37 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: EX01A00	Initial Entry
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2.b

Date	Location	User	Value	Reason
Aug-15-2020 18:30:37 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Excl 2 usio n Nu mbe r: Crit Known infe erio ction with h n De uman immu scrip nodeficienc tion: y virus (HI V), hepatitis C virus (HC V), or hepat itis B virus (HBV) Crit NO erio n me t?:	Initial Entry

090177e196ae2e95\Final\Final On: 01-Apr-2021 03:17 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 30-Jul-2020 21:27

Site No: 1231

Subject No: 12311379

Generated By:

(b) (4)

Form: INCLUSION/EXCLUSION CRITERIA - eCRF
Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 16:45

			Crit EX02A00	
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			n ID	
			: (Fo	
			r Pfi	
			zer u	
			se on	
			ly):	

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form: INCLUSION/EXCLUSION CRITERIA - eCRF
Audit Trail History

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Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1231

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

Subject No: 12311379

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Generated By:

Generated Time (GMT): 29-Mar-2021 16:45

(b) (4)

2.b Exclusion Number:

Date	Location	User	Value	Reason
Aug-15-2020 18:30:37 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 2	Initial Entry

2.b Criterion Description:

Date	Location	User	Value	Reason
Aug-15-2020 18:30:37 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Known infection w ith human immuno deficiency virus (H IV), hepatitis C vir us (HCV), or hepat itis B virus (HBV)	Initial Entry

2.b Criterion met?

Date	Location	User	Value	Reason
Aug-15-2020 18:30:37 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

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

Date	Location	User	Value	Reason
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090177e196ae2e95\Final\Final On: 01-Apr-2021 03:17 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

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Site No: 1231

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

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Generated By:

Generated Time (GMT): 29-Mar-2021 16:45

(b) (4)

Aug-15-2020 18:30:37 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: EX02A00	Initial Entry
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2.c

Date	Location	User	Value	Reason
Aug-15-2020 18:30:37 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Exc 3 lusi on Nu mbe r: Crit History of se erio vere adverse n D reaction asso escr ciated with a ipti vaccine and/ on: or severe all ergic reactio n (eg, anaph ylaxis) to an y component of the study i ntervention(s)	Initial Entry

090177e196ae2e95\Final\Final On: 01-Apr-2021 03:17 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form: INCLUSION/EXCLUSION CRITERIA - eCRF
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Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1231

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Mayor Dr. Cosme Argerich

Subject No: 12311379

Subject Initials: ---

Generated By:

Generated Time (GMT): 29-Mar-2021 16:45

(b) (4)

			<p>Crit NO erion m et?:</p> <p>Crit EX03A00 erion n I D: (</p> <p>For Pfizer use only)</p> <p>:</p>	
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090177e196ae2e95\Final\Final On: 01-Apr-2021 03:17 (GMT)

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(b) (4)

2.c Exclusion Number:

Date	Location	User	Value	Reason
Aug-15-2020 18:30:37 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 3	Initial Entry

2.c Criterion Description:

Date	Location	User	Value	Reason
Aug-15-2020 18:30:37 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: History of severe a dverse reaction ass ociated with a vacc ine and/or severe a llergic reaction (eg , anaphylaxis) to a ny component of t he study interventi on(s)	Initial Entry

2.c Criterion met?

Date	Location	User	Value	Reason
Aug-15-2020 18:30:37 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

090177e196ae2e95\Final\Final On: 01-Apr-2021 03:17 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form: INCLUSION/EXCLUSION CRITERIA - eCRF
Audit Trail History

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Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1231

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

Subject No: 12311379

Subject Initials: ---

Generated By:

Generated Time (GMT): 29-Mar-2021 16:45

(b) (4)

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

Date	Location	User	Value	Reason
Aug-15-2020 18:30:37 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: EX03A00	Initial Entry

2.d

Date	Location	User	Value	Reason
Aug-15-2020 18:30:37 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Exclus 4 ion Nu mber: Criteri Receipt o on Des f medicati criptio ons inten n: ded to pre vent COV ID-19 Criteri NO on met ?: Criteri EX04A00 on ID: (For P fizer u se only):	Initial Entry

090177e196ae2e95\Final\Final On: 01-Apr-2021 03:17 (GMT)

Header Text: C4591001

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Subject Initials: ---

Generated By:

Generated Time (GMT): 29-Mar-2021 16:45

(b) (4)

2.d Exclusion Number:

Date	Location	User	Value	Reason
Aug-15-2020 18:30:37 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 4	Initial Entry

2.d Criterion Description:

Date	Location	User	Value	Reason
Aug-15-2020 18:30:37 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Receipt of medicat ions intended to pr event COVID-19	Initial Entry

2.d Criterion met?

Date	Location	User	Value	Reason
Aug-15-2020 18:30:37 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

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

Date	Location	User	Value	Reason
Aug-15-2020 18:30:37 (UTC-03:00) City	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: EX04A00	Initial Entry

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Header Text: C4591001

Visit: V1_DAY1_VAX1_L

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Mayor Dr. Cosme Argerich

Subject No: 12311379

Subject Initials: ---

Generated By:

Generated Time (GMT): 29-Mar-2021 16:45

(b) (4)

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2.e

Date	Location	User	Value	Reason
Aug-15-2020 18:30:37 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<p>Data Entry:</p> <p>Excl 8</p> <p>usio</p> <p>n N</p> <p>um</p> <p>ber:</p> <p>Crit Immunocom</p> <p>erio promised in</p> <p>n D individuals wit</p> <p>escr h known or s</p> <p>ipti uspected im</p> <p>on: munodeficie</p> <p>ncy, as deter</p> <p>mined by his</p> <p>tory and/or l</p> <p>aboratory/ph</p> <p>ysical exami</p> <p>nation</p> <p>Crit NO</p> <p>erio</p> <p>n m</p> <p>et?:</p>	Initial Entry

090177e196ae2e95\Final\Final On: 01-Apr-2021 03:17 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 30-Jul-2020 21:27

Site No: 1231

Subject No: 12311379

Generated By:

(b) (4)

Form: INCLUSION/EXCLUSION CRITERIA - eCRF
Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 16:45

			Crit EX08A00 erio n ID : (F or P fize r us e on ly):	
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Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form: INCLUSION/EXCLUSION CRITERIA - eCRF
Audit Trail History

Form Version: 30-Jul-2020 21:27

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1231

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

Subject No: 12311379

Subject Initials: ---

Generated By:

Generated Time (GMT): 29-Mar-2021 16:45

(b) (4)

2.e Exclusion Number:

Date	Location	User	Value	Reason
Aug-15-2020 18:30:37 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 8	Initial Entry

2.e Criterion Description:

Date	Location	User	Value	Reason
Aug-15-2020 18:30:37 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Immunocompromi sed individuals wit h known or suspect ed immunodeficien cy, as determined b y history and/or la boratory/physical e xamination	Initial Entry

2.e Criterion met?

Date	Location	User	Value	Reason
Aug-15-2020 18:30:37 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

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

090177e196ae2e95\Final\Final On: 01-Apr-2021 03:17 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form: INCLUSION/EXCLUSION CRITERIA - eCRF
Audit Trail History

Form Version: 30-Jul-2020 21:27

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1231

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

Subject No: 12311379

Subject Initials: ---

Generated By:

Generated Time (GMT): 29-Mar-2021 16:45

(b) (4)

Date	Location	User	Value	Reason
Aug-15-2020 18:30:37 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: EX08A00	Initial Entry

2.f

Date	Location	User	Value	Reason
Aug-15-2020 18:30:37 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Excl 10 usio n N um ber: Crit Bleeding dia erio thesis or con n D dition associ escr ated with pr ipti olonged blee on: ding that wo uld, in the o pinion of the investigator, contraindicat e intramuscu lar injection	Initial Entry

090177e196ae2e95\Final\Final On: 01-Apr-2021 03:17 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form: INCLUSION/EXCLUSION CRITERIA - eCRF
Audit Trail History

Form Version: 30-Jul-2020 21:27

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1231

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

Subject No: 12311379

Subject Initials: ---

Generated By:

Generated Time (GMT): 29-Mar-2021 16:45

(b) (4)

			<p>Crit NO erio n m et?: Crit EX10A00 erio n I D: (For Pfiz er u se o nly) :</p>	
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090177e196ae2e95\Final\Final On: 01-Apr-2021 03:17 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form: INCLUSION/EXCLUSION CRITERIA - eCRF
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Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1231

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

Subject No: 12311379

Subject Initials: ---

Generated By:

Generated Time (GMT): 29-Mar-2021 16:45

(b) (4)

2.f Exclusion Number:

Date	Location	User	Value	Reason
Aug-15-2020 18:30:37 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 10	Initial Entry

2.f Criterion Description:

Date	Location	User	Value	Reason
Aug-15-2020 18:30:37 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Bleeding diathesis or condition associ ated with prolonge d bleeding that wo uld, in the opinion of the investigator, contraindicate intra muscular injection	Initial Entry

2.f Criterion met?

Date	Location	User	Value	Reason
Aug-15-2020 18:30:37 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

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

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Header Text: C4591001

Visit: V1_DAY1_VAX1_L

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Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1231

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

Subject No: 12311379

Subject Initials: ---

Generated By:

Generated Time (GMT): 29-Mar-2021 16:45

(b) (4)

Date	Location	User	Value	Reason
Aug-15-2020 18:30:37 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: EX10A00	Initial Entry

2.g

Date	Location	User	Value	Reason
Aug-15-2020 18:30:37 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Exclusi 11 on Nu mber: Criteri Women on Desc who are ription: pregnant or breast feeding Criteri NO on met ?: Criteri EX11A0 on ID: (0 For Pfi zer use only):	Initial Entry

090177e196ae2e95\Final\Final On: 01-Apr-2021 03:17 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form: INCLUSION/EXCLUSION CRITERIA - eCRF
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Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1231

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

Subject No: 12311379

Subject Initials: ---

Generated By:

Generated Time (GMT): 29-Mar-2021 16:45

(b) (4)

2.g Exclusion Number:

Date	Location	User	Value	Reason
Aug-15-2020 18:30:37 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 11	Initial Entry

2.g Criterion Description:

Date	Location	User	Value	Reason
Aug-15-2020 18:30:37 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Women who are pr egnant or breastfee ding	Initial Entry

2.g Criterion met?

Date	Location	User	Value	Reason
Aug-15-2020 18:30:37 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

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

Date	Location	User	Value	Reason
Aug-15-2020 18:30:37 (UTC-03:00) City	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: EX11A00	Initial Entry

090177e196ae2e95\Final\Final On: 01-Apr-2021 03:17 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form: INCLUSION/EXCLUSION CRITERIA - eCRF
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Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1231

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

Subject No: 12311379

Subject Initials: ---

Generated By:

Generated Time (GMT): 29-Mar-2021 16:45

(b) (4)

of Buenos Aires

2.h

Date	Location	User	Value	Reason
Aug-15-2020 18:30:37 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<p>Data Entry:</p> <p>Exclusion Number:</p> <p>Criterion Description: Previous vaccination with any coronavirus vaccine</p> <p>Criterion met?: NO</p> <p>Criterion ID: EX12A00 (For Pfizer use only)</p>	Initial Entry

090177e196ae2e95\Final\Final On: 01-Apr-2021 03:17 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form: INCLUSION/EXCLUSION CRITERIA - eCRF
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Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1231

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

Subject No: 12311379

Subject Initials: ---

Generated By:

Generated Time (GMT): 29-Mar-2021 16:45

(b) (4)

2.h Exclusion Number:

Date	Location	User	Value	Reason
Aug-15-2020 18:30:37 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 12	Initial Entry

2.h Criterion Description:

Date	Location	User	Value	Reason
Aug-15-2020 18:30:37 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Previous vaccinati on with any corona virus vaccine	Initial Entry

2.h Criterion met?

Date	Location	User	Value	Reason
Aug-15-2020 18:30:37 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

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

Date	Location	User	Value	Reason
Aug-15-2020 18:30:37 (UTC-03:00) City	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: EX12A00	Initial Entry

090177e196ae2e95\Final\Final On: 01-Apr-2021 03:17 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form: INCLUSION/EXCLUSION CRITERIA - eCRF
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Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1231

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

Subject No: 12311379

Subject Initials: ---

Generated By:

Generated Time (GMT): 29-Mar-2021 16:45

(b) (4)

of Buenos Aires

2.i

Date	Location	User	Value	Reason
Aug-15-2020 18:30:37 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<p>Data Entry:</p> <p>Excl 13</p> <p>usio</p> <p>n Nu</p> <p>mbe</p> <p>r:</p> <p>Crite Subjects wh</p> <p>riou o receive i</p> <p>Desc mmunosup</p> <p>ripti pressive the</p> <p>on: rapy, such a</p> <p>s cytotoxic</p> <p>agents or sy</p> <p>stemic corti</p> <p>costeroids</p> <p>Crite NO</p> <p>riou</p> <p>met?</p> <p>:</p>	Initial Entry

090177e196ae2e95\Final\Final On: 01-Apr-2021 03:17 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

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Site No: 1231

Subject No: 12311379

Generated By:

(b) (4)

Form: INCLUSION/EXCLUSION CRITERIA - eCRF
Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1231) Hospital Militar Central Cirujano
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Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 16:45

			Crite EX13A01 rion ID: (For Pfize r use only) :	
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Header Text: C4591001

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Form: INCLUSION/EXCLUSION CRITERIA - eCRF
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Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1231

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

Subject No: 12311379

Subject Initials: ---

Generated By:

Generated Time (GMT): 29-Mar-2021 16:45

(b) (4)

2.i Exclusion Number:

Date	Location	User	Value	Reason
Aug-15-2020 18:30:37 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 13	Initial Entry

2.i Criterion Description:

Date	Location	User	Value	Reason
Aug-15-2020 18:30:37 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Subjects who receive immunosuppressive therapy, such as cytotoxic agents or systemic corticosteroids	Initial Entry

2.i Criterion met?

Date	Location	User	Value	Reason
Aug-15-2020 18:30:37 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

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

Date	Location	User	Value	Reason
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090177e196ae2e95\Final\Final On: 01-Apr-2021 03:17 (GMT)

Header Text: C4591001

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Form: INCLUSION/EXCLUSION CRITERIA - eCRF
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Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1231

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

Subject No: 12311379

Subject Initials: ---

Generated By:

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(b) (4)

Aug-15-2020 18:30:37 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: EX13A01	Initial Entry
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2.j

Date	Location	User	Value	Reason
Aug-15-2020 18:30:37 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Excl 15 usio n N um ber: Crit Receipt of bl erio ood/plasma n D products or i eser mmunoglob ipti ulin, from 6 on: 0 days befor e study inter vention adm inistration or planned rece ipt througho ut the study Crit NO erio n m et?:	Initial Entry

090177e196ae2e95\Final\Final On: 01-Apr-2021 03:17 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 30-Jul-2020 21:27

Site No: 1231

Subject No: 12311379

Generated By:

(b) (4)

Form: INCLUSION/EXCLUSION CRITERIA - eCRF
Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1231) Hospital Militar Central Cirujano
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Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 16:45

			Crit EX14A01 erio n I D: (For Pfiz er u se o nly) :	
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090177e196ae2e95\Final\Final On: 01-Apr-2021 03:17 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form: INCLUSION/EXCLUSION CRITERIA - eCRF
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Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1231

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

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Subject Initials: ---

Generated By:

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(b) (4)

2.j Exclusion Number:

Date	Location	User	Value	Reason
Aug-15-2020 18:30:37 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 15	Initial Entry

2.j Criterion Description:

Date	Location	User	Value	Reason
Aug-15-2020 18:30:37 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Receipt of blood/pl asma products or i mmunoglobulin, fr om 60 days before study intervention administration or p lanned receipt thro ughout the study	Initial Entry

2.j Criterion met?

Date	Location	User	Value	Reason
Aug-15-2020 18:30:37 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

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

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Header Text: C4591001

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Site No: 1231

Subject No: 12311379

Generated By:

(b) (4)

Form: INCLUSION/EXCLUSION CRITERIA - eCRF
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Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 16:45

Date	Location	User	Value	Reason
Aug-15-2020 18:30:37 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: EX14A01	Initial Entry

090177e196ae2e95\Final\Final On: 01-Apr-2021 03:17 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

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Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1231

Site Name: (1231) Hospital Militar Central Cirujano
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2.k

Date	Location	User	Value	Reason
Aug-15-2020 18:30:37 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Excl 16 usio n N umb er: Crit Participatio erio n in other st n De udies involv scri ing study in ptio tervention n: within 28 d ays prior to study entry and/or durin g study part icipation Crit NO erio n m et?:	Initial Entry

090177e196ae2e95\Final\Final On: 01-Apr-2021 03:17 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

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Subject No: 12311379

Generated By:

(b) (4)

Form: INCLUSION/EXCLUSION CRITERIA - eCRF
Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 16:45

			Crit EX15A01 erio n ID : (Fo r Pfi zer use only):	
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090177e196ae2e95\Final\Final On: 01-Apr-2021 03:17 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form: INCLUSION/EXCLUSION CRITERIA - eCRF
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Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1231

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

Subject No: 12311379

Subject Initials: ---

Generated By:

Generated Time (GMT): 29-Mar-2021 16:45

(b) (4)

2.k Exclusion Number:

Date	Location	User	Value	Reason
Aug-15-2020 18:30:37 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 16	Initial Entry

2.k Criterion Description:

Date	Location	User	Value	Reason
Aug-15-2020 18:30:37 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Participation in other studies involving study intervention within 28 days prior to study entry and/or during study participation	Initial Entry

2.k Criterion met?

Date	Location	User	Value	Reason
Aug-15-2020 18:30:37 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

090177e196ae2e95\Final\Final On: 01-Apr-2021 03:17 (GMT)

Header Text: C4591001

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Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1231

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

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Subject Initials: ---

Generated By:

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(b) (4)

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

Date	Location	User	Value	Reason
Aug-15-2020 18:30:37 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: EX15A01	Initial Entry

2.l

Date	Location	User	Value	Reason
Aug-15-2020 18:30:37 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Excl 17 usion Num ber: Crite Previous p riou articipation Desc in other stu ripti dies involv on: ing study i ntervention containing lipid nanop articles Crite NO riou met? :	Initial Entry

090177e196ae2e95\Final\Final On: 01-Apr-2021 03:17 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

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Site No: 1231

Subject No: 12311379

Generated By:

(b) (4)

Form: INCLUSION/EXCLUSION CRITERIA - eCRF
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Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 16:45

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Header Text: C4591001

Visit: V1_DAY1_VAX1_L

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Site No: 1231

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

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(b) (4)

2.1 Exclusion Number:

Date	Location	User	Value	Reason
Aug-15-2020 18:30:37 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 17	Initial Entry

2.1 Criterion Description:

Date	Location	User	Value	Reason
Aug-15-2020 18:30:37 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Previous participation in other studies involving study intervention containing lipid nanoparticles	Initial Entry

2.1 Criterion met?

Date	Location	User	Value	Reason
Aug-15-2020 18:30:37 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2.1 Criterion ID: (For Pfizer use only)

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Subject No: 12311379

Subject Initials: ---

Generated By:

Generated Time (GMT): 29-Mar-2021 16:45

(b) (4)

Date	Location	User	Value	Reason
Aug-15-2020 18:30:37 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: EX16A01	Initial Entry

2.m

Date	Location	User	Value	Reason
Aug-15-2020 18:30:37 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Exc 22 lusi on Nu mb er:	Initial Entry

090177e196ae2e95\Final\Final On: 01-Apr-2021 03:17 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 30-Jul-2020 21:27

Site No: 1231

Subject No: 12311379

Generated By:

(b) (4)

Form: INCLUSION/EXCLUSION CRITERIA - eCRF
Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 16:45

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Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form: INCLUSION/EXCLUSION CRITERIA - eCRF
Audit Trail History

Form Version: 30-Jul-2020 21:27

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1231

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

Subject No: 12311379

Subject Initials: ---

Generated By:

Generated Time (GMT): 29-Mar-2021 16:45

(b) (4)

2.m Exclusion Number:

Date	Location	User	Value	Reason
Aug-15-2020 18:30:37 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 22	Initial Entry

2.m Criterion Description:

Date	Location	User	Value	Reason
Aug-15-2020 18:30:37 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Investigator site staff or Pfizer employees directly involved in the conduct of the study, site staff otherwise supervised by the investigator, and their respective family members	Initial Entry

2.m Criterion met?

Date	Location	User	Value	Reason
Aug-15-2020 18:30:37 (UTC-03:00)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

090177e196ae2e95\Final\Final On: 01-Apr-2021 03:17 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form: INCLUSION/EXCLUSION CRITERIA - eCRF
Audit Trail History

Form Version: 30-Jul-2020 21:27

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1231

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

Subject No: 12311379

Subject Initials: ---

Generated By:

Generated Time (GMT): 29-Mar-2021 16:45

(b) (4)

City of Buenos Aires				
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2.m Criterion ID: (For Pfizer use only)

Date	Location	User	Value	Reason
Aug-15-2020 18:30:37 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: EX21A01	Initial Entry

090177e196ae2e95\Final\Final On: 01-Apr-2021 03:17 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form: DISPOSITION - SCREENING - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1231

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

Subject No: 12311379

Subject Initials: ---

Generated By:

Generated Time (GMT): 29-Mar-2021 16:45

(b) (4)

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1. Date of Completion/Discontinuation/Death

Date	Location	User	Value	Reason
Aug-15-2020 18:30:47 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Aug/15/2020	Initial Entry

2. Phase of Disposition:

Date	Location	User	Value	Reason
Aug-15-2020 18:30:47 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SCREENING	Initial Entry

3. Status:

Date	Location	User	Value	Reason
Aug-15-2020 18:30:47 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: COMPLETED	Initial Entry

090177e196ae2e95\Final\Final On: 01-Apr-2021 03:17 (GMT)

Header Text: C4591001**Visit:** V1_DAY1_VAX1_L**Form Version:** 22-Apr-2020 21:03**Site No:** 1231**Subject No:** 12311379**Generated By:**

(b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History**Form Status:** Data Complete, Locked, Frozen, Verified**Site Name:** (1231) Hospital Militar Central Cirujano Mayor Dr. Cosme Argerich**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 16:45[Back to Form](#)*I.a*

Date	Location	User	Value	Reason
Aug-15-2020 21:07:36 (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: Jan/1/200 5 Ongoing: YES	Initial Entry

I.a Line/MH Number:

Date	Location	User	Value	Reason
Aug-15-2020 21:07:36 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 1	Initial Entry

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

Date	Location	User	Value	Reason
Aug-15-2020 21:07:36 (UTC-03:00) City	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED] [REDACTED]	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, Locked, Frozen, Verified

Site No: 1231

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

Subject No: 12311379

Subject Initials: ---

Generated By:

Generated Time (GMT): 29-Mar-2021 16:45

(b) (4)

of Buenos Aires		(b) (4), (b) (6)		
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1.a Start Date:

Date	Location	User	Value	Reason
Aug-15-2020 21:07:36 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Jan/1/2005	Initial Entry

1.a Ongoing:

Date	Location	User	Value	Reason
Aug-15-2020 21:07:36 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

1.b

Date	Location	User	Value	Reason
Jan-17-2021 18:17:28 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Nu 2 mber: Medical Hist PSA ele ory Term: vation Start Date: Aug/12/ 2018 Ongoing: YES	Initial Entry

090177e196ae2e95\Final\Final On: 01-Apr-2021 03:17 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1231

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

Subject No: 12311379

Subject Initials: ---

Generated By:

Generated Time (GMT): 29-Mar-2021 16:45

(b) (4)

1.b Line/MH Number:

Date	Location	User	Value	Reason
Jan-17-2021 18:17:28 (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
Jan-17-2021 18:17:28 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: PSA elevation	Initial Entry

1.b Start Date:

Date	Location	User	Value	Reason
Jan-17-2021 18:17:28 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Aug/12/2018	Initial Entry

1.b Ongoing:

Date	Location	User	Value	Reason
Jan-17-2021 18:17:28 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

090177e196ae2e95\Final\Final On: 01-Apr-2021 03:17 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1231

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

Subject No: 12311379

Subject Initials: ---

Generated By:

Generated Time (GMT): 29-Mar-2021 16:45

(b) (4)

of Buenos Aires				
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Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form: VITAL SIGNS - BASELINE - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:28

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1231

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

Subject No: 12311379

Subject Initials: ---

Generated By:

Generated Time (GMT): 29-Mar-2021 16:45

(b) (4)

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1. Date:

Date	Location	User	Value	Reason
Aug-15-2020 21:09:22 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Aug/15/2020	Initial Entry

2. Weight:

Date	Location	User	Value	Reason
Aug-15-2020 21:09:22 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 91.6	Initial Entry

3. Unit:

Date	Location	User	Value	Reason
Aug-15-2020 21:09:22 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: kg	Initial Entry

4. Height:

Date	Location	User	Value	Reason
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090177e196ae2e95\Final\Final On: 01-Apr-2021 03:17 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form: VITAL SIGNS - BASELINE - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:28

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1231

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

Subject No: 12311379

Subject Initials: ---

Generated By:

Generated Time (GMT): 29-Mar-2021 16:45

(b) (4)

Aug-15-2020 21:09:22 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 174.0	Initial Entry
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5. Unit:

Date	Location	User	Value	Reason
Aug-15-2020 21:09:22 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: cm	Initial Entry

6. Body Mass Index:

Date	Location	User	Value	Reason
Aug-15-2020 21:09:22 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 30.3	Initial Entry

7.a

Date	Location	User	Value	Reason
Aug-15-2020 21:09:22 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Record Identifier: 1 Temperature: 37.0	Initial Entry

090177e196ae2e95\Final\Final On: 01-Apr-2021 03:17 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form: VITAL SIGNS - BASELINE - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:28

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1231

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

Subject No: 12311379

Subject Initials: ---

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Generated Time (GMT): 29-Mar-2021 16:45

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7.a Record Identifier:

Date	Location	User	Value	Reason
Aug-15-2020 21:09:22 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 1	Initial Entry

7.a Temperature:

Date	Location	User	Value	Reason
Aug-15-2020 21:09:22 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 37.0	Initial Entry

7.a Unit:

Date	Location	User	Value	Reason
Aug-15-2020 21:09:22 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: C	Initial Entry

090177e196ae2e95\Final\Final On: 01-Apr-2021 03:17 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form: VITAL SIGNS - BASELINE - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:28

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1231

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

Subject No: 12311379

Subject Initials: ---

Generated By:

Generated Time (GMT): 29-Mar-2021 16:45

(b) (4)

7.a Temperature Location:

Date	Location	User	Value	Reason
Aug-15-2020 21:09:22 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6) [Redacted] [Redacted] [Redacted]	Data Entry: ORAL CAVITY	Initial Entry

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1231

Subject No: 12311379

Generated By:

(b) (4)

Form: RANDOMIZATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 16:45

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1. Randomization Date :

Date	Location	User	Value	Reason
Aug-15-2020 21:09:41 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Aug/15/2020	Initial Entry

2. Randomization Number:

Date	Location	User	Value	Reason
Aug-15-2020 21:09:41 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 229565	Initial Entry

090177e196ae2e95\Final\Final On: 01-Apr-2021 03:17 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1231

Subject No: 12311379

Generated By:

(b) (4)

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

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 16:45

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1. Data Origin

Date	Location	User	Value	Reason
Aug-15-2020 21:09:49 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Aug-15-2020 21:09:49 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SERUM	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Aug-16-2020 11:34:32 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Aug-15-2020 21:09:49 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes

090177e196ae2e95\Final\Final On: 01-Apr-2021 03:17 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1231

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

Subject No: 12311379

Subject Initials: ---

Generated By:

Generated Time (GMT): 29-Mar-2021 16:45

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				are entered. Please review and correct as appropriate.
Aug-15-2020 21:09:49 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Date of Collection: Aug/15/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Aug-16-2020 11:34:32 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample I BLCVN D: V	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Aug-16-2020 11:34:32 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BLCVNV	Initial Entry

5.b

Date	Location	User	Value	Reason
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090177e196ae2e95\Final\Final On: 01-Apr-2021 03:17 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1231

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

Subject No: 12311379

Subject Initials: ---

Generated By:

Generated Time (GMT): 29-Mar-2021 16:45

(b) (4)

Aug-16-2020 11:34:40 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID BLCVN : T	Initial Entry
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5.b Sample ID

Date	Location	User	Value	Reason
Aug-16-2020 11:34:40 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BLCVNT	Initial Entry

5.c

Date	Location	User	Value	Reason
Aug-16-2020 12:59:12 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID BM83X : C	Initial Entry

5.c Sample ID

Date	Location	User	Value	Reason
Aug-16-2020 12:59:12 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BM83XC	Initial Entry

5.d

090177e196ae2e95\Final\Final On: 01-Apr-2021 03:17 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1231

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

Subject No: 12311379

Subject Initials: ---

Generated By:

Generated Time (GMT): 29-Mar-2021 16:45

(b) (4)

Date	Location	User	Value	Reason
Aug-16-2020 12:59:21 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID BM83X : B	Initial Entry

5.d Sample ID

Date	Location	User	Value	Reason
Aug-16-2020 12:59:21 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BM83XB	Initial Entry

5.e

Date	Location	User	Value	Reason
Aug-16-2020 12:59:35 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID BM840 : B	Initial Entry

5.e Sample ID

Date	Location	User	Value	Reason
Aug-16-2020 12:59:35 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BM840B	Initial Entry

090177e196ae2e95\Final\Final On: 01-Apr-2021 03:17 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1231

Subject No: 12311379

Generated By:

(b) (4)

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

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 16:45

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1. Data Origin

Date	Location	User	Value	Reason
Aug-15-2020 21:10:05 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Aug-15-2020 21:10:05 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: NASAL_SWAB	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Aug-16-2020 12:58:52 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 4: Closed	Close Auto Query
Aug-16-2020 12:58:41 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 4: Opened	There are more than 1 barcode present for sample

090177e196ae2e95\Final\Final On: 01-Apr-2021 03:17 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1231

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

Subject No: 12311379

Subject Initials: ---

Generated By:

Generated Time (GMT): 29-Mar-2021 16:45

(b) (4)

				collection. Please review and correct as appropriate.
Aug-16-2020 12:58:41 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 3: Closed	Close Auto Query
Aug-16-2020 12:58:26 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 3: Opened	There are more than 1 barcode present for sample collection. Please review and correct as appropriate.
Aug-16-2020 12:58:26 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Closed	Close Auto Query
Aug-16-2020 12:57:25 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Opened	There are more than 1 barcode present for sample collection. Please review and correct as appropriate.

090177e196ae2e95\Final\Final On: 01-Apr-2021 03:17 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1231

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

Subject No: 12311379

Subject Initials: ---

Generated By:

Generated Time (GMT): 29-Mar-2021 16:45

(b) (4)

Aug-16-2020 10:13:43 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Aug-15-2020 21:10:05 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Aug-15-2020 21:10:05 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6) [Redacted]	Data Entry: YES Date of Collection: Aug/15/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Aug-16-2020 10:13:43 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6) [Redacted]	Data Entry: Sample I BM84 D: 49	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
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090177e196ae2e95\Final\Final On: 01-Apr-2021 03:17 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1231

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

Subject No: 12311379

Subject Initials: ---

Generated By:

Generated Time (GMT): 29-Mar-2021 16:45

(b) (4)

Aug-16-2020 10:13:43 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6) [Redacted]	Data Entry: BM8449	Initial Entry
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5.b

Date	Location	User	Value	Reason
Aug-16-2020 12:58:26 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6) [Redacted]	Data Entry: Sample I BM83X D: C	Transcription Error (DELETED)
Aug-16-2020 12:57:25 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6) [Redacted]	Data Entry: Sample I BM83X D: C	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Aug-16-2020 12:58:26 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6) [Redacted]	Data Entry: BM83XC	Transcription Error (DELETED)
Aug-16-2020 12:57:25 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6) [Redacted]	Data Entry: BM83XC	Initial Entry

090177e196ae2e95\Final\Final On: 01-Apr-2021 03:17 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1231

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

Subject No: 12311379

Subject Initials: ---

Generated By:

Generated Time (GMT): 29-Mar-2021 16:45

(b) (4)

5.c

Date	Location	User	Value	Reason
Aug-16-2020 12:58:41 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample I BM83X D: B	Transcription Error (DELETED)
Aug-16-2020 12:57:31 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample I BM83X D: B	Initial Entry

5.c Sample ID

Date	Location	User	Value	Reason
Aug-16-2020 12:58:41 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BM83XB	Transcription Error (DELETED)
Aug-16-2020 12:57:31 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BM83XB	Initial Entry

5.d

Date	Location	User	Value	Reason
Aug-16-2020 12:58:52	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample I BM840	Transcription Error

090177e196ae2e95\Final\Final On: 01-Apr-2021 03:17 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1231

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

Subject No: 12311379

Subject Initials: ---

Generated By:

Generated Time (GMT): 29-Mar-2021 16:45

(b) (4)

(UTC-03:00) City of Buenos Aires		(b) (4), (b) (6)	D: B	(DELETED)
Aug-16-2020 12:57:39 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample I BM840 D: B	Initial Entry

5.d Sample ID

Date	Location	User	Value	Reason
Aug-16-2020 12:58:52 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BM840B	Transcription Error (DELETED)
Aug-16-2020 12:57:39 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BM840B	Initial Entry

090177e196ae2e95\Final\Final On: 01-Apr-2021 03:17 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:04

Site No: 1231

Subject No: 12311379

Generated By:

(b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 16:45

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1. Was there a temporary delay of vaccination?

Date	Location	User	Value	Reason
Aug-15-2020 21:10:36 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2. Treatment Name

Date	Location	User	Value	Reason
Aug-15-2020 21:10:36 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: BLINDED THERAPY	Initial Entry

3. Formulation:

Date	Location	User	Value	Reason
Aug-15-2020 21:10:36 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: INJECTION	Initial Entry

4. Dose Date Time:

Date	Location	User	Value	Reason
Aug-15-2020	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Initial Entry

090177e196ae2e95\Final\Final On: 01-Apr-2021 03:17 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:04

Site No: 1231

Subject No: 12311379

Generated By:

(b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 16:45

21:10:36
(UTC-03:00) City
of Buenos Aires

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

Aug/15/2020 15:35

5. Anatomical Location:

Date	Location	User	Value	Reason
Aug-15-2020 21:10:36 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: DELTOID MUSCLE	Initial Entry

6. Body Side:

Date	Location	User	Value	Reason
Aug-15-2020 21:10:36 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: LEFT	Initial Entry

7. Route:

Date	Location	User	Value	Reason
Aug-15-2020 21:10:36 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: INTRAMUSCULAR	Initial Entry

10. Timeframe Subject Was Observed

Date	Location	User	Value	Reason
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090177e196ae2e95\Final\Final On: 01-Apr-2021 03:17 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form: VACCINATION - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1231

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

Subject No: 12311379

Subject Initials: ---

Generated By:

Generated Time (GMT): 29-Mar-2021 16:45

(b) (4)

Aug-15-2020 21:10:36 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: THE PROTOCOL SPE CIFIED OBSERVATIO N PERIOD	Initial Entry
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11. Was the subject observed for at least the protocol specified observation period after investigational product administration?

Date	Location	User	Value	Reason
Aug-15-2020 21:10:36 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6) [Redacted] [Redacted] [Redacted]	Data Entry: YES	Initial Entry

090177e196ae2e95\Final\Final On: 01-Apr-2021 03:17 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form: REACTOGENICITY DIARY - eCRF Audit Trail History

Form Version: 06-Jul-2020 21:53

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1231

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

Subject No: 12311379

Subject Initials: ---

Generated By:

Generated Time (GMT): 29-Mar-2021 16:45

(b) (4)

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1. Select appropriate response - Reactogenicity diary collection

Date	Location	User	Value	Reason
Aug-15-2020 21:10:43 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6) [Redacted] [Redacted] [Redacted]	Data Entry: YES - REACTOGENI CITY E-DIARY COL LECTED FOR THIS SUBJECT	Initial Entry

090177e196ae2e95\Final\Final On: 01-Apr-2021 03:17 (GMT)

Header Text: C4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:02

Site No: 1231

Subject No: 12311379

Generated By:

(b) (4)

Form: DATE OF VISIT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 16:45

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1. Date of Visit

Date	Location	User	Value	Reason
Sep-07-2020 19:14:46 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	Martina Davalli (b) (4)	Data Entry: Sep/7/2020	Initial Entry

090177e196ae2e95\Final\Final On: 01-Apr-2021 03:17 (GMT)

Header Text: C4591001

Visit: V2_VAX2_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1231

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

Subject No: 12311379

Subject Initials: ---

Generated By:

Generated Time (GMT): 29-Mar-2021 16:45

(b) (4)

[Back to Form](#)

1. Were medications to treat fever/pain given on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Sep-07-2020 19:15:03 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	Martina Davalli (b) (4)	Data Entry: NO	Initial Entry

2.a

Date	Location	User	Value	Reason
Sep-07-2020 19:15:03 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	Martina Davalli (b) (4)	Data Entry: Symptom:: F E V E R Were fever or s N ystemic sympto O ms present on t he last day the Subject Diary was completed? :	Initial Entry

2.a Symptom:

090177e196ae2e95\Final\Final On: 01-Apr-2021 03:17 (GMT)

Date	Location	User	Value	Reason
Sep-07-2020 19:15:03 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	Martina Davalli (b) (4)	Data Entry: FEVER	Initial Entry

2.a Were fever or systemic symptoms present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Sep-07-2020 19:15:03 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	Martina Davalli (b) (4)	Data Entry: NO	Initial Entry

2.b

Date	Location	User	Value	Reason
Sep-07-2020 19:15:03 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	Martina Davalli (b) (4)	<p>Data Entry:</p> <p>Symptom:: FA TI G U E</p> <p>Were fever or s N ystemic sympto O ms present on t he last day the Subject Diary was completed ?:</p>	Initial Entry

2.b Symptom:				
Date	Location	User	Value	Reason
Sep-07-2020 19:15:03 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	Martina Davalli (b) (4)	Data Entry: FATIGUE	Initial Entry
2.b Were fever or systemic symptoms present on the last day the Subject Diary was completed?				
Date	Location	User	Value	Reason
Sep-07-2020 19:15:03 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	Martina Davalli (b) (4)	Data Entry: NO	Initial Entry
2.c				
Date	Location	User	Value	Reason
Sep-07-2020 19:15:03 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	Martina Davalli (b) (4)	Data Entry: Symptom:: HE A D AC HE Were fever or s N ystemic sympt O oms present on the last day the Subject Diary was completed ?:	Initial Entry

2.c Symptom:				
Date	Location	User	Value	Reason
Sep-07-2020 19:15:03 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	Martina Davalli (b) (4)	Data Entry: HEADACHE	Initial Entry
2.c Were fever or systemic symptoms present on the last day the Subject Diary was completed?				
Date	Location	User	Value	Reason
Sep-07-2020 19:15:03 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	Martina Davalli (b) (4)	Data Entry: NO	Initial Entry
2.d				
Date	Location	User	Value	Reason
Sep-07-2020 19:15:03 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	Martina Davalli (b) (4)	Data Entry: Symptom:: C HI L L S Were fever or s N ystemic sympto O ms present on t he last day the Subject Diary was completed? :	Initial Entry

2.d Symptom:				
Date	Location	User	Value	Reason
Sep-07-2020 19:15:03 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	Martina Davalli (b) (4)	Data Entry: CHILLS	Initial Entry
2.d Were fever or systemic symptoms present on the last day the Subject Diary was completed?				
Date	Location	User	Value	Reason
Sep-07-2020 19:15:03 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	Martina Davalli (b) (4)	Data Entry: NO	Initial Entry
2.e				
Date	Location	User	Value	Reason
Sep-07-2020 19:15:03 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	Martina Davalli (b) (4)	Data Entry: Symptom:: VO MI TI NG Were fever or systemic symp toms present o n the last day t he Subject Dia ry was complet ed?: NO	Initial Entry

2.e Symptom:				
Date	Location	User	Value	Reason
Sep-07-2020 19:15:03 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	Martina Davalli (b) (4)	Data Entry: VOMITING	Initial Entry
2.e Were fever or systemic symptoms present on the last day the Subject Diary was completed?				
Date	Location	User	Value	Reason
Sep-07-2020 19:15:03 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	Martina Davalli (b) (4)	Data Entry: NO	Initial Entry
2.f				
Date	Location	User	Value	Reason
Sep-07-2020 19:15:03 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	Martina Davalli (b) (4)	Data Entry: Symptom:: DI A RR HE A Were fever or s N ystemic sympt O oms present on the last day the Subject Diary was completed ?:	Initial Entry

2.f Symptom:				
Date	Location	User	Value	Reason
Sep-07-2020 19:15:03 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	Martina Davalli (b) (4)	Data Entry: DIARRHEA	Initial Entry
2.f Were fever or systemic symptoms present on the last day the Subject Diary was completed?				
Date	Location	User	Value	Reason
Sep-07-2020 19:15:03 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	Martina Davalli (b) (4)	Data Entry: NO	Initial Entry
2.g				
Date	Location	User	Value	Reason
Sep-07-2020 19:15:03 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	Martina Davalli (b) (4)	Data Entry: Symptom:: NEW OR W ORSE NED MUS CLE P AIN Were fever or systemic symptoms p resent on th e last day th e Subject Di ary was co mpleted?: NO	Initial Entry

2.g Symptom:				
Date	Location	User	Value	Reason
Sep-07-2020 19:15:03 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	Martina Davalli (b) (4)	Data Entry: NEW OR WORSE NED MUSCLE PAIN	Initial Entry
2.g Were fever or systemic symptoms present on the last day the Subject Diary was completed?				
Date	Location	User	Value	Reason
Sep-07-2020 19:15:03 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	Martina Davalli (b) (4)	Data Entry: NO	Initial Entry
2.h				
Date	Location	User	Value	Reason
Sep-07-2020 19:15:03 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	Martina Davalli (b) (4)	Data Entry: Symptom:: NEW OR W ORSE NED JOIN T PAI N Were fever NO or systemic symptoms p resent on th e last day th e Subject Di ary was com pleted?:	Initial Entry

2.h Symptom:

Date	Location	User	Value	Reason
Sep-07-2020 19:15:03 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	Martina Davalli (b) (4)	Data Entry: NEW OR WORSEN ED JOINT PAIN	Initial Entry

2.h Were fever or systemic symptoms present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Sep-07-2020 19:15:03 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	Martina Davalli (b) (4)	Data Entry: NO	Initial Entry

3. Injection Site Location:

Date	Location	User	Value	Reason
Sep-07-2020 19:15:03 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: DELTOID MUSCLE	Initial Entry

4. Injection Site Body Side:

Date	Location	User	Value	Reason
Sep-07-2020 19:15:03 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	Martina Davalli (b) (4)	Data Entry: LEFT	Initial Entry

5.a

Date	Location	User	Value	Reason
Sep-07-2020 19:15:03 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	Martina Davalli (b) (4)	Data Entry: Injection Site RE Reaction::: D N ES	Initial Entry

			Were injection site reactions present on the last day the Subject Diary was completed?:	S N O
5.a Injection Site Reaction:				
Date	Location	User	Value	Reason
Sep-07-2020 19:15:03 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	Martina Davalli (b) (4)	Data Entry: REDNESS	Initial Entry
5.a Were injection site reactions present on the last day the Subject Diary was completed?				
Date	Location	User	Value	Reason
Sep-07-2020 19:15:03 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	Martina Davalli (b) (4)	Data Entry: NO	Initial Entry
5.b				
Date	Location	User	Value	Reason
Sep-07-2020 19:15:03 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	Martina Davalli (b) (4)	Data Entry: Injection Site Reaction:: SW EL LI NG Were injection site reactions present on the last day the Subject Diary was completed?:	Initial Entry

5.b Injection Site Reaction:

Date	Location	User	Value	Reason
Sep-07-2020 19:15:03 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	Martina Davalli (b) (4)	Data Entry: SWELLING	Initial Entry

5.b Were injection site reactions present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Sep-07-2020 19:15:03 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	Martina Davalli (b) (4)	Data Entry: NO	Initial Entry

5.c

Date	Location	User	Value	Reason
Sep-07-2020 19:15:03 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	Martina Davalli (b) (4)	Data Entry: Injection Site PAI Reaction:: N A T IN JEC TIO N SI TE Were injectio NO n site reactio ns present on the last day t he Subject Di ary was com pleted?:	Initial Entry

5.c Injection Site Reaction:

Date	Location	User	Value	Reason
Sep-07-2020 19:15:03 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	Martina Davalli (b) (4)	Data Entry: PAIN AT INJECTIO N SITE	Initial Entry

5.c Were injection site reactions present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Sep-07-2020 19:15:03 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	Martina Davalli (b) (4)	Data Entry: NO	Initial Entry

Header Text: C4591001

Visit: V2_VAX2_L

Form Version: 21-Aug-2020 02:51

Site No: 1231

Subject No: 12311379

Generated By:

(b) (4)

Form: VITAL SIGNS - TEMP - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 16:45

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1. Date:

Date	Location	User	Value	Reason
Sep-07-2020 19:15:15 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	Martina Davalli (b) (4)	Data Entry: Sep/7/2020	Initial Entry

2.a

Date	Location	User	Value	Reason
Sep-07-2020 19:15:15 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	Martina Davalli (b) (4)	Data Entry: Record Identifier:: Temperature: Temperature Core Unit: Temperature Oral Core Location: Y	Initial Entry

2.a Record Identifier:

Date	Location	User	Value	Reason
Sep-07-2020 19:15:15 (UTC-03:00) City	ACV0PFEINFP6000	Martina Davalli (b) (4)	Data Entry: 1	Initial Entry

090177e196ae2e95\Final\Final On: 01-Apr-2021 03:17 (GMT)

Header Text: C4591001

Visit: V2_VAX2_L

Form: VITAL SIGNS - TEMP - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:51

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1231

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

Subject No: 12311379

Subject Initials: ---

Generated By:

Generated Time (GMT): 29-Mar-2021 16:45

(b) (4)

of Buenos Aires				
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2.a Temperature:

Date	Location	User	Value	Reason
Sep-07-2020 19:15:15 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	Martina Davalli (b) (4)	Data Entry: 36.8	Initial Entry

2.a Unit:

Date	Location	User	Value	Reason
Sep-07-2020 19:15:15 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	Martina Davalli (b) (4)	Data Entry: C	Initial Entry

2.a Temperature Location:

Date	Location	User	Value	Reason
Sep-07-2020 19:15:15 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	Martina Davalli (b) (4)	Data Entry: ORAL CAVITY	Initial Entry

090177e196ae2e95\Final\Final On: 01-Apr-2021 03:17 (GMT)

Header Text: C4591001

Visit: V2_VAX2_L

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1231

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

Subject No: 12311379

Subject Initials: ---

Generated By:

Generated Time (GMT): 29-Mar-2021 16:45

(b) (4)

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1. Data Origin

Date	Location	User	Value	Reason
Sep-07-2020 19:15:22 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Sep-07-2020 19:15:22 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: NASAL_SWAB	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Sep-08-2020 09:42:54 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Sep-08-2020 06:07:31 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6) [Redacted]	Query 1: Opened	'Sample Collected?' is Yes, however no barcodes

090177e196ae2e95\Final\Final On: 01-Apr-2021 03:17 (GMT)

Header Text: C4591001

Visit: V2_VAX2_L

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1231

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

Subject No: 12311379

Subject Initials: ---

Generated By:

Generated Time (GMT): 29-Mar-2021 16:45

(b) (4)

				are entered. Please review and correct as appropriate.
Sep-07-2020 19:15:22 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Sep-07-2020 19:15:22 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	Martina Davalli (b) (4)	Data Entry: YES Date of Collection : Sep/7/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Sep-08-2020 09:42:54 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample I BP1TM D: 8	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
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090177e196ae2e95\Final\Final On: 01-Apr-2021 03:17 (GMT)

Header Text: C4591001

Visit: V2_VAX2_L

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1231

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

Subject No: 12311379

Subject Initials: ---

Generated By:

Generated Time (GMT): 29-Mar-2021 16:45

(b) (4)

Sep-08-2020 09:42:54 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6) [Redacted] [Redacted]	Data Entry: BP1TM8	Initial Entry
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Header Text: C4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:04

Site No: 1231

Subject No: 12311379

Generated By:

(b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 16:45

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1. Was there a temporary delay of vaccination?

Date	Location	User	Value	Reason
Sep-07-2020 19:15:37 (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-07-2020 19:15:37 (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-07-2020 19:15:37 (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-07-2020	ACV0PFEINFP6000	Martina	Data Entry:	Initial Entry

090177e196ae2e95\Final\Final On: 01-Apr-2021 03:17 (GMT)

Header Text: C4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:04

Site No: 1231

Subject No: 12311379

Generated By:

(b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 16:45

19:15:37
(UTC-03:00) City
of Buenos Aires

Davalli
(b) (4)

Sep/7/2020 18:40

5. Anatomical Location:

Date	Location	User	Value	Reason
Sep-07-2020 19:15:37 (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-07-2020 19:15:37 (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-07-2020 19:15:37 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: INTRAMUSCULAR	Initial Entry

10. Timeframe Subject Was Observed

Date	Location	User	Value	Reason
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090177e196ae2e95\Final\Final On: 01-Apr-2021 03:17 (GMT)

Header Text: C4591001

Visit: V2_VAX2_L

Form: VACCINATION - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1231

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

Subject No: 12311379

Subject Initials: ---

Generated By:

Generated Time (GMT): 29-Mar-2021 16:45

(b) (4)

Sep-07-2020 19:15:37 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: THE PROTOCOL SPECIFIED OBSERVATION PERIOD	Initial Entry
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11. Was the subject observed for at least the protocol specified observation period after investigational product administration?

Date	Location	User	Value	Reason
Sep-07-2020 19:15:37 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	Martina Davalli (b) (4)	Data Entry: YES	Initial Entry

090177e196ae2e95\Final\Final On: 01-Apr-2021 03:17 (GMT)

Header Text: C4591001

Visit: V3_MONTH1_POSTVAX2_L

Form: DATE OF VISIT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1231

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

Subject No: 12311379

Subject Initials: ---

Generated By:

Generated Time (GMT): 29-Mar-2021 16:45

(b) (4)

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1. Date of Visit

Date	Location	User	Value	Reason
Oct-07-2020 13:22:24 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6) [Redacted] [Redacted]	Data Entry: Oct/7/2020	Initial Entry

090177e196ae2e95\Final\Final On: 01-Apr-2021 03:17 (GMT)

Header Text: C4591001**Visit:** V3_MONTH1_POSTVAX2_L **Form:** VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History**Form Version:** 30-Jul-2020 21:30**Form Status:** Data Complete, Locked, Frozen, Verified**Site No:** 1231**Site Name:** (1231) Hospital Militar Central Cirujano Mayor Dr. Cosme Argerich**Subject No:** 12311379**Subject Initials:** ---**Generated By:****Generated Time (GMT):** 29-Mar-2021 16:45

(b) (4)

[Back to Form](#)**1. Were medications to treat fever/pain given on the last day the Subject Diary was completed?**

Date	Location	User	Value	Reason
Oct-07-2020 13:22:44 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED] [REDACTED]	Data Entry: NO	Initial Entry

2.a

Date	Location	User	Value	Reason
Oct-07-2020 13:22:44 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED] [REDACTED]	Data Entry: Symptom:: F E V E R Were fever or sy N stemic symptom O s present on the last day the Subj ect Diary was co mpleted?:	Initial Entry

2.a Symptom:

Date	Location	User	Value	Reason
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Oct-07-2020 13:22:44 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6) [Redacted] [Redacted]	Data Entry: FEVER	Initial Entry
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2.a Were fever or systemic symptoms present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Oct-07-2020 13:22:44 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6) [Redacted] [Redacted]	Data Entry: NO	Initial Entry

2.b

Date	Location	User	Value	Reason
Oct-07-2020 13:22:44 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6) [Redacted] [Redacted]	Data Entry: Symptom:: F A T I G U E Were fever or sy N stemic symptom O s present on the last day the Sub ject Diary was c ompleted?:	Initial Entry

2.b Symptom:				
Date	Location	User	Value	Reason
Oct-07-2020 13:22:44 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED] [REDACTED]	Data Entry: FATIGUE	Initial Entry
2.b Were fever or systemic symptoms present on the last day the Subject Diary was completed?				
Date	Location	User	Value	Reason
Oct-07-2020 13:22:44 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED] [REDACTED]	Data Entry: NO	Initial Entry
2.c				
Date	Location	User	Value	Reason
Oct-07-2020 13:22:44 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED] [REDACTED]	Data Entry: Symptom:: HE AD AC HE Were fever or s NO ystemic sympto ms present on t he last day the Subject Diary was completed? :	Initial Entry

2.c Symptom:				
Date	Location	User	Value	Reason
Oct-07-2020 13:22:44 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED] [REDACTED]	Data Entry: HEADACHE	Initial Entry
2.c Were fever or systemic symptoms present on the last day the Subject Diary was completed?				
Date	Location	User	Value	Reason
Oct-07-2020 13:22:44 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED] [REDACTED]	Data Entry: NO	Initial Entry
2.d				
Date	Location	User	Value	Reason
Oct-07-2020 13:22:44 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED] [REDACTED]	Data Entry: Symptom:: C HI L LS Were fever or sy N stemic symptom O s present on the last day the Subj ect Diary was co mpleted?:	Initial Entry

2.d Symptom:				
Date	Location	User	Value	Reason
Oct-07-2020 13:22:44 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED] [REDACTED]	Data Entry: CHILLS	Initial Entry
2.d Were fever or systemic symptoms present on the last day the Subject Diary was completed?				
Date	Location	User	Value	Reason
Oct-07-2020 13:22:44 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED] [REDACTED]	Data Entry: NO	Initial Entry
2.e				
Date	Location	User	Value	Reason
Oct-07-2020 13:22:44 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED] [REDACTED]	Data Entry: Symptom:: VO MI TI NG Were fever or s NO ystemic sympto ms present on t he last day the Subject Diary was completed? :	Initial Entry

2.e Symptom:				
Date	Location	User	Value	Reason
Oct-07-2020 13:22:44 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED] [REDACTED]	Data Entry: VOMITING	Initial Entry
2.e Were fever or systemic symptoms present on the last day the Subject Diary was completed?				
Date	Location	User	Value	Reason
Oct-07-2020 13:22:44 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED] [REDACTED]	Data Entry: NO	Initial Entry
2.f				
Date	Location	User	Value	Reason
Oct-07-2020 13:22:44 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED] [REDACTED]	Data Entry: Symptom:: DI AR RH EA Were fever or s N ystemic sympto O ms present on t he last day the Subject Diary w as completed?:	Initial Entry

2.f Symptom:				
Date	Location	User	Value	Reason
Oct-07-2020 13:22:44 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED] [REDACTED]	Data Entry: DIARRHEA	Initial Entry
2.f Were fever or systemic symptoms present on the last day the Subject Diary was completed?				
Date	Location	User	Value	Reason
Oct-07-2020 13:22:44 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED] [REDACTED]	Data Entry: NO	Initial Entry
2.g				
Date	Location	User	Value	Reason
Oct-07-2020 13:22:44 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED] [REDACTED]	Data Entry: Symptom:: NEW OR W ORSE NED MUS CLE P AIN Were fever o NO r systemic sy mptoms pres ent on the la st day the Su bject Diary was complet ed?:	Initial Entry

2.g Symptom:				
Date	Location	User	Value	Reason
Oct-07-2020 13:22:44 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED] [REDACTED]	Data Entry: NEW OR WORSE NED JOINT PAIN	Initial Entry
2.g Were fever or systemic symptoms present on the last day the Subject Diary was completed?				
Date	Location	User	Value	Reason
Oct-07-2020 13:22:44 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED] [REDACTED]	Data Entry: NO	Initial Entry
2.h				
Date	Location	User	Value	Reason
Oct-07-2020 13:22:44 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED] [REDACTED]	Data Entry: Symptom:: NEW OR W ORSE NED J OINT PAIN Were fever o r systemic sy mptoms pres ent on the la st day the Su bject Diary was complet ed?: NO	Initial Entry

2.h Symptom:

Date	Location	User	Value	Reason
Oct-07-2020 13:22:44 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED] [REDACTED]	Data Entry: NEW OR WORSE N ED JOINT PAIN	Initial Entry

2.h Were fever or systemic symptoms present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Oct-07-2020 13:22:44 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED] [REDACTED]	Data Entry: NO	Initial Entry

3. Injection Site Location:

Date	Location	User	Value	Reason
Oct-07-2020 13:22:44 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: DELTOID MUSCLE	Initial Entry

4. Injection Site Body Side:

Date	Location	User	Value	Reason
Oct-07-2020 13:22:44 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED] [REDACTED]	Data Entry: LEFT	Initial Entry

5.a

Date	Location	User	Value	Reason
Oct-07-2020 13:22:44 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED] [REDACTED]	Data Entry: Injection Site R RE action:: D NE SS	Initial Entry

			Were injection site reactions present on the last day the Subject Diary was completed?:	
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5.a Injection Site Reaction:

Date	Location	User	Value	Reason
Oct-07-2020 13:22:44 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED] [REDACTED]	Data Entry: REDNESS	Initial Entry

5.a Were injection site reactions present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Oct-07-2020 13:22:44 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED] [REDACTED]	Data Entry: NO	Initial Entry

5.b

Date	Location	User	Value	Reason
Oct-07-2020 13:22:44 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED] [REDACTED]	Data Entry: Injection Site Reaction: EL LI NG Were injection site reactions present on the last day the Subject Diary was completed?: NO	Initial Entry

5.b Injection Site Reaction:

Date	Location	User	Value	Reason
Oct-07-2020 13:22:44 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED] [REDACTED]	Data Entry: SWELLING	Initial Entry

5.b Were injection site reactions present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Oct-07-2020 13:22:44 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED] [REDACTED]	Data Entry: NO	Initial Entry

5.c

Date	Location	User	Value	Reason
Oct-07-2020 13:22:44 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED] [REDACTED]	Data Entry: Injection Site PAIN Reaction:: AT I NJE CTI ON SITE Were injectio NO n site reaction s present on t he last day th e Subject Dia ry was compl eted?:	Initial Entry

5.c Injection Site Reaction:

Date	Location	User	Value	Reason
Oct-07-2020 13:22:44 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED] [REDACTED]	Data Entry: PAIN AT INJECTIO N SITE	Initial Entry

5.c Were injection site reactions present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Oct-07-2020 13:22:44 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED] [REDACTED]	Data Entry: NO	Initial Entry

Header Text: C4591001

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

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

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

Subject No: 12311379 **Subject Initials:** ---

Generated By: (b) (4) **Generated Time (GMT):** 29-Mar-2021 16:45

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1. Data Origin

Date	Location	User	Value	Reason
Oct-07-2020 13:22:53 (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-07-2020 13:22:53 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SERUM	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Oct-07-2020 16:37:16 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Oct-07-2020 15:38:12 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6) [Redacted] [Redacted] [Redacted]	Query 1: Opened	'Sample Collected?' is Yes, however no barcodes

090177e196ae2e95\Final\Final On: 01-Apr-2021 03:17 (GMT)

Header Text: C4591001

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

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

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

Subject No: 12311379 Subject Initials: ---

Generated By: (b) (4) Generated Time (GMT): 29-Mar-2021 16:45

				are entered. Please review and correct as appropriate.
Oct-07-2020 13:22:53 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Oct-07-2020 13:22:53 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Date of Collection: Oct/7/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Oct-07-2020 16:37:16 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID BNVB2 : 6	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
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090177e196ae2e95\Final\Final On: 01-Apr-2021 03:17 (GMT)

Header Text: C4591001

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

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

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

Subject No: 12311379 Subject Initials: ---

Generated By: (b) (4) Generated Time (GMT): 29-Mar-2021 16:45

Oct-07-2020 16:37:16 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BNVB26	Initial Entry
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5.b

Date	Location	User	Value	Reason
Oct-07-2020 17:24:40 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID BNV33 : 1	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Oct-07-2020 17:24:40 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BNV331	Initial Entry

5.c

Date	Location	User	Value	Reason
Oct-07-2020 18:00:47 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID BPW75 : 9	Initial Entry

090177e196ae2e95\Final\Final On: 01-Apr-2021 03:17 (GMT)

Header Text: C4591001

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

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

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

Subject No: 12311379 **Subject Initials:** ---

Generated By: (b) (4) **Generated Time (GMT):** 29-Mar-2021 16:45

5.c Sample ID

Date	Location	User	Value	Reason
Oct-07-2020 18:00:47 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BPW759	Initial Entry

090177e196ae2e95\Final\Final On: 01-Apr-2021 03:17 (GMT)

Header Text: C4591001

Visit: End of Treatment - Unscheduled **Form:** DISPOSITION - TREATMENT - eCRF Audit Trail History

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

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

Subject No: 12311379 **Subject Initials:** ---

Generated By: (b) (4) **Generated Time (GMT):** 29-Mar-2021 16:45

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1. Date of Completion/Discontinuation/Death :

Date	Location	User	Value	Reason
Oct-09-2020 21:24:03 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Oct/7/2020	Initial Entry

2. Phase of Disposition:

Date	Location	User	Value	Reason
Oct-09-2020 21:24:03 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: VACCINATION	Initial Entry

3. Status:

Date	Location	User	Value	Reason
Oct-09-2020 21:24:03 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: COMPLETED	Initial Entry

090177e196ae2e95\Final\Final On: 01-Apr-2021 03:17 (GMT)

Header Text: C4591001

Visit: Follow-Up - Unscheduled

Form: DISPOSITION - FOLLOW-UP - eCRF Audit Trail History

Form Version: 15-Sep-2020 21:53

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1231

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

Subject No: 12311379

Subject Initials: ---

Generated By:

Generated Time (GMT): 29-Mar-2021 16:45

(b) (4)

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1. Date of Completion/Discontinuation/Death :

Date	Location	User	Value	Reason
Feb-25-2021 12:33:26 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Feb/24/2021	Initial Entry

2. Phase of Disposition:

Date	Location	User	Value	Reason
Feb-25-2021 12:33:26 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: FOLLOW-UP	Initial Entry

3. Status:

Date	Location	User	Value	Reason
Feb-25-2021 12:33:26 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: PROTOCOL DEVIATION	Initial Entry

4. Specify Status:

Date	Location	User	Value	Reason
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090177e196ae2e95\Final\Final On: 01-Apr-2021 03:17 (GMT)

Header Text: C4591001

Visit: Follow-Up - Unscheduled

Form: DISPOSITION - FOLLOW-UP - eCRF Audit Trail History

Form Version: 15-Sep-2020 21:53

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1231

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

Subject No: 12311379

Subject Initials: ---

Generated By:

Generated Time (GMT): 29-Mar-2021 16:45

(b) (4)

Feb-25-2021 12:33:26 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6) [Redacted] [Redacted]	Data Entry: The volunteer was given a vaccine not related to the study	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, Locked, Frozen, Verified

Site No: 1231

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

Subject No: 12311379

Subject Initials: ---

Generated By:

Generated Time (GMT): 29-Mar-2021 16:45

(b) (4)

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1. Date of Visit

Date	Location	User	Value	Reason
Jan-12-2021 15:51:39 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6) [Redacted] [Redacted] [Redacted]	Data Entry: Jan/12/2021	Initial Entry

090177e196ae2e95\Final\Final On: 01-Apr-2021 03:17 (GMT)

Header Text: C4591001

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

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

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

Subject No: 12311379 **Subject Initials:** ---

Generated By: (b) (4) **Generated Time (GMT):** 29-Mar-2021 16:45

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

Date	Location	User	Value	Reason
Jan-12-2021 15:51:46 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6) [Redacted] [Redacted] [Redacted]	Data Entry: Participant is NOT wil ling to return for Vacc ination 3 OR otherwise not eligible	Initial Entry

Header Text: C4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1231

Subject No: 12311379

Generated By:

(b) (4)

Form: ADVERSE EVENT REPORT - Audit Trail

Form Status:

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

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 16:45

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Date	Location	User	Value	Reason
Jan-13-2021 15:37:27 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6) [Redacted] [Redacted]	Form Created	

090177e196ae2e95\Final\Final On: 01-Apr-2021 03:17 (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, Verified

Site No: 1231

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

Subject No: 12311379

Subject Initials: ---

Generated By:

Generated Time (GMT): 29-Mar-2021 16:45

(b) (4)

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1. Category:

Date	Location	User	Value	Reason
Jan-13-2021 15:37:27 (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
Jan-13-2021 15:37:27 (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
Jan-26-2021 01:20:31 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Closed	Response satisfies query
Jan-19-2021 14:38:15 (UTC-03:00)	ACV0PFEINFP6000	Marjorie Buonanno (b) (4)	Query 3: Closed	Response satisfies query

090177e196ae2e95\Final\Final On: 01-Apr-2021 03:17 (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, Verified

Site No: 1231

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

Subject No: 12311379

Subject Initials: ---

Generated By:

Generated Time (GMT): 29-Mar-2021 16:45

(b) (4)

City of Buenos Aires				
Jan-18-2021 16:46:29 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Answered	the patient has not presented any clinical signs or symptoms associated with adenocarcinoma of the prostate. He only has a medical history of elevated PSA and has never been diagnosed with benign prostatic hypertrophy.
Jan-18-2021 09:09:42 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	Marjorie Buonanno (b) (4)	Query 3: Reissued:Opened	Thank you for your response however it does not answer the questions. Were there any clinical signs or symptoms leading to the diagnosis of prostate CA?
Jan-18-2021	ACV0PFEINFP6000	Marjorie	Query 1: Close	Response

090177e196ae2e95\Final\Final On: 01-Apr-2021 03:17 (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, Verified

Site No: 1231

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

Subject No: 12311379

Subject Initials: ---

Generated By:

Generated Time (GMT): 29-Mar-2021 16:45

(b) (4)

09:08:17 (UTC-03:00) City of Buenos Aires		Buonanno (b) (4)	d	satisfies query
Jan-17-2021 18:24:48 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Answered	Follow up SAE form was sent clarifying start dates of the patient's history (hypertension and PSA elevation).
Jan-17-2021 18:22:32 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Medical history was updated.
Jan-16-2021 19:21:56 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Answered	The patient began prostate radiotherapy on 11 JAN 2021 (39 sessions will be completed)
Jan-15-2021 16:59:29 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	Marjorie Buonanno (b) (4)	Query 3: Opened	GPD Clin: Please confirm if subject had any clinical signs associated with prostate

090177e196ae2e95\Final\Final On: 01-Apr-2021 03:17 (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, Verified

Site No: 1231

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

Subject No: 12311379

Subject Initials: ---

Generated By:

Generated Time (GMT): 29-Mar-2021 16:45

(b) (4)

				adenocarcinoma, e.g. urinary obstruction, difficulty urinating? Any diagnosis of benign prostatic hypertrophy?
Jan-15-2021 15:19:52 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Open ed	CLINICAL SAE report prior Med History section includes Hypertension; however start date does not match recorded Med Hx HTN onset on 1/1/2005. BP meds in SAE report started 2005; please review HTN onset date; update in a SAE followup report if appropriate
Jan-15-2021 14:16:59 (UTC-03:00) City of Buenos	ACV0PFEINFP6000	Marjorie Buonanno (b) (4)	Query 1: Open ed	GPD Clin: The SAE narrative submitted states the subject had

090177e196ae2e95\Final\Final On: 01-Apr-2021 03:17 (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, Verified

Site No: 1231

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

Subject No: 12311379

Subject Initials: ---

Generated By:

Generated Time (GMT): 29-Mar-2021 16:45

(b) (4)

Aires				medical history of elevated PSA since 2018 and was followed by urologist. Please add elevated PSA to medical history once DM unlocks med history CRF page.
Jan-13-2021 15:37:27 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Prostate adeno carcinoma.	Initial Entry

4. Start Date Time:

Date	Location	User	Value	Reason
Jan-13-2021 15:37:27 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Nov/20/2020 12:00	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Mar-02-2021 04:15:57	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query

090177e196ae2e95\Final\Final On: 01-Apr-2021 03:17 (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, Verified

Site No: 1231

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

Subject No: 12311379

Subject Initials: ---

Generated By:

Generated Time (GMT): 29-Mar-2021 16:45

(b) (4)

(UTC-03:00) City of Buenos Aires				
Feb-26-2021 15:50:17 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6) [Redacted]	Query 1: Answered	There are no more data on the adverse event prostate adenocarcinoma, because the subject withdrew from the study due to having received a vaccine not related to the study.
Feb-25-2021 12:33:26 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	'Disposition Follow-up form is completed and this Adverse Event is still ongoing. Please review and update as appropriate.
Jan-13-2021 15:37:27 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6) [Redacted]	Data Entry: YES	Initial Entry

090177e196ae2e95\Final\Final On: 01-Apr-2021 03:17 (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, Verified

Site No: 1231

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

Subject No: 12311379

Subject Initials: ---

Generated By:

Generated Time (GMT): 29-Mar-2021 16:45

(b) (4)

6. Toxicity Grade:

Date	Location	User	Value	Reason
Jan-13-2021 15:37:27 (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 medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).

Date	Location	User	Value	Reason
Jan-18-2021 07:06:41 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Jan-13-2021 15:37:27 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	For AE Prostate adenocarcinoma.: Response to "Is the adverse event serious?" is 'Yes' but "Serious Adverse Event Number" is blank.

090177e196ae2e95\Final\Final On: 01-Apr-2021 03:17 (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, Verified

Site No: 1231

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

Subject No: 12311379

Subject Initials: ---

Generated By:

Generated Time (GMT): 29-Mar-2021 16:45

(b) (4)

<p>Jan-13-2021 15:37:27 (UTC-03:00) City of Buenos Aires</p>	<p>ACV0PFEINFP6000</p>	<p>(b) (4), (b) (6)</p>	<p>Data Entry: YES Is this serious event associated with congenital anomaly or birth defect? NO Did this serious event result in death? NO Did this serious event require or prolong hospitalization? NO Did this serious event result in persistent or significant disability/incapacity? NO Is this serious event life threatening</p>	<p>Initial Entry</p>
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090177e196ae2e95\Final\Final On: 01-Apr-2021 03:17 (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, Verified

Site No: 1231

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

Subject No: 12311379

Subject Initials: ---

Generated By:

Generated Time (GMT): 29-Mar-2021 16:45

(b) (4)

			?	
			NO	
			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
Jan-13-2021 15:37:27 (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
Jan-13-2021 15:37:27 (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>	Initial Entry

090177e196ae2e95\Final\Final On: 01-Apr-2021 03:17 (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, Verified

Site No: 1231

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

Subject No: 12311379

Subject Initials: ---

Generated By:

Generated Time (GMT): 29-Mar-2021 16:45

(b) (4)

unknown

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Jan-13-2021 15:37:27 (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
Jan-29-2021 08:36:10 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	New Information
Jan-13-2021 15:37:27 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Jan-13-2021 15:37:27 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

090177e196ae2e95\Final\Final On: 01-Apr-2021 03:17 (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, Verified

Site No: 1231

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

Subject No: 12311379

Subject Initials: ---

Generated By:

Generated Time (GMT): 29-Mar-2021 16:45

(b) (4)

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

Date	Location	User	Value	Reason
Jan-13-2021 15:37:27 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NOT RECOVERED/ NOT RESOLVED	Initial Entry

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

Date	Location	User	Value	Reason
Jan-13-2021 15:37:27 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

15. Serious Adverse Event Number: For Pfizer Use Only

Date	Location	User	Value	Reason
Jan-18-2021 07:06:41 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 2021028480	Initial Entry

090177e196ae2e95\Final\Final On: 01-Apr-2021 03:17 (GMT)

Header Text: C4591001

Visit: Logs - Unscheduled

Form: CONCOMITANT MEDICATIONS - NON
STUDY VACCINATIONS - Audit Trail

Form Version: 22-Apr-2020 21:03

Form Status:

Site No: 1231

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

Subject No: 12311379

Subject Initials: ---

Generated By:

Generated Time (GMT): 29-Mar-2021 16:45

(b) (4)

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Date	Location	User	Value	Reason
Feb-25-2021 12:35:49 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6) [Redacted] [Redacted]	Form Created	

090177e196ae2e95\Final\Final On: 01-Apr-2021 03:17 (GMT)

Header Text: C4591001

Visit: Logs - Unscheduled

Form: CONCOMITANT MEDICATIONS - NON STUDY VACCINATIONS - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1231

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

Subject No: 12311379

Subject Initials: ---

Generated By:

Generated Time (GMT): 29-Mar-2021 16:45

(b) (4)

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1. What is the medication identifier?

Date	Location	User	Value	Reason
Feb-25-2021 12:35:49 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 1	Initial Entry

2. Category:

Date	Location	User	Value	Reason
Feb-25-2021 12:35:49 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: VACCINATIONS	Initial Entry

3. Concomitant Medications Pre-specified:

Date	Location	User	Value	Reason
Feb-25-2021 12:35:49 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: NO	Initial Entry

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).

090177e196ae2e95\Final\Final On: 01-Apr-2021 03:17 (GMT)

Header Text: C4591001

Visit: Logs - Unscheduled

Form: CONCOMITANT MEDICATIONS - NON STUDY VACCINATIONS - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1231

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

Subject No: 12311379

Subject Initials: ---

Generated By:

Generated Time (GMT): 29-Mar-2021 16:45

(b) (4)

Date	Location	User	Value	Reason
Feb-25-2021 12:35:49 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Gam-COVID-Vac (trade name Sputnik V).	Initial Entry

5. Date:

Date	Location	User	Value	Reason
Feb-25-2021 12:35:49 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Feb/18/2021	Initial Entry

090177e196ae2e95\Final\Final On: 01-Apr-2021 03:17 (GMT)

Header Text: C4591001

Visit: Subject Status - Unscheduled

Form: SUBJECT STATUS - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Verified

Site No: 1231

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

Subject No: 12311379

Subject Initials: ---

Generated By:

Generated Time (GMT): 29-Mar-2021 16:45

(b) (4)

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1. Subject Status

Date	Location	User	Value	Reason
Mar-18-2021 18:20:47 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	Hayley Wyper (b) (4)	Query 1: Closed	per site response
Mar-17-2021 15:03:01 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	No unblinding was performed prior to the volunteer receiving a Non-study covid-19 vaccine. Thank you
Mar-17-2021 10:57:25 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	Hayley Wyper (b) (4)	Query 1: Opened	CLINQUERY: Non-study covid-19 vaccine reported. No Treatment Unblind is reported for this subject before the discontinuation from study. Please review if

090177e196ae2e95\Final\Final On: 01-Apr-2021 03:17 (GMT)

Header Text: C4591001

Visit: Subject Status - Unscheduled

Form: SUBJECT STATUS - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Verified

Site No: 1231

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

Subject No: 12311379

Subject Initials: ---

Generated By:

Generated Time (GMT): 29-Mar-2021 16:45

(b) (4)

				correct; else update page if subject was informed of Rx assignment before end of study
Feb-25-2021 12:33:26 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: DISCONTINUED	Initial Entry
Oct-09-2020 21:24:03 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: FOLLOW-UP	Initial Entry
Aug-15-2020 21:09:41 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: ENROLLED/RAN DOMIZED	Initial Entry
Aug-15-2020 18:30:47 (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
Feb-25-2021 12:33:26 (UTC-03:00) City	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Feb/24/2021	Initial Entry

090177e196ae2e95\Final\Final On: 01-Apr-2021 03:17 (GMT)

Header Text: C4591001

Visit: Subject Status - Unscheduled

Form: SUBJECT STATUS - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Verified

Site No: 1231

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

Subject No: 12311379

Subject Initials: ---

Generated By:

Generated Time (GMT): 29-Mar-2021 16:45

(b) (4)

of Buenos Aires				
Oct-09-2020 21:24:03 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Oct/7/2020	Initial Entry
Aug-15-2020 21:09:41 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Aug/15/2020	Initial Entry
Aug-15-2020 18:30:47 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Aug/15/2020	Initial Entry

090177e196ae2e95\Final\Final On: 01-Apr-2021 03:17 (GMT)

Header Text: C4591001

Visit: Investigator Signature -
Unscheduled

Form Version: 22-Apr-2020 21:04

Site No: 1231

Subject No: 12311379

Generated By:

(b) (4)

Form: CASEBOOK SIGNATURE FORM - eCRF Audit
Trail History

Form Status: Data Complete, Signed, Verified

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

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 16:45

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1. Casebook Signature

Date	Location	User	Value	Reason
Oct-22-2020 14:02:11 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	Fernando Polack (b) (4)	Data Entry: Click Here to Enable	Initial Entry

090177e196ae2e95\Final\Final On: 01-Apr-2021 03:17 (GMT)