

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: 12313193

Subject Initials: ---

Generated By:

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

(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

090177e196ae2e69\Final\Final On: 01-Apr-2021 03:12 (GMT)

Header Text: C4591001

Visit: COHORT_SELECTION

Form Version: 22-Apr-2020 21:02

Site No: 1231

Subject No: 12313193

Generated By:

(b) (4)

Form: MAIN INFORMED CONSENT

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Informed Consent

1.	Consent Was:	OBTAINED Date Written Consent Obtained Aug/22/2020
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Header Text: C4591001

Visit: COHORT_SELECTION

Form: DEMOGRAPHY

Form Version: 06-Jul-2020 21:55

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1231

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

Subject No: 12313193

Subject Initials: ---

Generated By:

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

(b) (4)

[eCRF Audit Trail History](#)

Demography

1.	Subject ID	[12313193]
2.	Birth Date:	(b) (6)/1966
3.	Sex:	FEMALE
4.	Ethnicity:	HISPANIC OR LATINO(A) OR OF SPANISH ORIGIN
5.	Race: (Check X all that apply):	WHITE
6.	Racial Designation:	

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Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:02

Site No: 1231

Subject No: 12313193

Generated By:

(b) (4)

Form: DATE OF VISIT

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Date of Visit

1.	Date of Visit	Aug/22/2020
2.	Erroneous Visit	

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 21-Aug-2020 02:50

Site No: 1231

Subject No: 12313193

Generated By:

(b) (4)

Form: INCLUSION/EXCLUSION CRITERIA

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

[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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Site No: 1231

Subject No: 12313193

Generated By:

(b) (4)

Form: INCLUSION/EXCLUSION CRITERIA

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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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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Site No: 1231

Subject No: 12313193

Generated By:

(b) (4)

Form: INCLUSION/EXCLUSION CRITERIA

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

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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Subject No: 12313193

Generated By:

(b) (4)

Form: INCLUSION/EXCLUSION CRITERIA

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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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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Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 21-Aug-2020 02:50

Site No: 1231

Subject No: 12313193

Generated By:

(b) (4)

Form: INCLUSION/EXCLUSION CRITERIA

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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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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Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 21-Aug-2020 02:50

Site No: 1231

Subject No: 12313193

Generated By:

(b) (4)

Form: INCLUSION/EXCLUSION CRITERIA

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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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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Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1231

Subject No: 12313193

Generated By:

(b) (4)

Form: DISPOSITION - SCREENING

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Disposition - Screening

1.	Date of Completion/Discontinuation /Death	Aug/22/2020
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: 12313193

Generated By:

(b) (4)

Form: GENERAL MEDICAL HISTORY

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

[Form Comments](#)

[eCRF Audit Trail History](#)

Medical History Details

1.a	Line/MH Number:	[1]
	Disease/Syndrome /Surgery/Non-Drug Allergies/Drug Allergies:	[intermittent gross hematuria]
	Start Date:	Jan/14/2020
	Ongoing:	YES

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 21-Aug-2020 02:51

Site No: 1231

Subject No: 12313193

Generated By:

(b) (4)

Form: VITAL SIGNS - BASELINE

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Vital Signs

1.	Date:	Aug/22/2020
2.	Weight:	[52.05]
3.	Unit:	kg
4.	Height:	[167.0]
5.	Unit:	cm
6.	Body Mass Index:	[18.7]

Vital Signs Details

7.a	Record Identifier:	1
	Temperature:	[36.6]
	Unit:	C
	Temperature Location:	ORAL CAVITY

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Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 21-Aug-2020 02:49

Site No: 1231

Subject No: 12313193

Generated By:

(b) (4)

Form: LAB URINALYSIS - PREGNANCY TEST

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Lab Urinalysis

1.	Lab Panel:	URINALYSIS
2.	Lab Sub-Panel:	PREGNANCY
3.	Collection Date:	Aug/22/2020
4.	Laboratory Name and Address (Derived)	[STUDY SITE]
5.	Specimen Type:	URINE

Lab Result

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

090177e196ae2e69\Final\Final On: 01-Apr-2021 03:12 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1231

Subject No: 12313193

Generated By:

(b) (4)

Form: RANDOMIZATION

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Disposition

1.	Randomization Date :	Aug/22/2020
2.	Randomization Number:	[62077]
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:** 12313193**Subject Initials:** ---**Generated By:****Generated Time (GMT):** 29-Mar-2021 20:20

(b) (4)

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

1.	Data Origin	SITE
2.	Sample Type	SERUM
3.	Sample Collected?	YES Date of Collection: Aug/22/2020
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	[BJ49ZM]
5.b	Sample ID	[BJ49ZN]
5.c	Sample ID	[BJ49ZP]
5.d	Sample ID	[BHY6MH]
5.e	Sample ID	[BHY6MJ]
5.f	Sample ID	[BHY6MK]

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: 12313193

Subject Initials: ---

Generated By:

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

(b) (4)

[eCRF Audit Trail History](#)

Electronic Sample Tracking

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB
3.	Sample Collected?	YES Date of Collection: Aug/22/2020
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	[BP2CSV]
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Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:04

Site No: 1231

Subject No: 12313193

Generated By:

(b) (4)

Form: VACCINATION

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

[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/22/2020 14:40
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: V1_DAY1_VAX1_L

Form Version: 06-Jul-2020 21:53

Site No: 1231

Subject No: 12313193

Generated By:

(b) (4)

Form: REACTOGENICITY DIARY

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Reactogenicity Diary

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

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:02

Site No: 1231

Subject No: 12313193

Generated By:

(b) (4)

Form: DATE OF VISIT

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Date of Visit

1.	Date of Visit	Sep/10/2020
2.	Erroneous Visit	

Header Text: C4591001

Visit: V2_VAX2_L

Form: VITAL SIGNS - TEMP

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: 12313193

Subject Initials: ---

Generated By:

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

(b) (4)

[eCRF Audit Trail History](#)

Vital Signs

1.	Date:	Sep/10/2020
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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 Version: 21-Aug-2020 02:49

Site No: 1231

Subject No: 12313193

Generated By:

(b) (4)

Form: LAB URINALYSIS - PREGNANCY TEST

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Lab Urinalysis

1.	Lab Panel:	URINALYSIS
2.	Lab Sub-Panel:	PREGNANCY
3.	Collection Date:	Sep/10/2020
4.	Laboratory Name and Address (Derived)	[STUDY SITE]
5.	Specimen Type:	URINE

Lab Result

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

090177e196ae2e69\Final\Final On: 01-Apr-2021 03:12 (GMT)

Header Text: C4591001

Visit: V2_VAX2_L

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1231

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

Subject No: 12313193

Subject Initials: ---

Generated By:

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

(b) (4)

[eCRF Audit Trail History](#)

Electronic Sample Tracking

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB
3.	Sample Collected?	YES Date of Collection: Sep/10/2020
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	[BP23ZY]
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Header Text: C4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:04

Site No: 1231

Subject No: 12313193

Generated By:

(b) (4)

Form: VACCINATION

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

[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/10/2020 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

090177e196ae2e69\Final\Final On: 01-Apr-2021 03:12 (GMT)

Header Text: C4591001

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

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

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

Subject No: 12313193 **Subject Initials:** ---

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

(b) (4)

[eCRF Audit Trail History](#)

Date of Visit

1.	Date of Visit	Oct/9/2020
2.	Erroneous Visit	

Header Text: C4591001

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

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

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

Subject No: 12313193 **Subject Initials:** ---

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

[eCRF Audit Trail History](#)

Electronic Sample Tracking

1.	Data Origin	SITE
2.	Sample Type	SERUM
3.	Sample Collected?	YES Date of Collection: Oct/9/2020
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	[BPX13H]
5.b	Sample ID	[BJ51S1]
5.c	Sample ID	[BJ51VY]
5.d	Sample ID	[BJ51VZ]

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Header Text: C4591001

Visit: POT_COVID_ILL - New
Unscheduled Visit

Form: DATE OF VISIT - ILLNESS ONSET

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1231

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

Subject No: 12313193

Subject Initials: ---

Generated By:

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

(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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090177e196ae2e69\Final\Final On: 01-Apr-2021 03:12 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL - New
Unscheduled Visit

Form Version: 28-Mar-2021 02:35

Site No: 1231

Subject No: 12313193

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 20:20

Signs and Symptoms

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

Symptoms

4.	Symptoms:	
	Was symptom present?	

Symptoms - Other

5.	Symptoms - Other Text:	[]
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Header Text: C4591001

Visit: POT_COVID_ILL - New
Unscheduled Visit

Form Version: 22-Apr-2020 21:03

Site No: 1231

Subject No: 12313193

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 20:20

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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090177e196ae2e69\Final\Final On: 01-Apr-2021 03:12 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL - New
Unscheduled Visit

Form Version: 22-Apr-2020 21:03

Site No: 1231

Subject No: 12313193

Generated By:

(b) (4)

Form: ELECTRONIC SAMPLE TRACKING - NASAL
SWAB

Form Status: Not Started

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

Subject Initials: ---

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

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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090177e196ae2e69\Final\Final On: 01-Apr-2021 03:12 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL - New
Unscheduled Visit

Form Version: 28-Mar-2021 02:23

Site No: 1231

Subject No: 12313193

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 20:20

Health Care Utilization

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

Health Care Utilization Other

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

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

090177e196ae2e69\Final\Final On: 01-Apr-2021 03:12 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL - New
Unscheduled Visit

Form Version: 06-Jul-2020 21:52

Site No: 1231

Subject No: 12313193

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 20:20

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: 12313193

Subject Initials: ---

Generated By:

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

(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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090177e196ae2e69\Final\Final On: 01-Apr-2021 03:12 (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:** 12313193**Subject Initials:** ---**Generated By:****Generated Time (GMT):** 29-Mar-2021 20:20

(b) (4)

Electronic Sample Tracking

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

Aliquot

Please enter barcode for each aliquot.

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

Header Text: C4591001

Visit: Unplanned - 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: 12313193 **Subject Initials:** ---

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

Date of Visit

1.	Date of Visit	//
2.	Erroneous Visit	

Header Text: C4591001

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

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

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

Subject No: 12313193 **Subject Initials:** ---

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

(b) (4)

Unplanned Assessments

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

Header Text: C4591001

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

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

Site No: 1231

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

Subject No: 12313193

Subject Initials: ---

Generated By:

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

(b) (4)

[eCRF Audit Trail History](#)

Disposition - Treatment

1.	Date of Completion/Discontinuation/Death :	Oct/9/2020
2.	Phase of Disposition:	VACCINATION
3.	Status:	COMPLETED
4.	Specify Status:	[]

090177e196ae2e69\Final\Final On: 01-Apr-2021 03:12 (GMT)

Header Text: C4591001

Visit: Follow-Up - Unscheduled

Form Version: 15-Sep-2020 21:53

Site No: 1231

Subject No: 12313193

Generated By:

(b) (4)

Form: DISPOSITION - FOLLOW-UP

Form Status: Not Started

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

Subject Initials: ---

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

Disposition - Follow-Up

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

Header Text: C4591001

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

Form Version: 10-Oct-2020 15:57

Form Status: Not Started

Site No: 1231

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

Subject No: 12313193

Subject Initials: ---

Generated By:

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

(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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090177e196ae2e69\Final\Final On: 01-Apr-2021 03:12 (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:** 12313193**Subject Initials:** ---**Generated By:****Generated Time (GMT):** 29-Mar-2021 20:20

(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: 12313193

Subject Initials: ---

Generated By:

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

(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: 12313193

Subject Initials: ---

Generated By:

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

(b) (4)

Vital Signs

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

Vital Signs Details

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

090177e196ae2e69\Final\Final On: 01-Apr-2021 03:12 (GMT)

Header Text: C4591001

Visit: Unplanned Vaccination -
Unscheduled

Form Version: 20-Feb-2021 02:14

Site No: 1231

Subject No: 12313193

Generated By:

(b) (4)

Form: LAB URINALYSIS - PREGNANCY TEST

Form Status: Not Started

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

Subject Initials: ---

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

Lab Urinalysis

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

Lab Result

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

090177e196ae2e69\Final\Final On: 01-Apr-2021 03:12 (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: 12313193

Subject Initials: ---

Generated By:

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

(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?	

Header Text: C4591001

Visit: Unplanned Vaccination -
Unscheduled

Form Version: 10-Oct-2020 15:57

Site No: 1231

Subject No: 12313193

Generated By:

(b) (4)

Form: CONTACT OUTCOME - MONTH 1

Form Status: Not Started

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

Subject Initials: ---

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

Contact Outcome

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

Header Text: C4591001

Visit: Unplanned Vaccination -
Unscheduled

Form: CONTACT OUTCOME - MONTH 6

Form Version: 10-Oct-2020 16:01

Form Status: Not Started

Site No: 1231

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

Subject No: 12313193

Subject Initials: ---

Generated By:

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

(b) (4)

Contact Outcome

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

Header Text: C4591001

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

Unscheduled

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1231

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

Subject No: 12313193

Subject Initials: ---

Generated By:

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

(b) (4)

[eCRF Audit Trail History](#)

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

090177e196ae2e69\Final\Final On: 01-Apr-2021 03:12 (GMT)

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: 12313193

Subject Initials: ---

Generated By:

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

(b) (4)

[eCRF Audit Trail History](#)

Further Vaccination Confirmation

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

Header Text: C4591001

Visit: V101_VAX3

Form Version: 22-Apr-2020 21:02

Site No: 1231

Subject No: 12313193

Generated By:

(b) (4)

Form: DATE OF VISIT

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Date of Visit

1.	Date of Visit	Feb/3/2021
2.	Erroneous Visit	

Header Text: C4591001

Visit: V101_VAX3

Form: INFORMED CONSENT - FURTHER VACCINATION

Form Version: 10-Dec-2020 02:31

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1231

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

Subject No: 12313193

Subject Initials: ---

Generated By:

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

(b) (4)

[eCRF Audit Trail History](#)

Informed Consent - Further Vaccination

1.	Consent Was:	OBTAINED Date Written Consent Obtained Jan/15/2021
----	--------------	--

Header Text: C4591001

Visit: V101_VAX3

Form: INCLUSION/EXCLUSION CRITERIA - FURTHER VACCINATION

Form Version: 10-Dec-2020 02:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1231

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

Subject No: 12313193

Subject Initials: ---

Generated By:

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

(b) (4)

Form Comments

Inclusion Criteria Not Met

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

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

090177e196ae2e69\Final\Final On: 01-Apr-2021 03:12 (GMT)

Header Text: C4591001

Visit: V101_VAX3

Form: DISPOSITION - SCREENING FOR FURTHER VACCINATION

Form Version: 10-Dec-2020 02:31

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1231

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

Subject No: 12313193

Subject Initials: ---

Generated By:

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

(b) (4)

[eCRF Audit Trail History](#)

Disposition - Screening for Further Vaccination

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

Header Text: C4591001**Visit:** V101_VAX3**Form Version:** 14-Jan-2021 02:21**Site No:** 1231**Subject No:** 12313193**Generated By:**

(b) (4)

Form: LAB URINALYSIS - PREGNANCY TEST**Form Status:** Data Complete, Locked, Frozen, Verified**Site Name:** (1231) Hospital Militar Central Cirujano Mayor Dr. Cosme Argerich**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 20:20[eCRF Audit Trail History](#)**Lab Urinalysis**

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

Lab Result

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

Header Text: C4591001**Visit:** V101_VAX3**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY**Form Version:** 22-Apr-2020 21:03**Form Status:** Data Complete, Locked, Frozen, Verified**Site No:** 1231**Site Name:** (1231) Hospital Militar Central Cirujano Mayor Dr. Cosme Argerich**Subject No:** 12313193**Subject Initials:** ---**Generated By:****Generated Time (GMT):** 29-Mar-2021 20:20

(b) (4)

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

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

Aliquot

Please enter barcode for each aliquot.

5.a	Sample ID	[BPWC4G]
5.b	Sample ID	[BS43CP]
5.c	Sample ID	[BS43MP]
5.d	Sample ID	[BS43MR]

Header Text: C4591001

Visit: V101_VAX3

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: 12313193

Subject Initials: ---

Generated By:

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

(b) (4)

[eCRF Audit Trail History](#)

Electronic Sample Tracking

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

Aliquot

Please enter barcode for each aliquot.

5.a	Sample ID	[BPWCN0]
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090177e196ae2e69\Final\Final On: 01-Apr-2021 03:12 (GMT)

Header Text: C4591001

Visit: V101_VAX3

Form Version: 10-Dec-2020 02:26

Site No: 1231

Subject No: 12313193

Generated By:

(b) (4)

Form: VACCINATION

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Vaccination

1.	Was there a temporary delay of vaccination?	YES Date of First Delay: Jan/15/2021 Reason(s) for Temporary Delay of Vaccination FEVER OR ACUTE ILLNESS
2.	Treatment Name	[BNT162b2]
3.	Formulation:	INJECTION
4.	Dose Date Time:	Feb/3/2021 14:57
5.	Anatomical Location:	DELTOID MUSCLE
6.	Body Side:	LEFT
7.	Route:	INTRAMUSCULAR
8.	Actual Dose:	[30.0]
9.	Unit:	ug
10.	Timeframe Subject Was Observed	30 MINUTES
11.	Was the subject observed for at least the protocol specified observation period after investigational product administration?	YES

090177e196ae2e69\Final\Final On: 01-Apr-2021 03:12 (GMT)

Header Text: C4591001

Visit: V102_VAX4

Form Version: 22-Apr-2020 21:02

Site No: 1231

Subject No: 12313193

Generated By:

(b) (4)

Form: DATE OF VISIT

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Date of Visit

1.	Date of Visit	Feb/24/2021
2.	Erroneous Visit	

Header Text: C4591001**Visit:** V102_VAX4**Form Version:** 14-Jan-2021 02:21**Site No:** 1231**Subject No:** 12313193**Generated By:**

(b) (4)

Form: LAB URINALYSIS - PREGNANCY TEST**Form Status:** Data Complete, Locked, Frozen, Verified**Site Name:** (1231) Hospital Militar Central Cirujano
Mayor Dr. Cosme Argerich**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 20:20[eCRF Audit Trail History](#)**Lab Urinalysis**

1.	Lab Panel:	URINALYSIS
2.	Lab Sub-Panel:	PREGNANCY
3.	Collection Date:	Feb/24/2021
4.	Laboratory Name and Address (Derived)	[STUDY SITE]
5.	Specimen Type:	URINE

Lab Result

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

Header Text: C4591001

Visit: V102_VAX4

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: 12313193

Subject Initials: ---

Generated By:

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

(b) (4)

[eCRF Audit Trail History](#)

Electronic Sample Tracking

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB
3.	Sample Collected?	YES Date of Collection: Feb/24/2021
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[]

Aliquot

Please enter barcode for each aliquot.

5.a	Sample ID	[BR28H6]
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090177e196ae2e69\Final\Final On: 01-Apr-2021 03:12 (GMT)

Header Text: C4591001

Visit: V102_VAX4

Form Version: 10-Dec-2020 02:26

Site No: 1231

Subject No: 12313193

Generated By:

(b) (4)

Form: VACCINATION

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Vaccination

1.	Was there a temporary delay of vaccination?	NO
2.	Treatment Name	[BNT162b2]
3.	Formulation:	INJECTION
4.	Dose Date Time:	Feb/24/2021 16:25
5.	Anatomical Location:	DELTOID MUSCLE
6.	Body Side:	LEFT
7.	Route:	INTRAMUSCULAR
8.	Actual Dose:	[30.0]
9.	Unit:	ug
10.	Timeframe Subject Was Observed	30 MINUTES
11.	Was the subject observed for at least the protocol specified observation period after investigational product administration?	YES

090177e196ae2e69\Final\Final On: 01-Apr-2021 03:12 (GMT)

Header Text: C4591001

Visit: V103_MONTH1

Form Version: 22-Apr-2020 21:02

Site No: 1231

Subject No: 12313193

Generated By:

(b) (4)

Form: DATE OF VISIT

Form Status: Data Complete, Verified

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

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Date of Visit

1.	Date of Visit	Mar/25/2021
2.	Erroneous Visit	

Header Text: C4591001

Visit: V103_MONTH1

Form Version: 22-Apr-2020 21:04

Site No: 1231

Subject No: 12313193

Generated By:

(b) (4)

Form: CONTACT OUTCOME

Form Status: Data Complete, Verified

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

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Contact Outcome

1.	Contact Type:	TELEPHONE VISIT
2.	Was contact made?	YES Date of Contact: Mar/25/2021
3.	Comments:	[]

Header Text: C4591001

Visit: V104_MONTH6

Form Version: 22-Apr-2020 21:02

Site No: 1231

Subject No: 12313193

Generated By:

(b) (4)

Form: DATE OF VISIT

Form Status: Not Started

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

Subject Initials: ---

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

Date of Visit

1.	Date of Visit	//
2.	Erroneous Visit	

Header Text: C4591001

Visit: V104_MONTH6

Form Version: 22-Apr-2020 21:04

Site No: 1231

Subject No: 12313193

Generated By:

(b) (4)

Form: CONTACT OUTCOME

Form Status: Not Started

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

Subject Initials: ---

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

Contact Outcome

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

Header Text: C4591001

Visit: V105_MONTH18

Form Version: 22-Apr-2020 21:02

Site No: 1231

Subject No: 12313193

Generated By:

(b) (4)

Form: DATE OF VISIT

Form Status: Not Started

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

Subject Initials: ---

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

Date of Visit

1.	Date of Visit	//
2.	Erroneous Visit	

Header Text: C4591001

Visit: V105_MONTH18

Form Version: 22-Apr-2020 21:04

Site No: 1231

Subject No: 12313193

Generated By:

(b) (4)

Form: CONTACT OUTCOME

Form Status: Not Started

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

Subject Initials: ---

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

Contact Outcome

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

Header Text: C4591001

Visit:
FURTHER_VACCINATION_EOT -
Unscheduled

Form: DISPOSITION - TREATMENT

Form Version: 20-Feb-2021 02:26

Form Status: Data Complete, Verified

Site No: 1231

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

Subject No: 12313193

Subject Initials: ---

Generated By:

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

(b) (4)

[eCRF Audit Trail History](#)

Disposition - Treatment

1.	Date of Completion/Discontinuation/Death :	Mar/25/2021
2.	Phase of Disposition:	OPEN LABEL TREATMENT
3.	Status:	COMPLETED
4.	Specify Status:	[]

090177e196ae2e69\Final\Final On: 01-Apr-2021 03:12 (GMT)

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: 12313193

Subject Initials: ---

Generated By:

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

(b) (4)

#	Category	AE Identifier	Adverse Event	Start Date	Is the Adverse Event Still Ongoing	Form Instance
1.	ADVERSE EVENT	1	haematuria	Aug/25/2020 14:00	NO End Date Time: Sep/22/2020 08:00	Repeating Pages
2.	ADVERSE EVENT	2	Bladder polyp	Sep/18/2020 08:00	YES	Repeating Pages

090177e196ae2e69\Final\Final On: 01-Apr-2021 03:12 (GMT)

Header Text: C4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT

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: 12313193

Subject Initials: ---

Generated By:

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

(b) (4)

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[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)	[haematuria]
4.	Start Date Time:	Aug/25/2020 14:00
5.	Is the adverse event still ongoing?	NO End Date Time: Sep/22/2020 08:00
6.	Toxicity Grade:	1

090177e196ae2e69\Final\Final On: 01-Apr-2021 03:12 (GMT)

Header Text: C4591001**Visit:** Logs - Unscheduled**Form Version:** 22-Apr-2020 21:02**Site No:** 1231**Subject No:** 12313193**Generated By:**

(b) (4)

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

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

Header Text: C4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT

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: 12313193

Subject Initials: ---

Generated By:

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

(b) (4)

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

090177e196ae2e69\Final\Final On: 01-Apr-2021 03:12 (GMT)

Header Text: C4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1231

Subject No: 12313193

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 20:20

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[eCRF Audit Trail History](#)

[Form Audit Trail](#)

Adverse Event Report

1.	Category:	ADVERSE EVENT
2.	AE ID:	[2]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[Bladder polyp]
4.	Start Date Time:	Sep/18/2020 08:00
5.	Is the adverse event still ongoing?	YES
6.	Toxicity Grade:	1

090177e196ae2e69\Final\Final On: 01-Apr-2021 03:12 (GMT)

Header Text: C4591001**Visit:** Logs - Unscheduled**Form Version:** 22-Apr-2020 21:02**Site No:** 1231**Subject No:** 12313193**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 20:20

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

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: 12313193

Subject Initials: ---

Generated By:

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

(b) (4)

10.	Latest Action Taken with Study Treatment:	NOT APPLICABLE
11.	Was a Concomitant Medication given?	NO
12.	Was a Non-Drug Treatment given?	YES
13.	What was the outcome of this adverse event?:	RECOVERING/RESOLVING
14.	Did the adverse event cause the subject to be discontinued from the study?	NO
15.	Serious Adverse Event Number: For Pfizer Use Only	[2020404788]

090177e196ae2e69\Final\Final On: 01-Apr-2021 03:12 (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: 12313193

Subject Initials: ---

Generated By:

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

(b) (4)

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

090177e196ae2e69\Final\Final On: 01-Apr-2021 03:12 (GMT)

Header Text: C4591001

Visit: Logs - Unscheduled

Form Version: 17-Jul-2020 21:54

Site No: 1231

Subject No: 12313193

Generated By:

(b) (4)

Form: MEDICATION ERROR

Form Status: Not Started

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

Subject Initials: ---

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

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Medication Error

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

090177e196ae2e69\Final\Final On: 01-Apr-2021 03:12 (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: 12313193

Subject Initials: ---

Generated By:

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

(b) (4)

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

090177e196ae2e69\Final\Final On: 01-Apr-2021 03:12 (GMT)

Header Text: C4591001

Visit: Logs - Unscheduled

Form: CONCOMITANT MEDICATIONS - NON STUDY VACCINATIONS

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1231

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

Subject No: 12313193

Subject Initials: ---

Generated By:

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

(b) (4)

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Concomitant Medications

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

090177e196ae2e69\Final\Final On: 01-Apr-2021 03:12 (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: 12313193

Subject Initials: ---

Generated By:

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

(b) (4)

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

090177e196ae2e69\Final\Final On: 01-Apr-2021 03:12 (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: 12313193

Subject Initials: ---

Generated By:

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

(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?	

090177e196ae2e69\Final\Final On: 01-Apr-2021 03:12 (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: 12313193

Subject Initials: ---

Generated By:

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

(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: 12313193

Generated By:

(b) (4)

Form: RADIATION TREATMENT

Form Status: Not Started

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

Subject Initials: ---

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

[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?	

090177e196ae2e69\Final\Final On: 01-Apr-2021 03:12 (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: 12313193

Subject Initials: ---

Generated By:

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

(b) (4)

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

090177e196ae2e69\Final\Final On: 01-Apr-2021 03:12 (GMT)

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: 12313193

Subject Initials: ---

Generated By:

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

(b) (4)

[Back to Form](#)

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

Header Text: C4591001

Visit: Disposition - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1231

Subject No: 12313193

Generated By:

(b) (4)

Form: TREATMENT UNBLINDED

Form Status: Data Complete, Frozen, Verified

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

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Treatment Unblinded

1.	Date Treatment Unblinded :	Jan/12/2021
2.	Primary Reason for Unblinding:	ASSESS ELIGIBILITY FOR ADDITIONAL VACCINATION

Header Text: C4591001

Visit: Disposition - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1231

Subject No: 12313193

Generated By:

(b) (4)

Form: WITHDRAWAL OF CONSENT

Form Status: Not Started

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

Subject Initials: ---

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

Withdrawal Of Consent

1.	Withdrawal of Consent Date :	//
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Header Text: C4591001

Visit: Disposition - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1231

Subject No: 12313193

Generated By:

(b) (4)

Form: DEATH DETAILS CODED

Form Status: Not Started

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

Subject Initials: ---

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

Death Details

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

Cause of Death

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

090177e196ae2e69\Final\Final On: 01-Apr-2021 03:12 (GMT)

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: 12313193

Subject Initials: ---

Generated By:

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

(b) (4)

[eCRF Audit Trail History](#)

Subject Status

1.	Subject Status	FOLLOW-UP
2.	Subject Status Date	Oct/9/2020

Header Text: C4591001

Visit: Investigator Signature -
Unscheduled

Form Version: 22-Apr-2020 21:04

Site No: 1231

Subject No: 12313193

Generated By:

(b) (4)

Form: CASEBOOK SIGNATURE FORM

Form Status: Data Complete, Verified

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

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Casebook Signature Form

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

Visit: Investigator Signature -
Unscheduled

Form: CASEBOOK SIGNATURE FORM

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Verified

Site No: 1231

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

Subject No: 12313193

Subject Initials: ---

Generated By:

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

(b) (4)

[Audit Trail](#)

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

- CRF_Sign
- CRF_Sign_1

Name	Signature Meaning	Date	Type	Action
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Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1231

Subject No: 12313193

Generated By:

(b) (4)

Form: GENERAL MEDICAL HISTORY - Comments

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

[Back to Form](#)

Item	Date	User	Comment
Form	Oct-14-2020 17:09:43 (UTC-03:00) City of Buenos Aires	(b) (4), (b) (6) [Redacted]	
Form	Aug-22-2020 15:22:36 (UTC-03:00) City of Buenos Aires	(b) (4), (b) (6) [Redacted]	Not Applicable

Header Text: C4591001

Visit: V101_VAX3

Form: INCLUSION/EXCLUSION CRITERIA - FURTHER VACCINATION - Comments

Form Version: 10-Dec-2020 02:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1231

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

Subject No: 12313193

Subject Initials: ---

Generated By:

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

(b) (4)

[Back to Form](#)

Item	Date	User	Comment
Form	Jan-18-2021 13:13:43 (UTC-03:00) City of Buenos Aires	(b) (4), (b) (6) [Redacted] [Redacted]	Not Applicable

Header Text: C4591001

Visit: Investigator Signature -
Unscheduled

Form: CASEBOOK SIGNATURE FORM - Signature
History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Verified

Site No: 1231

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

Subject No: 12313193

Subject Initials: ---

Generated By:

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

(b) (4)

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

- CRF_Sign
- CRF_Sign_1

Name	Signature Meaning	Date	Type	Action
(b) (6)	N/A	Mar-25-2021 15:04:56 (UTC-03:00) City of Buenos Aires		Edit - All signatures invalidated

Affidavit:

N/A

Yanina Rivera	Approved	Mar-09-2021 14:45:58 (UTC-03:00) City of Buenos Aires	BOOK	Signed
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Affidavit:

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

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

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

090177e196ae2e69\Final\Final On: 01-Apr-2021 03:12 (GMT)

Header Text: C4591001

Visit: Investigator Signature -
Unscheduled

Form: CASEBOOK SIGNATURE FORM - Signature
History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Verified

Site No: 1231

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

Subject No: 12313193

Subject Initials: ---

Generated By:

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

(b) (4)

(b) (6)	N/A	Feb-24-2021 17:58:46 (UTC-03:00) City of Buenos Aires		Edit - All signatures invalidated
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Affidavit:

N/A

(b) (6)	Approved	Feb-22-2021 15:56:13 (UTC-03:00) City of Buenos Aires	BOOK	Signed
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Affidavit:

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

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

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

(b) (6)	N/A	Feb-18-2021 16:07:01 (UTC-03:00) City of Buenos Aires		Edit - All signatures invalidated
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Affidavit:

N/A

(b) (6)	Approved	Feb-04-2021 20:49:09 (UTC-03:00) City of Buenos Aires	BOOK	Signed
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090177e196ae2e69\Final\Final On: 01-Apr-2021 03:12 (GMT)

Header Text: C4591001

Visit: Investigator Signature -
Unscheduled

Form: CASEBOOK SIGNATURE FORM - Signature
History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Verified

Site No: 1231

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

Subject No: 12313193

Subject Initials: ---

Generated By:

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

(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	Feb-03-2021 15:51:26 (UTC-03:00) City of Buenos Aires		Edit - All signatures invalidated
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Affidavit:

N/A

(b) (6)	Approved	Jan-20-2021 21:22:58 (UTC-03:00) City of Buenos Aires	BOOK	Signed
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090177e196ae2e69\Final\Final On: 01-Apr-2021 03:12 (GMT)

Header Text: C4591001

Visit: Investigator Signature -
Unscheduled

Form: CASEBOOK SIGNATURE FORM - Signature
History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Verified

Site No: 1231

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

Subject No: 12313193

Subject Initials: ---

Generated By:

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

(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	Dec-09-2020 16:22:46 (UTC-03:00) City of Buenos Aires		Edit - All signatures invalidated
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Affidavit:

N/A

(b) (6)	Approved	Nov-27-2020 19:37:35 (UTC-03:00) City of Buenos Aires	BOOK	Signed
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090177e196ae2e69\Final\Final On: 01-Apr-2021 03:12 (GMT)

Header Text: C4591001

Visit: Investigator Signature -
Unscheduled

Form: CASEBOOK SIGNATURE FORM - Signature
History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Verified

Site No: 1231

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

Subject No: 12313193

Subject Initials: ---

Generated By:

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

(b) (4)

Affidavit:

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

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

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

(b) (6)	N/A	Nov-27-2020 19:11:34 (UTC-03:00) City of Buenos Aires		Edit - All signatures invalidated
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Affidavit:

N/A

(b) (6)	Approved	Nov-05-2020 13:22:30 (UTC-03:00) City of Buenos Aires	BOOK	Signed
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090177e196ae2e69\Final\Final On: 01-Apr-2021 03:12 (GMT)

Header Text: C4591001

Visit: Investigator Signature -
Unscheduled

Form: CASEBOOK SIGNATURE FORM - Signature
History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Verified

Site No: 1231

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

Subject No: 12313193

Subject Initials: ---

Generated By:

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

(b) (4)

Affidavit:

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

(b) (6)	N/A	Nov-02-2020 10:35:32 (UTC-03:00) City of Buenos Aires		Edit - All signatures invalidated
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Affidavit:

N/A

(b) (6)	Approved	Oct-30-2020 15:44:28 (UTC-03:00) City of Buenos Aires	BOOK	Signed
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090177e196ae2e69\Final\Final On: 01-Apr-2021 03:12 (GMT)

Header Text: C4591001

Visit: Investigator Signature -
Unscheduled

Form: CASEBOOK SIGNATURE FORM - Signature
History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Verified

Site No: 1231

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

Subject No: 12313193

Subject Initials: ---

Generated By:

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

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

(b) (6)	N/A	Oct-27-2020 10:26:34 (UTC-03:00) City of Buenos Aires		Edit - All signatures invalidated
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Affidavit:

N/A

(b) (6)	Approved	Oct-23-2020 19:17:12 (UTC-03:00) City of Buenos Aires	BOOK	Signed
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090177e196ae2e69\Final\Final On: 01-Apr-2021 03:12 (GMT)

Header Text: C4591001

Visit: Investigator Signature -
Unscheduled

Form: CASEBOOK SIGNATURE FORM - Signature
History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Verified

Site No: 1231

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

Subject No: 12313193

Subject Initials: ---

Generated By:

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

(b) (4)

Affidavit:

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

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

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

(b) (6)	N/A	Oct-23-2020 08:17:56 (UTC-03:00) City of Buenos Aires		Edit - All signatures invalidated
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Affidavit:

N/A

(b) (6)	Approved	Oct-22-2020 18:11:37 (UTC-03:00) City of Buenos Aires	BOOK	Signed
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090177e196ae2e69\Final\Final On: 01-Apr-2021 03:12 (GMT)

Header Text: C4591001

Visit: Investigator Signature -
Unscheduled

Form Version: 22-Apr-2020 21:04

Site No: 1231

Subject No: 12313193

Generated By:

(b) (4)

Form: CASEBOOK SIGNATURE FORM - Signature
History

Form Status: Data Complete, Verified

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

Subject Initials: ---

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

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.

090177e196ae2e69\Final\Final On: 01-Apr-2021 03:12 (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: 12313193

Subject Initials: ---

Generated By:

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

(b) (4)

[Back to Form](#)

1. Select appropriate response - Protocol version

Date	Location	User	Value	Reason
Aug-22-2020 15:21:34 (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-22-2020 15:21:34 (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: 12313193

Generated By:

(b) (4)

Form: MAIN INFORMED CONSENT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

[Back to Form](#)

1. Consent Was:

Date	Location	User	Value	Reason
Aug-22-2020 15:21:39 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: OBTAINED Date Written Con sent Obtained Aug/22/2020	Initial Entry

090177e196ae2e69\Final\Final On: 01-Apr-2021 03:12 (GMT)

Header Text: C4591001

Visit: COHORT_SELECTION

Form Version: 06-Jul-2020 21:55

Site No: 1231

Subject No: 12313193

Generated By:

(b) (4)

Form: DEMOGRAPHY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

[Back to Form](#)

1. Subject ID

Date	Location	User	Value	Reason
Aug-22-2020 13:41:51 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 12313193	Item copied from previous form

2. Birth Date:

Date	Location	User	Value	Reason
Aug-22-2020 13:41:31 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: (b) (6) 1966	Enrollment Entry

3. Sex:

Date	Location	User	Value	Reason
Aug-22-2020 15:21:48 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: FEMALE	Initial Entry

4. Ethnicity:

Date	Location	User	Value	Reason
Aug-22-2020	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Initial Entry

090177e196ae2e69\Final\Final On: 01-Apr-2021 03:12 (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: 12313193

Subject Initials: ---

Generated By:

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

(b) (4)

15:21:48 (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-22-2020 15:21:48 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: WHITE	Initial Entry

090177e196ae2e69\Final\Final On: 01-Apr-2021 03:12 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:02

Site No: 1231

Subject No: 12313193

Generated By:

(b) (4)

Form: DATE OF VISIT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

[Back to Form](#)

1. Date of Visit

Date	Location	User	Value	Reason
Aug-22-2020 15:21:59 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Aug/22/2020	Initial Entry

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form: INCLUSION/EXCLUSION CRITERIA - eCRF
Audit Trail History

Form Version: 21-Aug-2020 02:50

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1231

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

Subject No: 12313193

Subject Initials: ---

Generated By:

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

(b) (4)

[Back to Form](#)

1.a

Date	Location	User	Value	Reason
Aug-22-2020 15:22:15 (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 teri on Des cription : Male or female participant s between th e ages of 18 and 55 years, 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 teri on met ?: YES</p>	Initial Entry

090177e196ae2e69\Final\Final On: 01-Apr-2021 03:12 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form: INCLUSION/EXCLUSION CRITERIA - eCRF
Audit Trail History

Form Version: 21-Aug-2020 02:50

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1231

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

Subject No: 12313193

Subject Initials: ---

Generated By:

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

(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-22-2020 15:22:15 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 1	Initial Entry

1.a Criterion Description:

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

090177e196ae2e69\Final\Final On: 01-Apr-2021 03:12 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form: INCLUSION/EXCLUSION CRITERIA - eCRF
Audit Trail History

Form Version: 21-Aug-2020 02:50

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1231

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

Subject No: 12313193

Subject Initials: ---

Generated By:

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

(b) (4)

dependent upon study stage)

1.a Criterion met?

Date	Location	User	Value	Reason
Aug-22-2020 15:22:15 (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-22-2020 15:22:15 (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-22-2020 15:22:15 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Incl 2 usio n N um ber:	Initial Entry

090177e196ae2e69\Final\Final On: 01-Apr-2021 03:12 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 21-Aug-2020 02:50

Site No: 1231

Subject No: 12313193

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 20:20

			<p>Crit Participants erio who are willi n D ng and able t eser 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 Pfizer er u se o nly) :</p>	
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090177e196ae2e69\Final\Final On: 01-Apr-2021 03:12 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form: INCLUSION/EXCLUSION CRITERIA - eCRF
Audit Trail History

Form Version: 21-Aug-2020 02:50

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1231

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

Subject No: 12313193

Subject Initials: ---

Generated By:

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

(b) (4)

1.b Inclusion Number:

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

090177e196ae2e69\Final\Final On: 01-Apr-2021 03:12 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form: INCLUSION/EXCLUSION CRITERIA - eCRF
Audit Trail History

Form Version: 21-Aug-2020 02:50

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1231

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

Subject No: 12313193

Subject Initials: ---

Generated By:

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

(b) (4)

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

Date	Location	User	Value	Reason
Aug-22-2020 15:22:15 (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-22-2020 15:22:15 (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

090177e196ae2e69\Final\Final On: 01-Apr-2021 03:12 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form: INCLUSION/EXCLUSION CRITERIA - eCRF
Audit Trail History

Form Version: 21-Aug-2020 02:50

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1231

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

Subject No: 12313193

Subject Initials: ---

Generated By:

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

(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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090177e196ae2e69\Final\Final On: 01-Apr-2021 03:12 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form: INCLUSION/EXCLUSION CRITERIA - eCRF
Audit Trail History

Form Version: 21-Aug-2020 02:50

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1231

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

Subject No: 12313193

Subject Initials: ---

Generated By:

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

(b) (4)

I.c Inclusion Number:

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

090177e196ae2e69\Final\Final On: 01-Apr-2021 03:12 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form: INCLUSION/EXCLUSION CRITERIA - eCRF
Audit Trail History

Form Version: 21-Aug-2020 02:50

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1231

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

Subject No: 12313193

Subject Initials: ---

Generated By:

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

(b) (4)

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

Date	Location	User	Value	Reason
Aug-22-2020 15:22:15 (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-22-2020 15:22:15 (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

090177e196ae2e69\Final\Final On: 01-Apr-2021 03:12 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 21-Aug-2020 02:50

Site No: 1231

Subject No: 12313193

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 20:20

			Crit YES erio n m et?: Crit IN04A00 erio n I D: (For Pfiz er u se o nly) :	
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090177e196ae2e69\Final\Final On: 01-Apr-2021 03:12 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form: INCLUSION/EXCLUSION CRITERIA - eCRF
Audit Trail History

Form Version: 21-Aug-2020 02:50

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1231

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

Subject No: 12313193

Subject Initials: ---

Generated By:

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

(b) (4)

1.d Inclusion Number:

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

090177e196ae2e69\Final\Final On: 01-Apr-2021 03:12 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form: INCLUSION/EXCLUSION CRITERIA - eCRF
Audit Trail History

Form Version: 21-Aug-2020 02:50

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1231

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

Subject No: 12313193

Subject Initials: ---

Generated By:

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

(b) (4)

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

Date	Location	User	Value	Reason
Aug-22-2020 15:22:15 (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-22-2020 15:22:15 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Exc 1 lusi on Nu mb er:	Initial Entry

090177e196ae2e69\Final\Final On: 01-Apr-2021 03:12 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form: INCLUSION/EXCLUSION CRITERIA - eCRF
Audit Trail History

Form Version: 21-Aug-2020 02:50

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1231

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

Subject No: 12313193

Subject Initials: ---

Generated By:

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

(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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090177e196ae2e69\Final\Final On: 01-Apr-2021 03:12 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form: INCLUSION/EXCLUSION CRITERIA - eCRF
Audit Trail History

Form Version: 21-Aug-2020 02:50

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1231

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

Subject No: 12313193

Subject Initials: ---

Generated By:

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

(b) (4)

Aug-22-2020 15:22:15 (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-22-2020 15:22:15 (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-22-2020 15:22:15 (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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090177e196ae2e69\Final\Final On: 01-Apr-2021 03:12 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form: INCLUSION/EXCLUSION CRITERIA - eCRF
Audit Trail History

Form Version: 21-Aug-2020 02:50

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1231

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

Subject No: 12313193

Subject Initials: ---

Generated By:

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

(b) (4)

Aug-22-2020 15:22:15 (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-22-2020 15:22:15 (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

090177e196ae2e69\Final\Final On: 01-Apr-2021 03:12 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 21-Aug-2020 02:50

Site No: 1231

Subject No: 12313193

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 20:20

			Crit EX02A00	
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			n ID	
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			zer u	
			se on	
			ly):	

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form: INCLUSION/EXCLUSION CRITERIA - eCRF
Audit Trail History

Form Version: 21-Aug-2020 02:50

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1231

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

Subject No: 12313193

Subject Initials: ---

Generated By:

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

(b) (4)

2.b Exclusion Number:

Date	Location	User	Value	Reason
Aug-22-2020 15:22:15 (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-22-2020 15:22:15 (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-22-2020 15:22:15 (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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090177e196ae2e69\Final\Final On: 01-Apr-2021 03:12 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form: INCLUSION/EXCLUSION CRITERIA - eCRF
Audit Trail History

Form Version: 21-Aug-2020 02:50

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1231

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

Subject No: 12313193

Subject Initials: ---

Generated By:

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

(b) (4)

Aug-22-2020 15:22:15 (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-22-2020 15:22:15 (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

090177e196ae2e69\Final\Final On: 01-Apr-2021 03:12 (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: 12313193

Subject Initials: ---

Generated By:

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

(b) (4)

			<p>Crit NO erion m et?: Crit EX03A00 erion n I D: (For Pfizer use only) :</p>	
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090177e196ae2e69\Final\Final On: 01-Apr-2021 03:12 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form: INCLUSION/EXCLUSION CRITERIA - eCRF
Audit Trail History

Form Version: 21-Aug-2020 02:50

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1231

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

Subject No: 12313193

Subject Initials: ---

Generated By:

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

(b) (4)

2.c Exclusion Number:

Date	Location	User	Value	Reason
Aug-22-2020 15:22:15 (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-22-2020 15:22:15 (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-22-2020 15:22:15 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

090177e196ae2e69\Final\Final On: 01-Apr-2021 03:12 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form: INCLUSION/EXCLUSION CRITERIA - eCRF
Audit Trail History

Form Version: 21-Aug-2020 02:50

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1231

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

Subject No: 12313193

Subject Initials: ---

Generated By:

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

(b) (4)

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

Date	Location	User	Value	Reason
Aug-22-2020 15:22:15 (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-22-2020 15:22:15 (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

090177e196ae2e69\Final\Final On: 01-Apr-2021 03:12 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form: INCLUSION/EXCLUSION CRITERIA - eCRF
Audit Trail History

Form Version: 21-Aug-2020 02:50

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1231

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

Subject No: 12313193

Subject Initials: ---

Generated By:

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

(b) (4)

2.d Exclusion Number:

Date	Location	User	Value	Reason
Aug-22-2020 15:22:15 (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-22-2020 15:22:15 (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-22-2020 15:22:15 (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-22-2020 15:22:15 (UTC-03:00) City	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: EX04A00	Initial Entry

090177e196ae2e69\Final\Final On: 01-Apr-2021 03:12 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form: INCLUSION/EXCLUSION CRITERIA - eCRF
Audit Trail History

Form Version: 21-Aug-2020 02:50

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1231

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

Subject No: 12313193

Subject Initials: ---

Generated By:

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

(b) (4)

of Buenos Aires

2.e

Date	Location	User	Value	Reason
Aug-22-2020 15:22:15 (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

090177e196ae2e69\Final\Final On: 01-Apr-2021 03:12 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 21-Aug-2020 02:50

Site No: 1231

Subject No: 12313193

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 20:20

			Crit EX08A00 erion ID : (F or P fize r us e on ly):	
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090177e196ae2e69\Final\Final On: 01-Apr-2021 03:12 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form: INCLUSION/EXCLUSION CRITERIA - eCRF
Audit Trail History

Form Version: 21-Aug-2020 02:50

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1231

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

Subject No: 12313193

Subject Initials: ---

Generated By:

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

(b) (4)

2.e Exclusion Number:

Date	Location	User	Value	Reason
Aug-22-2020 15:22:15 (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-22-2020 15:22:15 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Immunocompromised individuals with known or suspected immunodeficiency, as determined by history and/or laboratory/physical examination	Initial Entry

2.e Criterion met?

Date	Location	User	Value	Reason
Aug-22-2020 15:22:15 (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)

090177e196ae2e69\Final\Final On: 01-Apr-2021 03:12 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form: INCLUSION/EXCLUSION CRITERIA - eCRF
Audit Trail History

Form Version: 21-Aug-2020 02:50

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1231

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

Subject No: 12313193

Subject Initials: ---

Generated By:

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

(b) (4)

Date	Location	User	Value	Reason
Aug-22-2020 15:22:15 (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-22-2020 15:22:15 (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

090177e196ae2e69\Final\Final On: 01-Apr-2021 03:12 (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: 12313193

Subject Initials: ---

Generated By:

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

(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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090177e196ae2e69\Final\Final On: 01-Apr-2021 03:12 (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

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

Subject No: 12313193

Subject Initials: ---

Generated By:

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

(b) (4)

2.f Exclusion Number:

Date	Location	User	Value	Reason
Aug-22-2020 15:22:15 (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-22-2020 15:22:15 (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-22-2020 15:22:15 (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)

090177e196ae2e69\Final\Final On: 01-Apr-2021 03:12 (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
Mayor Dr. Cosme Argerich

Subject No: 12313193

Subject Initials: ---

Generated By:

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

(b) (4)

Date	Location	User	Value	Reason
Aug-22-2020 15:22:15 (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-22-2020 15:22:15 (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

090177e196ae2e69\Final\Final On: 01-Apr-2021 03:12 (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: 12313193

Subject Initials: ---

Generated By:

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

(b) (4)

2.g Exclusion Number:

Date	Location	User	Value	Reason
Aug-22-2020 15:22:15 (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-22-2020 15:22:15 (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-22-2020 15:22:15 (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-22-2020 15:22:15 (UTC-03:00) City	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: EX11A00	Initial Entry

090177e196ae2e69\Final\Final On: 01-Apr-2021 03:12 (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: 12313193

Subject Initials: ---

Generated By:

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

(b) (4)

of Buenos Aires

2.h

Date	Location	User	Value	Reason
Aug-22-2020 15:22:15 (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: EX12A0</p> <p>(For Printer use only):</p>	Initial Entry

090177e196ae2e69\Final\Final On: 01-Apr-2021 03:12 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form: INCLUSION/EXCLUSION CRITERIA - eCRF
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Mayor Dr. Cosme Argerich

Subject No: 12313193

Subject Initials: ---

Generated By:

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(b) (4)

2.h Exclusion Number:

Date	Location	User	Value	Reason
Aug-22-2020 15:22:15 (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-22-2020 15:22:15 (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-22-2020 15:22:15 (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-22-2020 15:22:15 (UTC-03:00) City	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: EX12A00	Initial Entry

090177e196ae2e69\Final\Final On: 01-Apr-2021 03:12 (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: 12313193

Subject Initials: ---

Generated By:

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

(b) (4)

of Buenos Aires

2.i

Date	Location	User	Value	Reason
Aug-22-2020 15:22:15 (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

090177e196ae2e69\Final\Final On: 01-Apr-2021 03:12 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 21-Aug-2020 02:50

Site No: 1231

Subject No: 12313193

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 20:20

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

Visit: V1_DAY1_VAX1_L

Form: INCLUSION/EXCLUSION CRITERIA - eCRF
Audit Trail History

Form Version: 21-Aug-2020 02:50

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1231

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

Subject No: 12313193

Subject Initials: ---

Generated By:

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

(b) (4)

2.i Exclusion Number:

Date	Location	User	Value	Reason
Aug-22-2020 15:22:15 (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-22-2020 15:22:15 (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-22-2020 15:22:15 (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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090177e196ae2e69\Final\Final On: 01-Apr-2021 03:12 (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: 12313193

Subject Initials: ---

Generated By:

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

(b) (4)

Aug-22-2020 15:22:15 (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-22-2020 15:22:15 (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

090177e196ae2e69\Final\Final On: 01-Apr-2021 03:12 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

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Site No: 1231

Subject No: 12313193

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 20:20

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090177e196ae2e69\Final\Final On: 01-Apr-2021 03:12 (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: 12313193

Subject Initials: ---

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

(b) (4)

2.j Exclusion Number:

Date	Location	User	Value	Reason
Aug-22-2020 15:22:15 (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-22-2020 15:22:15 (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-22-2020 15:22:15 (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)

090177e196ae2e69\Final\Final On: 01-Apr-2021 03:12 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

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Mayor Dr. Cosme Argerich

Subject No: 12313193

Subject Initials: ---

Generated By:

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

(b) (4)

Date	Location	User	Value	Reason
Aug-22-2020 15:22:15 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: EX14A01	Initial Entry

090177e196ae2e69\Final\Final On: 01-Apr-2021 03:12 (GMT)

Header Text: C4591001

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Form: INCLUSION/EXCLUSION CRITERIA - eCRF
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Form Version: 21-Aug-2020 02:50

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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Generated By:

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(b) (4)

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2.k

Date	Location	User	Value	Reason
Aug-22-2020 15:22:15 (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

090177e196ae2e69\Final\Final On: 01-Apr-2021 03:12 (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: 12313193

Subject Initials: ---

Generated By:

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

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090177e196ae2e69\Final\Final On: 01-Apr-2021 03:12 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form: INCLUSION/EXCLUSION CRITERIA - eCRF
Audit Trail History

Form Version: 21-Aug-2020 02:50

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1231

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

Subject No: 12313193

Subject Initials: ---

Generated By:

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

(b) (4)

2.k Exclusion Number:

Date	Location	User	Value	Reason
Aug-22-2020 15:22:15 (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-22-2020 15:22:15 (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-22-2020 15:22:15 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

090177e196ae2e69\Final\Final On: 01-Apr-2021 03:12 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form: INCLUSION/EXCLUSION CRITERIA - eCRF
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Form Version: 21-Aug-2020 02:50

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1231

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

Subject No: 12313193

Subject Initials: ---

Generated By:

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(b) (4)

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

Date	Location	User	Value	Reason
Aug-22-2020 15:22:15 (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-22-2020 15:22:15 (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

090177e196ae2e69\Final\Final On: 01-Apr-2021 03:12 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 21-Aug-2020 02:50

Site No: 1231

Subject No: 12313193

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: ---

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Header Text: C4591001

Visit: V1_DAY1_VAX1_L

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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: 12313193

Subject Initials: ---

Generated By:

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

(b) (4)

2.1 Exclusion Number:

Date	Location	User	Value	Reason
Aug-22-2020 15:22:15 (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-22-2020 15:22:15 (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-22-2020 15:22:15 (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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Header Text: C4591001

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Mayor Dr. Cosme Argerich

Subject No: 12313193

Subject Initials: ---

Generated By:

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(b) (6)

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

090177e196ae2e69\Final\Final On: 01-Apr-2021 03:12 (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

Subject No: 12313193

Subject Initials: ---

Generated By:

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

(b) (4)

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Site No: 1231

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

Subject No: 12313193

Subject Initials: ---

Generated By:

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(b) (4)

2.m Exclusion Number:

Date	Location	User	Value	Reason
Aug-22-2020 15:22:15 (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-22-2020 15:22:15 (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-22-2020 15:22:15 (UTC-03:00)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

090177e196ae2e69\Final\Final On: 01-Apr-2021 03:12 (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: 12313193

Subject Initials: ---

Generated By:

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

(b) (4)

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

Date	Location	User	Value	Reason
Aug-22-2020 15:22:15 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: EX21A01	Initial Entry

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Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1231

Subject No: 12313193

Generated By:

(b) (4)

Form: DISPOSITION - SCREENING - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

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1. Date of Completion/Discontinuation/Death

Date	Location	User	Value	Reason
Aug-22-2020 15:22:23 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Aug/22/2020	Initial Entry

2. Phase of Disposition:

Date	Location	User	Value	Reason
Aug-22-2020 15:22:23 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SCREENING	Initial Entry

3. Status:

Date	Location	User	Value	Reason
Aug-22-2020 15:22:23 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: COMPLETED	Initial Entry

090177e196ae2e69\Final\Final On: 01-Apr-2021 03:12 (GMT)

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Site No: 1231

Subject No: 12313193

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: ---

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1.a

Date	Location	User	Value	Reason
Nov-27-2020 19:11:34 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Line/M 1 H Number: Medical History Term: intermittent gross hematuria Start Date: Jan/14/2020 Ongoing: YES :	New Information
Oct-14-2020 17:12:12 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/M 1 H Number: Medical History Term: intermittent gross hematuria Start Date: Jul/UNK/2020 Ongoing: YES :	Initial Entry

090177e196ae2e69\Final\Final On: 01-Apr-2021 03:12 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form: GENERAL MEDICAL HISTORY - 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: 12313193

Subject Initials: ---

Generated By:

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

(b) (4)

1.a Line/MH Number:

Date	Location	User	Value	Reason
Oct-14-2020 17:12:12 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 1	Initial Entry

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

Date	Location	User	Value	Reason
Oct-30-2020 20:47:37 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Closed	Response satisfies query
Oct-29-2020 20:20:07 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Answered	Yes, it was sent on 27OCT2020, in which the dates of the events are clarified
Oct-29-2020 14:59:29 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Reissued:Opened	Clinical Did the center FAX in a SAE safety followup with the correct date of July 2020 for hematuria?

090177e196ae2e69\Final\Final On: 01-Apr-2021 03:12 (GMT)

Header Text: C4591001

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Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

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Site No: 1231

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

Subject No: 12313193

Subject Initials: ---

Generated By:

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(b) (4)

<p>Oct-29-2020 12:44:53 (UTC-03:00) City of Buenos Aires</p>	<p>ACV0PFEINFP6000</p>	<p>(b) (4), (b) (6)</p>	<p>Query 2: Answered</p>	<p>Date 14Jan2020 for medical history of hematuria is a loading mistake, date was corrected in medical records, the correct date is July 2020 Thank you</p>
<p>Oct-28-2020 11:52:53 (UTC-03:00) City of Buenos Aires</p>	<p>ACV0PFEINFP6000</p>	<p>(b) (4), (b) (6)</p>	<p>Query 2: Reissued:Opened</p>	<p>Clinical Please update SAE, which states "The medical history included hematuria from 14Jan2020 and ongoing (subject referred that she had an isolated hematuria episode on 14Jan2020 that resolved spontaneously."</p>
<p>Oct-27-2020 11:13:20 (UTC-03:00) City of Buenos</p>	<p>ACV0PFEINFP6000</p>	<p>(b) (4), (b) (6)</p>	<p>Query 2: Answered</p>	<p>It is clarified that the adverse event Hematuria, is</p>

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

Subject No: 12313193

Subject Initials: ---

Generated By:

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(b) (4)

Aires				referred by the volunteer as antecedents since July 2020, without knowing how to refer to the exact day. The January start date is wrong. Thank you
Oct-26-2020 14:13:25 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Reissued:Opened	CLINICAL With July20 onset date for hematuria, PLEASE UPDATE the SAE which has "Med Hx included hematuria from 14Jan20 ... isolated hematuria episode on 14Jan2020 that resolved spontaneously. Hematuria returned on 25Aug20."

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Subject Initials: ---

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(b) (4)

Oct-23-2020 19:03:10 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Answered	The correct date is July 2020 as the medical history document it. Thank you
Oct-23-2020 16:00:36 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Reissued:Opened	Clinical - onset dates for gross hematuria do not match (Jan 2020 in SAE/Jul2020 2020 in AE); please review and match the onset date, reporting whichever is correct in both SAE and AE
Oct-22-2020 13:19:13 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Answered	Original value is correct
Oct-21-2020 15:00:47 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Opened	CLINICAL SAE report med Hx states subject had 1 episode of gross

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Site No: 1231

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

Subject No: 12313193

Subject Initials: ---

Generated By:

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(b) (4)

				hematuria on 14 Jan 2020. Please review term 'Intermittent Gross Hematuria) and onset; if correct then please update from July 2020 onset (goes to medical stability)
Oct-16-2020 16:45:19 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	Samuel Dychter (b) (4)	Query 1: Closed	Response satisfies query
Oct-16-2020 10:48:40 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	No etiology till today
Oct-15-2020 14:43:09 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	Samuel Dychter (b) (4)	Query 1: Opened	GPD Clin: Has an etiology been identified for the gross hematuria?
Oct-14-2020 17:12:12	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: intermittent gros	Initial Entry

090177e196ae2e69\Final\Final On: 01-Apr-2021 03:12 (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: 12313193

Subject Initials: ---

Generated By:

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

(b) (4)

(UTC-03:00) City of Buenos Aires			s hematuria	
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1.a Start Date:

Date	Location	User	Value	Reason
Dec-02-2020 13:11:50 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Nov-27-2020 19:11:34 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	New Information
Nov-27-2020 19:11:34 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Jan/14/2020	New Information
Nov-27-2020 08:40:42 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	Clin: Please confirm start date of this medical history as entry related to SAE report states that this symptom started on 14th January 2020

090177e196ae2e69\Final\Final On: 01-Apr-2021 03:12 (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: 12313193

Subject Initials: ---

Generated By:

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

(b) (4)

Oct-14-2020 17:12:12 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Jul/UNK/2020	Initial Entry
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1.a Ongoing:

Date	Location	User	Value	Reason
Oct-14-2020 17:12:12 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

090177e196ae2e69\Final\Final On: 01-Apr-2021 03:12 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form: VITAL SIGNS - BASELINE - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:51

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1231

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

Subject No: 12313193

Subject Initials: ---

Generated By:

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

(b) (4)

[Back to Form](#)

1. Date:

Date	Location	User	Value	Reason
Aug-22-2020 15:23:03 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Aug/22/2020	Initial Entry

2. Weight:

Date	Location	User	Value	Reason
Aug-22-2020 15:23:03 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 52.05	Initial Entry

3. Unit:

Date	Location	User	Value	Reason
Aug-22-2020 15:23:03 (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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090177e196ae2e69\Final\Final On: 01-Apr-2021 03:12 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form: VITAL SIGNS - BASELINE - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:51

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1231

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

Subject No: 12313193

Subject Initials: ---

Generated By:

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

(b) (4)

Aug-22-2020 15:23:03 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 167.0	Initial Entry
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5. Unit:

Date	Location	User	Value	Reason
Aug-22-2020 15:23:03 (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-22-2020 15:23:03 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 18.7	Initial Entry

7.a

Date	Location	User	Value	Reason
Aug-22-2020 15:23:03 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Record I 1 dentifier: : Temperat 36.6 ure:	Initial Entry

090177e196ae2e69\Final\Final On: 01-Apr-2021 03:12 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form: VITAL SIGNS - BASELINE - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:51

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1231

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

Subject No: 12313193

Subject Initials: ---

Generated By:

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

(b) (4)

			Temperat C ure Unit: Temperat ORAL ure Locat CAVI ion:: TY	
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7.a Record Identifier:

Date	Location	User	Value	Reason
Aug-22-2020 15:23:03 (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-22-2020 15:23:03 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 36.6	Initial Entry

7.a Unit:

Date	Location	User	Value	Reason
Aug-22-2020 15:23:03 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: C	Initial Entry

090177e196ae2e69\Final\Final On: 01-Apr-2021 03:12 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form: VITAL SIGNS - BASELINE - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:51

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1231

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

Subject No: 12313193

Subject Initials: ---

Generated By:

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

(b) (4)

7.a Temperature Location:

Date	Location	User	Value	Reason
Aug-22-2020 15:23:03 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: ORAL CAVITY	Initial Entry

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

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

Form Version: 21-Aug-2020 02:49

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1231

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

Subject No: 12313193

Subject Initials: ---

Generated By:

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

(b) (4)

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1. Lab Panel:

Date	Location	User	Value	Reason
Aug-22-2020 15:23:11 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: URINALYSIS	Initial Entry

2. Lab Sub-Panel:

Date	Location	User	Value	Reason
Aug-22-2020 15:23:11 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: PREGNANCY	Initial Entry

3. Collection Date:

Date	Location	User	Value	Reason
Aug-22-2020 15:23:11 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Aug/22/2020	Initial Entry

4. Laboratory Name and Address (Derived)

Date	Location	User	Value	Reason
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090177e196ae2e69\Final\Final On: 01-Apr-2021 03:12 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

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

Form Version: 21-Aug-2020 02:49

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1231

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

Subject No: 12313193

Subject Initials: ---

Generated By:

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

(b) (4)

Aug-22-2020 15:23:11 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: STUDY SITE	Initial Entry
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5. Specimen Type:

Date	Location	User	Value	Reason
Aug-22-2020 15:23:11 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: URINE	Initial Entry

6.a

Date	Location	User	Value	Reason
Aug-22-2020 15:23:11 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sponsor- 113 Defined I dentifier: Test:: Choriogon adotropin Beta_PX11 3 Result:: NEGATIV E Not Done ::	Initial Entry

6.a Sponsor ID:

090177e196ae2e69\Final\Final On: 01-Apr-2021 03:12 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

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

Form Version: 21-Aug-2020 02:49

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1231

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

Subject No: 12313193

Subject Initials: ---

Generated By:

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

(b) (4)

Date	Location	User	Value	Reason
Aug-22-2020 15:23:11 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 113	Initial Entry

6.a Test:

Date	Location	User	Value	Reason
Aug-22-2020 15:23:11 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Choriogonadotropi n Beta_PX113	Initial Entry

6.a Result:

Date	Location	User	Value	Reason
Aug-22-2020 15:23:11 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NEGATIVE	Initial Entry

090177e196ae2e69\Final\Final On: 01-Apr-2021 03:12 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1231

Subject No: 12313193

Generated By:

(b) (4)

Form: RANDOMIZATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

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1. Randomization Date :

Date	Location	User	Value	Reason
Aug-22-2020 15:23:17 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Aug/22/2020	Initial Entry

2. Randomization Number:

Date	Location	User	Value	Reason
Aug-22-2020 15:23:17 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 62077	Initial Entry

090177e196ae2e69\Final\Final On: 01-Apr-2021 03:12 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1231

Subject No: 12313193

Generated By:

(b) (4)

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

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

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1. Data Origin

Date	Location	User	Value	Reason
Aug-22-2020 15:23:24 (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-22-2020 15:23:24 (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-29-2020 15:52:17 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Aug-24-2020 02:52:40 (UTC-03:00)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Query 1: Opened	'Sample Collected?' is Yes, however

090177e196ae2e69\Final\Final On: 01-Apr-2021 03:12 (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: 12313193

Subject Initials: ---

Generated By:

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

(b) (4)

City of Buenos Aires				no barcodes are entered. Please review and correct as appropriate.
Aug-22-2020 15:23:24 (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-22-2020 15:23:24 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Date of Collection: Aug/22/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Aug-29-2020 15:52:17 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID BJ49Z : M	Initial Entry

5.a Sample ID

090177e196ae2e69\Final\Final On: 01-Apr-2021 03:12 (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: 12313193

Subject Initials: ---

Generated By:

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

(b) (4)

Date	Location	User	Value	Reason
Aug-29-2020 15:52:17 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BJ49ZM	Initial Entry

5.b

Date	Location	User	Value	Reason
Aug-29-2020 15:52:28 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID BJ49Z : N	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Aug-29-2020 15:52:28 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BJ49ZN	Initial Entry

5.c

Date	Location	User	Value	Reason
Aug-29-2020 15:52:41 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID BJ49Z : P	Initial Entry

090177e196ae2e69\Final\Final On: 01-Apr-2021 03:12 (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: 12313193

Subject Initials: ---

Generated By:

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

(b) (4)

5.c Sample ID

Date	Location	User	Value	Reason
Aug-29-2020 15:52:41 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BJ49ZP	Initial Entry

5.d

Date	Location	User	Value	Reason
Aug-29-2020 17:48:47 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample I BHY6M D: H	Initial Entry

5.d Sample ID

Date	Location	User	Value	Reason
Aug-29-2020 17:48:47 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BHY6MH	Initial Entry

5.e

Date	Location	User	Value	Reason
Aug-29-2020 17:48:52 (UTC-03:00) City	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample I BHY6 D: MJ	Initial Entry

090177e196ae2e69\Final\Final On: 01-Apr-2021 03:12 (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: 12313193

Subject Initials: ---

Generated By:

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

(b) (4)

of Buenos Aires

5.e Sample ID

Date	Location	User	Value	Reason
Aug-29-2020 17:48:52 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BHY6MJ	Initial Entry

5.f

Date	Location	User	Value	Reason
Aug-29-2020 17:48:57 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample I BHY6M D: K	Initial Entry

5.f Sample ID

Date	Location	User	Value	Reason
Aug-29-2020 17:48:57 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BHY6MK	Initial Entry

090177e196ae2e69\Final\Final On: 01-Apr-2021 03:12 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1231

Subject No: 12313193

Generated By:

(b) (4)

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

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

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1. Data Origin

Date	Location	User	Value	Reason
Aug-22-2020 15:23:30 (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-22-2020 15:23:30 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: NASAL_SWAB	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Aug-28-2020 22:18:26 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Aug-24-2020 02:52:40 (UTC-03:00)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Query 1: Opened	'Sample Collected?' is Yes, however

090177e196ae2e69\Final\Final On: 01-Apr-2021 03:12 (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: 12313193

Subject Initials: ---

Generated By:

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

(b) (4)

City of Buenos Aires				no barcodes are entered. Please review and correct as appropriate.
Aug-22-2020 15:23:30 (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-22-2020 15:23:30 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Date of Collection: Aug/22/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Aug-28-2020 22:18:26 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample I BP2CS D: V	Initial Entry

5.a Sample ID

090177e196ae2e69\Final\Final On: 01-Apr-2021 03:12 (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: 12313193

Subject Initials: ---

Generated By:

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

(b) (4)

Date	Location	User	Value	Reason
Aug-28-2020 22:18:26 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BP2CSV	Initial Entry

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:04

Site No: 1231

Subject No: 12313193

Generated By:

(b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

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1. Was there a temporary delay of vaccination?

Date	Location	User	Value	Reason
Aug-22-2020 15:23:40 (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-22-2020 15:23:40 (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-22-2020 15:23:40 (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-22-2020	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Initial Entry

090177e196ae2e69\Final\Final On: 01-Apr-2021 03:12 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:04

Site No: 1231

Subject No: 12313193

Generated By:

(b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

15:23:40
(UTC-03:00) City
of Buenos Aires

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

Aug/22/2020 14:4
0

5. Anatomical Location:

Date	Location	User	Value	Reason
Aug-22-2020 15:23:40 (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-22-2020 15:23:40 (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-22-2020 15:23:40 (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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090177e196ae2e69\Final\Final On: 01-Apr-2021 03:12 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:04

Site No: 1231

Subject No: 12313193

Generated By:

(b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

Aug-22-2020 15:23:40 (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-22-2020 15:23:40 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

090177e196ae2e69\Final\Final On: 01-Apr-2021 03:12 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 06-Jul-2020 21:53

Site No: 1231

Subject No: 12313193

Generated By:

(b) (4)

Form: REACTOGENICITY DIARY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

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1. Select appropriate response - Reactogenicity diary collection

Date	Location	User	Value	Reason
Aug-22-2020 15:23:52 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO - REACTOGE NICITY E-DIARY NOT COLLECTE D FOR THIS SUB JECT	Initial Entry

090177e196ae2e69\Final\Final On: 01-Apr-2021 03:12 (GMT)

Header Text: C4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:02

Site No: 1231

Subject No: 12313193

Generated By:

(b) (4)

Form: DATE OF VISIT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

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1. Date of Visit

Date	Location	User	Value	Reason
Sep-10-2020 16:46:19 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sep/10/2020	Initial Entry

090177e196ae2e69\Final\Final On: 01-Apr-2021 03:12 (GMT)

Header Text: C4591001

Visit: V2_VAX2_L

Form Version: 21-Aug-2020 02:51

Site No: 1231

Subject No: 12313193

Generated By:

(b) (4)

Form: VITAL SIGNS - TEMP - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

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1. Date:

Date	Location	User	Value	Reason
Sep-10-2020 16:46:32 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sep/10/2020	Initial Entry

2.a

Date	Location	User	Value	Reason
Sep-10-2020 16:46:32 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Record Identifier: : Temperature: Temperature Unit: Temperature Location: Temperature Unit:	Initial Entry

2.a Record Identifier:

Date	Location	User	Value	Reason
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090177e196ae2e69\Final\Final On: 01-Apr-2021 03:12 (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: 12313193

Subject Initials: ---

Generated By:

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

(b) (4)

Sep-10-2020 16:46:32 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 1	Initial Entry
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2.a Temperature:

Date	Location	User	Value	Reason
Sep-10-2020 16:46:32 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 36.8	Initial Entry

2.a Unit:

Date	Location	User	Value	Reason
Sep-10-2020 16:46:32 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: C	Initial Entry

2.a Temperature Location:

Date	Location	User	Value	Reason
Sep-10-2020 16:46:32 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: ORAL CAVITY	Initial Entry

090177e196ae2e69\Final\Final On: 01-Apr-2021 03:12 (GMT)

Header Text: C4591001

Visit: V2_VAX2_L

Form Version: 21-Aug-2020 02:51

Site No: 1231

Subject No: 12313193

Generated By:

(b) (4)

Form: VITAL SIGNS - TEMP - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

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Header Text: C4591001

Visit: V2_VAX2_L

Form Version: 21-Aug-2020 02:49

Site No: 1231

Subject No: 12313193

Generated By:

(b) (4)

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

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

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1. Lab Panel:

Date	Location	User	Value	Reason
Sep-10-2020 16:46:47 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: URINALYSIS	Initial Entry

2. Lab Sub-Panel:

Date	Location	User	Value	Reason
Sep-10-2020 16:46:47 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: PREGNANCY	Initial Entry

3. Collection Date:

Date	Location	User	Value	Reason
Sep-10-2020 16:46:47 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6) [Redacted]	Data Entry: Sep/10/2020	Initial Entry

4. Laboratory Name and Address (Derived)

Date	Location	User	Value	Reason
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090177e196ae2e69\Final\Final On: 01-Apr-2021 03:12 (GMT)

Header Text: C4591001

Visit: V2_VAX2_L

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

Form Version: 21-Aug-2020 02:49

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1231

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

Subject No: 12313193

Subject Initials: ---

Generated By:

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

(b) (4)

Sep-10-2020 16:46:47 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: STUDY SITE	Initial Entry
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5. Specimen Type:

Date	Location	User	Value	Reason
Sep-10-2020 16:46:47 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: URINE	Initial Entry

6.a

Date	Location	User	Value	Reason
Sep-10-2020 16:46:47 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sponsor- 113 Defined Identifier: Test:: Choriogon adotropin Beta_PX11 3 Result:: NEGATIV E Not Done ::	Initial Entry

6.a Sponsor ID:

090177e196ae2e69\Final\Final On: 01-Apr-2021 03:12 (GMT)

Header Text: C4591001

Visit: V2_VAX2_L

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

Form Version: 21-Aug-2020 02:49

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1231

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

Subject No: 12313193

Subject Initials: ---

Generated By:

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

(b) (4)

Date	Location	User	Value	Reason
Sep-10-2020 16:46:47 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 113	Initial Entry

6.a Test:

Date	Location	User	Value	Reason
Sep-10-2020 16:46:47 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Choriogonadotropin Beta_PX113	Initial Entry

6.a Result:

Date	Location	User	Value	Reason
Sep-10-2020 16:46:47 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NEGATIVE	Initial Entry

090177e196ae2e69\Final\Final On: 01-Apr-2021 03:12 (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: 12313193

Subject Initials: ---

Generated By:

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

(b) (4)

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1. Data Origin

Date	Location	User	Value	Reason
Sep-10-2020 16:46:54 (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-10-2020 16:46:54 (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-11-2020 13:35:25 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Sep-11-2020 03:13:02 (UTC-03:00)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	'Sample Collected?' is Yes, however

090177e196ae2e69\Final\Final On: 01-Apr-2021 03:12 (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: 12313193

Subject Initials: ---

Generated By:

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

(b) (4)

City of Buenos Aires				no barcodes are entered. Please review and correct as appropriate.
Sep-10-2020 16:46:54 (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-10-2020 16:46:54 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Date of Collection: Sep/10/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Sep-11-2020 13:35:25 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample I BP23Z D: Y	Initial Entry

5.a Sample ID

090177e196ae2e69\Final\Final On: 01-Apr-2021 03:12 (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: 12313193

Subject Initials: ---

Generated By:

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

(b) (4)

Date	Location	User	Value	Reason
Sep-11-2020 13:35:25 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Data Entry: BP23ZY	Initial Entry

Header Text: C4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:04

Site No: 1231

Subject No: 12313193

Generated By:

(b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

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1. Was there a temporary delay of vaccination?

Date	Location	User	Value	Reason
Sep-10-2020 16:47:05 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2. Treatment Name

Date	Location	User	Value	Reason
Sep-10-2020 16:47:05 (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-10-2020 16:47:05 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: INJECTION	Initial Entry

4. Dose Date Time:

Date	Location	User	Value	Reason
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090177e196ae2e69\Final\Final On: 01-Apr-2021 03:12 (GMT)

Header Text: C4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:04

Site No: 1231

Subject No: 12313193

Generated By:

(b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

Sep-10-2020 16:47:05 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sep/10/2020 15:35	Initial Entry
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5. Anatomical Location:

Date	Location	User	Value	Reason
Sep-10-2020 16:47:05 (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-10-2020 16:47:05 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: LEFT	Initial Entry

7. Route:

Date	Location	User	Value	Reason
Sep-10-2020 16:47:05 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: INTRAMUSCULAR	Initial Entry

090177e196ae2e69\Final\Final On: 01-Apr-2021 03:12 (GMT)

Header Text: C4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:04

Site No: 1231

Subject No: 12313193

Generated By:

(b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

10. Timeframe Subject Was Observed

Date	Location	User	Value	Reason
Sep-10-2020 16:47:05 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: THE PROTOCOL SPE CIFIED OBSERVATIO N PERIOD	Initial Entry

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

Date	Location	User	Value	Reason
Sep-10-2020 16:47:05 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

090177e196ae2e69\Final\Final On: 01-Apr-2021 03:12 (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: 12313193

Subject Initials: ---

Generated By:

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

(b) (4)

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1. Date of Visit

Date	Location	User	Value	Reason
Oct-09-2020 19:29:57 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Oct/9/2020	Initial Entry

090177e196ae2e69\Final\Final On: 01-Apr-2021 03:12 (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: 12313193 **Subject Initials:** ---

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

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1. Data Origin

Date	Location	User	Value	Reason
Oct-09-2020 19:26:01 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Oct-09-2020 19:26:01 (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-09-2020 19:26:09 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Oct-09-2020 19:26:01 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes

090177e196ae2e69\Final\Final On: 01-Apr-2021 03:12 (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: 12313193 Subject Initials: ---

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

				are entered. Please review and correct as appropriate.
Oct-09-2020 19:26:01 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Date of Collection: Oct/9/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Oct-09-2020 19:26:09 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample I BPX13 D: H	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Oct-09-2020 19:26:09 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BPX13H	Initial Entry

5.b

Date	Location	User	Value	Reason
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090177e196ae2e69\Final\Final On: 01-Apr-2021 03:12 (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: 12313193 Subject Initials: ---

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

Oct-09-2020 19:55:31 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID BJ51S : 1	Initial Entry
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5.b Sample ID

Date	Location	User	Value	Reason
Oct-09-2020 19:55:31 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BJ51S1	Initial Entry

5.c

Date	Location	User	Value	Reason
Oct-09-2020 20:20:37 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID BJ51V : Y	Initial Entry

5.c Sample ID

Date	Location	User	Value	Reason
Oct-09-2020 20:20:37 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BJ51VY	Initial Entry

5.d

090177e196ae2e69\Final\Final On: 01-Apr-2021 03:12 (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: 12313193 **Subject Initials:** ---

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

(b) (4)

Date	Location	User	Value	Reason
Oct-09-2020 20:20:49 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID BJ51V : Z	Initial Entry

5.d Sample ID

Date	Location	User	Value	Reason
Oct-09-2020 20:20:49 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BJ51VZ	Initial Entry

090177e196ae2e69\Final\Final On: 01-Apr-2021 03:12 (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: 12313193 **Subject Initials:** ---

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

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1. Date of Completion/Discontinuation/Death :

Date	Location	User	Value	Reason
Oct-09-2020 19:30:23 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Oct/9/2020	Initial Entry

2. Phase of Disposition:

Date	Location	User	Value	Reason
Oct-09-2020 19:30:23 (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 19:30:23 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: COMPLETED	Initial Entry

090177e196ae2e69\Final\Final On: 01-Apr-2021 03:12 (GMT)

Header Text: C4591001

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

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1231

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

Subject No: 12313193

Subject Initials: ---

Generated By:

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

(b) (4)

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1. Date of Visit

Date	Location	User	Value	Reason
Jan-12-2021 14:23:34 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Jan/11/2021	Initial Entry

Header Text: C4591001

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

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

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

Subject No: 12313193 **Subject Initials:** ---

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

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

Date	Location	User	Value	Reason
Jan-13-2021 13:13:55 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Jan-13-2021 02:00:45 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Query 1: Opened	The response indicates participant was unblinded, however the TREATMENT UNBLINDED date is missing in the DISP visit. Please complete this date.
Jan-12-2021 14:24:51 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidat e	The response indicates participant was unblinded, however the TREATMENT UNBLINDED date is missing

090177e196ae2e69\Final\Final On: 01-Apr-2021 03:12 (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: 12313193 **Subject Initials:** ---

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

(b) (4)

				in the DISP visit. Please complete this date.
Jan-12-2021 14:24:51 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Participant is willing to return for Vaccination 3 Participant is: eligible per local/national recommendations and confirmed to have received only placebo at Vaccination 1/2	Initial Entry

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Header Text: C4591001

Visit: V101_VAX3

Form Version: 22-Apr-2020 21:02

Site No: 1231

Subject No: 12313193

Generated By:

(b) (4)

Form: DATE OF VISIT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

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1. Date of Visit

Date	Location	User	Value	Reason
Feb-03-2021 15:54:06 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Deleted	New Information
Feb-03-2021 15:54:06 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Feb/3/2021	New Information
Jan-22-2021 05:41:18 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reissued :Candidate	Please review this query once data is entered on LAB PREG, SWAB PFE and SAMP TRK forms.
Jan-21-2021 14:58:24 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Sadly, we do not know the exact date when the biopsy will be available to decide

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Header Text: C4591001

Visit: V101_VAX3

Form Version: 22-Apr-2020 21:02

Site No: 1231

Subject No: 12313193

Generated By:

(b) (4)

Form: DATE OF VISIT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

				whether he should continue with the vaccination schedule or not. We will update this form as soon as possible.
Jan-21-2021 03:33:38 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reissued :Opened	Please confirm date at which data will be available for data entry. Or update missing CRFs if data is now available.
Jan-20-2021 11:33:56 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Subject was temporary delayed due to 'acute illness', as it was explained in another query in this form. Data should have not been uploaded until V101 could be reschedule... what do you

090177e196ae2e69\Final\Final On: 01-Apr-2021 03:12 (GMT)

Header Text: C4591001

Visit: V101_VAX3

Form Version: 22-Apr-2020 21:02

Site No: 1231

Subject No: 12313193

Generated By:

(b) (4)

Form: DATE OF VISIT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

				prefer me to do? Erase data or leave the items incomplete until then?
Jan-20-2021 06:22:33 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	DM: Kindly consider to update missing LAB PREG, SWAB PFE and SAMP TRK forms or else clarify. Thank you.
Jan-18-2021 13:13:13 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Jan/15/2021	Initial Entry

090177e196ae2e69\Final\Final On: 01-Apr-2021 03:12 (GMT)

Header Text: C4591001

Visit: V101_VAX3

Form: INFORMED CONSENT - FURTHER
VACCINATION - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:31

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1231

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

Subject No: 12313193

Subject Initials: ---

Generated By:

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

(b) (4)

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1. Consent Was:

Date	Location	User	Value	Reason
Feb-05-2021 02:13:56 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Feb-04-2021 15:24:32 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	there was a temporary delay. the subject signed on his first visit. that`s why the difference in the dates.
Feb-03-2021 15:54:06 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	Date Informed Consent Obtained is not the same as the Date of Visit. Please correct as necessary.

090177e196ae2e69\Final\Final On: 01-Apr-2021 03:12 (GMT)

Header Text: C4591001

Visit: V101_VAX3

Form: INFORMED CONSENT - FURTHER
VACCINATION - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:31

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1231

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

Subject No: 12313193

Subject Initials: ---

Generated By:

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

(b) (4)

Jan-18-2021 13:13:28 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6) [Redacted] [Redacted]	Data Entry: OBTAINED Date Written Co nsent Obtained Jan/15/2021	Initial Entry
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090177e196ae2e69\Final\Final On: 01-Apr-2021 03:12 (GMT)

Header Text: C4591001

Visit: V101_VAX3

Form: DISPOSITION - SCREENING FOR FURTHER VACCINATION - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:31

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1231

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

Subject No: 12313193

Subject Initials: ---

Generated By:

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

(b) (4)

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1. Date of Completion/Discontinuation/Death :

Date	Location	User	Value	Reason
Feb-19-2021 06:56:15 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Feb-18-2021 16:07:01 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Changed Information
Feb-18-2021 16:07:01 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Feb/3/2021	Changed Information
Feb-18-2021 04:50:11 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	Date is reported as 15Jan2021, but subject received vaccination on 03Feb2021. Please confirm the date is

090177e196ae2e69\Final\Final On: 01-Apr-2021 03:12 (GMT)

Header Text: C4591001

Visit: V101_VAX3

Form: DISPOSITION - SCREENING FOR FURTHER VACCINATION - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:31

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1231

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

Subject No: 12313193

Subject Initials: ---

Generated By:

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

(b) (4)

				correct as entered or update if necessary. Otherwise clarify. Thank you.
Jan-18-2021 13:14:01 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6) [Redacted] [Redacted]	Data Entry: Jan/15/2021	Initial Entry

2. Phase of Disposition:

Date	Location	User	Value	Reason
Jan-18-2021 13:14:01 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: REPEAT SCREENING 1	Initial Entry

3. Status:

Date	Location	User	Value	Reason
Jan-18-2021 13:14:01 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6) [Redacted] [Redacted]	Data Entry: COMPLETED	Initial Entry

090177e196ae2e69\Final\Final On: 01-Apr-2021 03:12 (GMT)

Header Text: C4591001**Visit:** V101_VAX3**Form:** LAB URINALYSIS - PREGNANCY TEST -
eCRF Audit Trail History**Form Version:** 14-Jan-2021 02:21**Form Status:** Data Complete, Locked, Frozen, Verified**Site No:** 1231**Site Name:** (1231) Hospital Militar Central Cirujano
Mayor Dr. Cosme Argerich**Subject No:** 12313193**Subject Initials:** ---**Generated By:****Generated Time (GMT):** 29-Mar-2021 20:20

(b) (4)

[Back to Form](#)**1. Lab Panel:**

Date	Location	User	Value	Reason
Feb-03-2021 15:51:26 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: URINALYSIS	Initial Entry

2. Lab Sub-Panel:

Date	Location	User	Value	Reason
Feb-03-2021 15:51:26 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: PREGNANCY	Initial Entry

3. Collection Date:

Date	Location	User	Value	Reason
Feb-03-2021 15:51:26 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) [REDACTED] (4), [REDACTED] (b) (6) [REDACTED]	Data Entry: Feb/3/2021	Initial Entry

4. Laboratory Name and Address (Derived)

Date	Location	User	Value	Reason
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Header Text: C4591001

Visit: V101_VAX3

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

Form Version: 14-Jan-2021 02:21

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1231

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

Subject No: 12313193

Subject Initials: ---

Generated By:

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

(b) (4)

Feb-03-2021 15:51:26 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: STUDY SITE	Initial Entry
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5. Specimen Type:

Date	Location	User	Value	Reason
Feb-03-2021 15:51:26 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: URINE	Initial Entry

6.a

Date	Location	User	Value	Reason
Feb-03-2021 15:51:26 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sponsor- 113 Defined Identifier: Test:: Choriogon adotropin Beta_PX11 3 Result:: NEGATIV E Not Done ::	Initial Entry

6.a Sponsor ID:

090177e196ae2e69\Final\Final On: 01-Apr-2021 03:12 (GMT)

Header Text: C4591001

Visit: V101_VAX3

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

Form Version: 14-Jan-2021 02:21

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1231

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

Subject No: 12313193

Subject Initials: ---

Generated By:

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

(b) (4)

Date	Location	User	Value	Reason
Feb-03-2021 15:51:26 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 113	Initial Entry

6.a Test:

Date	Location	User	Value	Reason
Feb-03-2021 15:51:26 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Choriogonadotropin B eta_PX113	Initial Entry

6.a Result:

Date	Location	User	Value	Reason
Feb-03-2021 15:51:26 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NEGATIVE	Initial Entry

090177e196ae2e69\Final\Final On: 01-Apr-2021 03:12 (GMT)

Header Text: C4591001

Visit: V101_VAX3

Form Version: 22-Apr-2020 21:03

Site No: 1231

Subject No: 12313193

Generated By:

(b) (4)

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

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

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1. Data Origin

Date	Location	User	Value	Reason
Feb-03-2021 15:51:40 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Feb-03-2021 15:51:40 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SERUM	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Feb-04-2021 15:43:01 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Feb-04-2021 06:47:44 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	'Sample Collected?' is Yes, however no barcodes

090177e196ae2e69\Final\Final On: 01-Apr-2021 03:12 (GMT)

Header Text: C4591001

Visit: V101_VAX3

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1231

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

Subject No: 12313193

Subject Initials: ---

Generated By:

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

(b) (4)

				are entered. Please review and correct as appropriate.
Feb-03-2021 15:51:40 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Feb-03-2021 15:51:40 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Date of Collection: Feb/3/2021	Initial Entry

5.a

Date	Location	User	Value	Reason
Feb-04-2021 15:43:01 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample I BPWC4 D: G	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
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090177e196ae2e69\Final\Final On: 01-Apr-2021 03:12 (GMT)

Header Text: C4591001

Visit: V101_VAX3

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1231

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

Subject No: 12313193

Subject Initials: ---

Generated By:

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

(b) (4)

Feb-04-2021 15:43:01 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BPWC4G	Initial Entry
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5.b

Date	Location	User	Value	Reason
Feb-04-2021 17:11:13 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID BS43C : P	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Feb-04-2021 17:11:13 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BS43CP	Initial Entry

5.c

Date	Location	User	Value	Reason
Feb-04-2021 18:16:36 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID BS43M : P	Initial Entry

090177e196ae2e69\Final\Final On: 01-Apr-2021 03:12 (GMT)

Header Text: C4591001

Visit: V101_VAX3

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1231

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

Subject No: 12313193

Subject Initials: ---

Generated By:

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

(b) (4)

5.c Sample ID

Date	Location	User	Value	Reason
Feb-04-2021 18:16:36 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BS43MP	Initial Entry

5.d

Date	Location	User	Value	Reason
Feb-04-2021 18:16:47 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample I BS43M D: R	Initial Entry

5.d Sample ID

Date	Location	User	Value	Reason
Feb-04-2021 18:16:47 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BS43MR	Initial Entry

090177e196ae2e69\Final\Final On: 01-Apr-2021 03:12 (GMT)

Header Text: C4591001

Visit: V101_VAX3

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1231

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

Subject No: 12313193

Subject Initials: ---

Generated By:

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

(b) (4)

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1. Data Origin

Date	Location	User	Value	Reason
Feb-03-2021 15:51:54 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Feb-03-2021 15:51:54 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: NASAL_SWAB	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Feb-04-2021 09:37:57 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Feb-04-2021 06:47:44 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	'Sample Collected?' is Yes, however no barcodes

090177e196ae2e69\Final\Final On: 01-Apr-2021 03:12 (GMT)

Header Text: C4591001

Visit: V101_VAX3

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1231

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

Subject No: 12313193

Subject Initials: ---

Generated By:

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

(b) (4)

				are entered. Please review and correct as appropriate.
Feb-03-2021 15:53:32 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6) [Redacted]	Data Entry: YES Date of Collection: Feb/3/2021	New Information
Feb-03-2021 15:51:54 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Feb-03-2021 15:51:54 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6) [Redacted]	Data Entry: YES	Initial Entry

5.a

Date	Location	User	Value	Reason
Feb-04-2021 09:37:57 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6) [Redacted]	Data Entry: Sample I BPWCN D: 0	Initial Entry

090177e196ae2e69\Final\Final On: 01-Apr-2021 03:12 (GMT)

Header Text: C4591001

Visit: V101_VAX3

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1231

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

Subject No: 12313193

Subject Initials: ---

Generated By:

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

(b) (4)

5.a Sample ID

Date	Location	User	Value	Reason
Feb-04-2021 09:37:57 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6) [Redacted] [Redacted]	Data Entry: BPWCN0	Initial Entry

Header Text: C4591001

Visit: V101_VAX3

Form Version: 10-Dec-2020 02:26

Site No: 1231

Subject No: 12313193

Generated By:

(b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

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1. Was there a temporary delay of vaccination?

Date	Location	User	Value	Reason
Feb-04-2021 17:43:54 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Closed	Response satisfies query
Feb-04-2021 15:30:17 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 3: Closed	Close Auto Query
Feb-04-2021 15:30:17 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Date of First Delay: Jan/15/2021 Reason(s) for Temporary Delay of Vaccination FEVER OR ACUTE ILLNESS	Transcription Error

090177e196ae2e69\Final\Final On: 01-Apr-2021 03:12 (GMT)

Header Text: C4591001

Visit: V101_VAX3

Form: VACCINATION - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:26

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1231

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

Subject No: 12313193

Subject Initials: ---

Generated By:

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

(b) (4)

Feb-04-2021 15:26:47 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 3: Open ed	Date of First Delay is a future date relative to when it was entered on 04/Feb/2021. Please review and update as appropriate.
Feb-04-2021 15:26:47 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Answered	Transcription Error
Feb-04-2021 15:26:47 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Date of First Delay: Feb/15/2021 Reason(s) for Temporary Delay of Vaccination FEVER OR ACUTE ILLNESS	Transcription Error
Feb-04-2021	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Open	CLINQUERY:

090177e196ae2e69\Final\Final On: 01-Apr-2021 03:12 (GMT)

Header Text: C4591001

Visit: V101_VAX3

Form Version: 10-Dec-2020 02:26

Site No: 1231

Subject No: 12313193

Generated By:

(b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

13:17:11 (UTC-03:00) City of Buenos Aires		(b) (4), (b) (6)	ed	please clarify if 'Was there a temporary delay of vaccination?' should be YES. Previously, delay on date of 15Jan2021 was indicated due to FEVER OR ACUTE ILLNESS related to the AE of bladder polyp. This information clarifies the delay.
Feb-03-2021 15:52:11 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	New Information
Jan-20-2021 17:19:21 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Jan-19-2021 20:30:57 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	A day before visit 101, subject had a cystography +

090177e196ae2e69\Final\Final On: 01-Apr-2021 03:12 (GMT)

Header Text: C4591001

Visit: V101_VAX3

Form Version: 10-Dec-2020 02:26

Site No: 1231

Subject No: 12313193

Generated By:

(b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

Aires				biopsy as a postoperative control for the bladder polyp resection (which resulted to be an urothelial adenocarcinoma). Given that the biopsy result is not available yet, we decided to delay vaccination.
Jan-19-2021 15:43:25 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Open ed	CLINQUERY: temporary delay is reported as YES with date of 15Jan2021 and reason FEVER OR ACUTE ILLNESS. Please clarify why this reason was provided; clarify if this is related to the ongoing AE of bladder polyp.
Jan-18-2021 13:14:37 (UTC-03:00)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Date of First	Initial Entry

090177e196ae2e69\Final\Final On: 01-Apr-2021 03:12 (GMT)

Header Text: C4591001

Visit: V101_VAX3

Form Version: 10-Dec-2020 02:26

Site No: 1231

Subject No: 12313193

Generated By:

(b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

City of Buenos Aires			Delay: Jan/15/2021 Reason(s) for Temporary Delay of Vaccination FEVER OR ACUTE ILLNESS	
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2. Treatment Name

Date	Location	User	Value	Reason
Feb-03-2021 15:52:32 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: BNT162b2	Initial Entry

3. Formulation:

Date	Location	User	Value	Reason
Feb-03-2021 15:52:32 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: INJECTION	Initial Entry

4. Dose Date Time:

Date	Location	User	Value	Reason
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090177e196ae2e69\Final\Final On: 01-Apr-2021 03:12 (GMT)

Header Text: C4591001

Visit: V101_VAX3

Form Version: 10-Dec-2020 02:26

Site No: 1231

Subject No: 12313193

Generated By:

(b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

Feb-04-2021 15:30:17 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Closed	Close Auto Query
Feb-04-2021 15:26:47 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Opened	"Dose Date" is before "Date of First delay" 15/Feb/2021. Please review and update as appropriate.
Feb-03-2021 15:54:06 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Feb-03-2021 15:52:32 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	Dose Date is not equal to Date of Visit 15/Jan/2021 of the corresponding Visit. Please review and update as appropriate.
Feb-03-2021 15:52:32 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Feb/3/2021 14:57	Initial Entry

090177e196ae2e69\Final\Final On: 01-Apr-2021 03:12 (GMT)

Header Text: C4591001

Visit: V101_VAX3

Form Version: 10-Dec-2020 02:26

Site No: 1231

Subject No: 12313193

Generated By:

(b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

5. Anatomical Location:

Date	Location	User	Value	Reason
Feb-03-2021 15:52:32 (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
Feb-03-2021 15:52:32 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: LEFT	Initial Entry

7. Route:

Date	Location	User	Value	Reason
Feb-03-2021 15:52:32 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: INTRAMUSCULAR	Initial Entry

8. Actual Dose:

Date	Location	User	Value	Reason
Feb-03-2021 15:52:32 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 30.0	Initial Entry

090177e196ae2e69\Final\Final On: 01-Apr-2021 03:12 (GMT)

Header Text: C4591001

Visit: V101_VAX3

Form: VACCINATION - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:26

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1231

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

Subject No: 12313193

Subject Initials: ---

Generated By:

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

(b) (4)

9. Unit:

Date	Location	User	Value	Reason
Feb-03-2021 15:52:32 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: ug	Initial Entry

10. Timeframe Subject Was Observed

Date	Location	User	Value	Reason
Feb-03-2021 15:52:32 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 30 MINUTES	Initial Entry

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

Date	Location	User	Value	Reason
Feb-03-2021 15:52:32 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

090177e196ae2e69\Final\Final On: 01-Apr-2021 03:12 (GMT)

Header Text: C4591001

Visit: V102_VAX4

Form Version: 22-Apr-2020 21:02

Site No: 1231

Subject No: 12313193

Generated By:

(b) (4)

Form: DATE OF VISIT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

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1. Date of Visit

Date	Location	User	Value	Reason
Feb-24-2021 17:58:46 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Feb/24/2021	Initial Entry

090177e196ae2e69\Final\Final On: 01-Apr-2021 03:12 (GMT)

Header Text: C4591001

Visit: V102_VAX4

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

Form Version: 14-Jan-2021 02:21

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1231

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

Subject No: 12313193

Subject Initials: ---

Generated By:

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

(b) (4)

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1. Lab Panel:

Date	Location	User	Value	Reason
Feb-24-2021 17:58:57 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: URINALYSIS	Initial Entry

2. Lab Sub-Panel:

Date	Location	User	Value	Reason
Feb-24-2021 17:58:57 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: PREGNANCY	Initial Entry

3. Collection Date:

Date	Location	User	Value	Reason
Feb-24-2021 17:58:57 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Feb/24/2021	Initial Entry

4. Laboratory Name and Address (Derived)

Date	Location	User	Value	Reason
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090177e196ae2e69\Final\Final On: 01-Apr-2021 03:12 (GMT)

Header Text: C4591001

Visit: V102_VAX4

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

Form Version: 14-Jan-2021 02:21

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1231

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

Subject No: 12313193

Subject Initials: ---

Generated By:

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

(b) (4)

Feb-24-2021 17:58:57 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: STUDY SITE	Initial Entry
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5. Specimen Type:

Date	Location	User	Value	Reason
Feb-24-2021 17:58:57 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: URINE	Initial Entry

6.a

Date	Location	User	Value	Reason
Feb-24-2021 17:58:57 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sponsor- 113 Defined I dentifier: Test:: Choriogon adotropin Beta_PX11 3 Result:: NEGATIV E Not Done ::	Initial Entry

6.a Sponsor ID:

090177e196ae2e69\Final\Final On: 01-Apr-2021 03:12 (GMT)

Header Text: C4591001

Visit: V102_VAX4

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

Form Version: 14-Jan-2021 02:21

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1231

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

Subject No: 12313193

Subject Initials: ---

Generated By:

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

(b) (4)

Date	Location	User	Value	Reason
Feb-24-2021 17:58:57 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 113	Initial Entry

6.a Test:

Date	Location	User	Value	Reason
Feb-24-2021 17:58:57 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Choriogonadotropin Beta_PX113	Initial Entry

6.a Result:

Date	Location	User	Value	Reason
Feb-24-2021 17:58:57 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NEGATIVE	Initial Entry

090177e196ae2e69\Final\Final On: 01-Apr-2021 03:12 (GMT)

Header Text: C4591001

Visit: V102_VAX4

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: 12313193

Subject Initials: ---

Generated By:

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

(b) (4)

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1. Data Origin

Date	Location	User	Value	Reason
Feb-24-2021 17:59:07 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Feb-24-2021 17:59:07 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: NASAL_SWAB	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Feb-24-2021 18:40:35 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Feb-24-2021 17:59:07 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes

090177e196ae2e69\Final\Final On: 01-Apr-2021 03:12 (GMT)

Header Text: C4591001

Visit: V102_VAX4

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: 12313193

Subject Initials: ---

Generated By:

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

(b) (4)

				are entered. Please review and correct as appropriate.
Feb-24-2021 17:59:07 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Date of Collection: Feb/24/2021	Initial Entry

5.a

Date	Location	User	Value	Reason
Feb-24-2021 18:40:35 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID BR28H : 6	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Feb-24-2021 18:40:35 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BR28H6	Initial Entry

090177e196ae2e69\Final\Final On: 01-Apr-2021 03:12 (GMT)

Header Text: C4591001

Visit: V102_VAX4

Form Version: 10-Dec-2020 02:26

Site No: 1231

Subject No: 12313193

Generated By:

(b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

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1. Was there a temporary delay of vaccination?

Date	Location	User	Value	Reason
Feb-24-2021 17:59:48 (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
Feb-24-2021 17:59:48 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: BNT162b2	Initial Entry

3. Formulation:

Date	Location	User	Value	Reason
Feb-24-2021 17:59:48 (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
Feb-24-2021	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Initial Entry

090177e196ae2e69\Final\Final On: 01-Apr-2021 03:12 (GMT)

Header Text: C4591001

Visit: V102_VAX4

Form Version: 10-Dec-2020 02:26

Site No: 1231

Subject No: 12313193

Generated By:

(b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

17:59:48
(UTC-03:00) City
of Buenos Aires

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

Feb/24/2021 16:25

5. Anatomical Location:

Date	Location	User	Value	Reason
Feb-24-2021 17:59:48 (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
Feb-24-2021 17:59:48 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: LEFT	Initial Entry

7. Route:

Date	Location	User	Value	Reason
Feb-24-2021 17:59:48 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: INTRAMUSCULAR	Initial Entry

8. Actual Dose:

Date	Location	User	Value	Reason
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090177e196ae2e69\Final\Final On: 01-Apr-2021 03:12 (GMT)

Header Text: C4591001

Visit: V102_VAX4

Form: VACCINATION - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:26

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1231

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

Subject No: 12313193

Subject Initials: ---

Generated By:

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

(b) (4)

Feb-24-2021 17:59:48 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 30.0	Initial Entry
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9. Unit:

Date	Location	User	Value	Reason
Feb-24-2021 17:59:48 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: ug	Initial Entry

10. Timeframe Subject Was Observed

Date	Location	User	Value	Reason
Feb-24-2021 17:59:48 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 30 MINUTES	Initial Entry

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

Date	Location	User	Value	Reason
Feb-24-2021 17:59:48 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

090177e196ae2e69\Final\Final On: 01-Apr-2021 03:12 (GMT)

Header Text: C4591001

Visit: V103_MONTH1

Form Version: 22-Apr-2020 21:02

Site No: 1231

Subject No: 12313193

Generated By:

(b) (4)

Form: DATE OF VISIT - eCRF Audit Trail History

Form Status: Data Complete, Verified

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

Subject Initials: ---

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

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1. Date of Visit

Date	Location	User	Value	Reason
Mar-25-2021 15:04:56 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Mar/25/2021	Initial Entry

090177e196ae2e69\Final\Final On: 01-Apr-2021 03:12 (GMT)

Header Text: C4591001

Visit: V103_MONTH1

Form: CONTACT OUTCOME - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Verified

Site No: 1231

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

Subject No: 12313193

Subject Initials: ---

Generated By:

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

(b) (4)

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1. Contact Type:

Date	Location	User	Value	Reason
Mar-25-2021 15:05:07 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: TELEPHONE VISIT	Initial Entry

2. Was contact made?

Date	Location	User	Value	Reason
Mar-25-2021 15:05:07 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Date of Contact: Mar/25/2021	Initial Entry

Header Text: C4591001

Visit:
FURTHER_VACCINATION_EOT -
Unscheduled

Form: DISPOSITION - TREATMENT - eCRF Audit
Trail History

Form Version: 20-Feb-2021 02:26

Form Status: Data Complete, Verified

Site No: 1231

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

Subject No: 12313193

Subject Initials: ---

Generated By:

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

(b) (4)

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1. Date of Completion/Discontinuation/Death :

Date	Location	User	Value	Reason
Mar-25-2021 15:05:26 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Mar/25/2021	Initial Entry

2. Phase of Disposition:

Date	Location	User	Value	Reason
Mar-25-2021 15:05:26 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: OPEN LABEL TREAT MENT	Initial Entry

3. Status:

Date	Location	User	Value	Reason
Mar-25-2021 15:05:26 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: COMPLETED	Initial Entry

090177e196ae2e69\Final\Final On: 01-Apr-2021 03:12 (GMT)

Header Text: C4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1231

Subject No: 12313193

Generated By:

(b) (4)

Form: ADVERSE EVENT REPORT - Audit Trail

Form Status:

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

Subject Initials: ---

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

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Date	Location	User	Value	Reason
Oct-14-2020 08:33:30 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Created	

Header Text: C4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - Audit Trail

Form Version: 22-Apr-2020 21:02

Form Status:

Site No: 1231

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

Subject No: 12313193

Subject Initials: ---

Generated By:

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

(b) (4)

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Date	Location	User	Value	Reason
Oct-14-2020 12:59:02 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Created	

090177e196ae2e69\Final\Final On: 01-Apr-2021 03:12 (GMT)

Header Text: C4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1231

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

Subject No: 12313193

Subject Initials: ---

Generated By:

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

(b) (4)

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1. Category:

Date	Location	User	Value	Reason
Oct-14-2020 08:33:30 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: ADVERSE EVENT	Initial Entry

2. AE ID:

Date	Location	User	Value	Reason
Oct-14-2020 08:33:30 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 1	Initial Entry

3. Adverse Event:

(If possible specify diagnosis, not individual symptoms)

Date	Location	User	Value	Reason
Oct-14-2020 08:33:30 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: haematuria	Initial Entry

4. Start Date Time:

Date	Location	User	Value	Reason
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Visit: Logs - Unscheduled

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Subject No: 12313193

Subject Initials: ---

Generated By:

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

(b) (4)

Oct-14-2020 08:33:30 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Aug/25/2020 14:00	Initial Entry
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5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Oct-22-2020 19:57:02 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Oct-22-2020 16:47:08 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	New Information
Oct-22-2020 16:47:08 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO End Date Time: Sep/22/2020 08:00	New Information
Oct-21-2020 13:43:50 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	CLINQUERY: please clarify if this event has resolved. If so, please provide the stop date.

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Oct-14-2020 08:33:30 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6) [Redacted]	Data Entry: YES	Initial Entry
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6. Toxicity Grade:

Date	Location	User	Value	Reason
Oct-23-2020 16:01:28 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6) [Redacted]	Query 1: Closed	Response satisfies query
Oct-22-2020 16:48:42 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6) [Redacted]	Query 1: Answered	Intermittent macroscopic hematuria represents a worsening in the intensity of the event.
Oct-20-2020 16:34:47 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6) [Redacted]	Query 1: Opened	CLINICAL Subject has Med Hx of Intermittent Gross Hematuria (onset Jul 2020); does this adverse event represent

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(b) (4)

				a continuation of this Med Hx condition, or a worsening?
Oct-14-2020 08:33:30 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 1	Initial Entry

7. Is the adverse event serious?

If Yes, NOTIFY PFIZER IMMEDIATELY.

Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).

Date	Location	User	Value	Reason
Oct-14-2020 08:33:30 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

8. Is this adverse event the result of a study Medication Error?

If Yes, record the type of medication error on the Medication Error Log.

Date	Location	User	Value	Reason
Oct-14-2020 08:33:30	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

090177e196ae2e69\Final\Final On: 01-Apr-2021 03:12 (GMT)

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Generated By:

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(b) (4)

(UTC-03:00) City of Buenos Aires

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

9. Is this event related to study treatment:

Date	Location	User	Value	Reason
Oct-14-2020 08:33:30 (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> Bladder polyp	Initial Entry

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Oct-14-2020 08:33:30 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NOT APPLICABLE	Initial Entry

11. Was a Concomitant Medication given?

Date	Location	User	Value	Reason
Oct-14-2020	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Initial Entry

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Header Text: C4591001

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

Subject No: 12313193

Subject Initials: ---

Generated By:

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

(b) (4)

08:33:30 (UTC-03:00) City of Buenos Aires		(b) (4), (b) (6)	NO	
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12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Oct-14-2020 08:33:30 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

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

Date	Location	User	Value	Reason
Oct-22-2020 16:49:14 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Oct-22-2020 16:49:14 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: RECOVERED/RESOLVED	New Information
Oct-22-2020 16:47:08 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	For AE haematuria: Response to "What was the outcome of this adverse event?" is 'Not

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Subject Initials: ---

Generated By:

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(b) (4)

				Recovered/Not Resolved' but AE End Date/Time is present.
Oct-14-2020 08:33:30 (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
Oct-14-2020 08:33:30 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

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(b) (4)

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1. Category:

Date	Location	User	Value	Reason
Oct-14-2020 12:59:02 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: ADVERSE EVENT	Initial Entry

2. AE ID:

Date	Location	User	Value	Reason
Oct-14-2020 12:59:02 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 2	Initial Entry

3. Adverse Event:

(If possible specify diagnosis, not individual symptoms)

Date	Location	User	Value	Reason
Nov-04-2020 21:26:27 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Closed	Response satisfies query
Nov-04-2020 17:29:21	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Answer ed	The information to

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Subject No: 12313193

Subject Initials: ---

Generated By:

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(b) (6)

(UTC-03:00) City of Buenos Aires		(b) (4), (b) (6)		complete the histological diagnosis is not available yet. The subject estimate to has the information in 2 weeks when the result of the biopsy is available. Thank you.
Nov-04-2020 15:02:52 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Opened	CLINQUERY: please provide the diagnosis of the bladder polyp, if available
Oct-27-2020 21:34:13 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Oct-27-2020 12:37:45 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	The specific diagnosis is not yet available.
Oct-26-2020	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	CLINQUERY:

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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)

17:52:28 (UTC-03:00) City of Buenos Aires		(b) (4), (b) (6)		please provide the diagnosis of the bladder polyp.
Oct-14-2020 12:59:02 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Bladder polyp	Initial Entry

4. Start Date Time:

Date	Location	User	Value	Reason
Oct-27-2020 22:18:16 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Oct-27-2020 13:03:09 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Original value is correct
Oct-26-2020 14:00:16 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reissued:Opened	CLINICAL - thank you for start date 12Sep20 by CT for bladder polyp. Please update start

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Subject Initials: ---

Generated By:

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(b) (4)

				date of AE and SAE appropriately.
Oct-23-2020 19:14:53 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	The diagnosis of bladder polyp is on 18th September by computer tomography.
Oct-23-2020 16:04:58 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reissued:Opened	Clinical - please hold query on Bladder Polyp onset date open until SAE safety update with update is submitted. Was first knowledge of Bladder polyp on 25Aug20, or earlier -
Oct-22-2020 16:59:51 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Changed data per query

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

Subject No: 12313193

Subject Initials: ---

Generated By:

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(b) (4)

Oct-20-2020 16:41:29 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	CLINICAL Polyp AE starts 18Sep20; however polyp was Hematuria AE cause on 25Aug20. In Vaccine study, SAE start date is when event starts; not day it meets serious criteria (item 11, SAE instruct). If SAE event began as non-serious, record that date.
Oct-14-2020 12:59:02 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sep/18/2020 08:00	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Dec-18-2020 11:32:32	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	New Information

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Subject Initials: ---

Generated By:

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(b) (4)

(UTC-03:00) City of Buenos Aires				
Dec-11-2020 19:34:29 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Query 4: Closed	Response satisfies query
Dec-11-2020 15:18:37 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Query 4: Answered	Good day. The pathology was provided by the subject with the following result: low grade papilar and urothelial carcinoma of the bladder. No treatment was indicated, and strict follow up will be performed, a cystoscopy every 3 months
Dec-11-2020 13:36:45 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Query 4: Reissued:Opened	CLINQUERY: response 09Dec is "New Information", please clarify.

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(b) (4)

				Per prior response, "Pending FU with urology and pathology results." In your response to this current query please provide this new information and any diagnosis, if available.
Dec-09-2020 16:22:46 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 4: Answered	New Information
Dec-09-2020 16:22:46 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO End Date Time : Oct/16/2020 14:00	New Information
Dec-09-2020 13:38:00 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 4: Opened	CLINQUERY: Per response, "On 26 nov, she was phone contacted for

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Subject Initials: ---

Generated By:

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(b) (4)

				follow up. Pending FU with urology and pathology results." please provide the diagnosis, if available, or update.
Dec-02-2020 14:26:16 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Closed	Response satisfies query
Dec-02-2020 10:56:33 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Answered	On 26 nov, she was phone contacted for follow up. Pending FU with urology and pathology results.
Nov-30-2020 17:35:07 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Opened	Per response 04Nov, "The information to complete the histological diagnosis is not available yet. The subject

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Subject Initials: ---

Generated By:

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(b) (4)

				estimate to has the information in 2 weeks when the result of the biopsy is available." please provide the diagnosis, if available, or update.
Nov-19-2020 19:13:35 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Closed	Response satisfies query
Nov-19-2020 15:11:07 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Answered	The information to complete the histological diagnosis is not available yet. Thank you
Nov-19-2020 14:03:32 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Opened	Per response 04Nov, "The information to complete the histological diagnosis is not available yet. The subject

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Subject Initials: ---

Generated By:

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(b) (4)

				estimate to has the information in 2 weeks when the result of the biopsy is available." please provide the diagnosis, if available, or update.
Nov-02-2020 10:42:20 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	New Information
Nov-02-2020 10:35:32 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO End Date Time : Oct/16/2020 14:00	New Information
Oct-30-2020 20:42:29 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Oct-29-2020 20:03:16	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Changed Information

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(UTC-03:00) City of Buenos Aires				
Oct-29-2020 20:03:16 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Changed Information
Oct-27-2020 22:23:49 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	Clinical Event end date is 16OCT2020; however, SAE report has no end date. Please review, and update as applicable
Oct-27-2020 14:53:17 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO End Date Time : Oct/16/2020 14:00	New Information
Oct-23-2020 08:17:56 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO End Date Time :	New Information

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(b) (4)

			Oct/16/2020 UNK:UNK	
Oct-14-2020 12:59:02 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

6. Toxicity Grade:

Date	Location	User	Value	Reason
Oct-14-2020 12:59:02 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 1	Initial Entry

7. Is the adverse event serious?

If Yes, NOTIFY PFIZER IMMEDIATELY.

Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).

Date	Location	User	Value	Reason
Nov-04-2020 14:26:41 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 6: Closed	Query closed; will follow for SAE update with the requested COVID test info

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Header Text: C4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Verified

Site No: 1231

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

Subject No: 12313193

Subject Initials: ---

Generated By:

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

(b) (4)

Nov-03-2020 11:32:47 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 6: Answered	I clarify that Covid testing was not performed because the AE is not related to COVID illness and the patient did not present any Covid symptoms. Follow-up SAE form was sent.
Nov-01-2020 21:23:36 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 6: Opened	CLINICAL Followup: COVID testing has not been reported in the SAE submitted to safety. Please submit a follow-up SAE form [#2020404788] to provide whether COVID testing was performed (yes/no) and if yes, the results.
Oct-26-2020 14:50:35 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Closed	Query closed; will follow to confirm SAE update with requested COVID test info
Oct-23-2020 16:24:48 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 5: Closed	Response satisfies query
Oct-23-2020 15:07:02	ACV0PFEINFP6000	auto query (autoquery)	Query 5: Answered	New Information

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Subject No: 12313193

Subject Initials: ---

Generated By:

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

(b) (4)

(UTC-03:00) City of Buenos Aires			wered	
Oct-23-2020 15:07:02 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Is this serious event associated with congenital anomaly or birth defect? NO Did this serious event result in death? NO Did th	New Information

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(b) (4)

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			<p>is serious event require or prolonged hospitalization?</p> <p>YES</p> <p>Did this serious event result in persistent or significant disability/incapacity?</p> <p>NO</p> <p>Is this serious event life threatening?</p>	
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Header Text: C4591001

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Subject No: 12313193

Subject Initials: ---

Generated By:

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

(b) (4)

			ning? NO Other medic ally i mport ant se rious event NO	
Oct-23-2020 09:08:46 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 5: Ope ned	SAE RECON:AER#2020404788 urinary bladder polyp(onset date:18Sep2020)was reported as serious in Safety database updated to non serious in AE CRF. Please confirm and update CRF. If safety update is required, submit a follow-up SAE Form.
Oct-23-2020 09:06:02 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 4: Dele ted	Query can be addressed internally
Oct-22-2020	ACV0PFEINFP6000	auto query	Query	For AE Bladder polyp:

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Form Status: Data Complete, Verified

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

Subject No: 12313193

Subject Initials: ---

Generated By:

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

(b) (4)

16:58:26
(UTC-03:00)
City of
Buenos Aires

(autoquery)

4: Cand
idate

Response to "Is the adverse event serious?" is 'No' but "Serious Adverse Event Number" is present.

Header Text: C4591001

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Form Status: Data Complete, Verified

Site No: 1231

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

Subject No: 12313193

Subject Initials: ---

Generated By:

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

(b) (4)

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7. Is the adverse event serious?

If Yes, NOTIFY PFIZER IMMEDIATELY.

Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).

Date	Location	User	Value	Reason
Oct-22-2020 16:58:26 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 3: Answered	Changed Information
Oct-22-2020 16:58:26 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Changed Information
Oct-21-2020 15:05:48 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Opened	CLINICAL COVID testing has not been reported in the SAE submitted to safety. Please submit a follow-up SAE form

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Form Status: Data Complete, Verified

Site No: 1231

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

Subject No: 12313193

Subject Initials: ---

Generated By:

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

(b) (4)

				[#2020404788] to provide whether COVID testing was performed (yes/no) and if yes, the results.
Oct-21-2020 15:04:36 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Closed	incorrect subject
Oct-21-2020 15:02:18 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Opened	CLINICAL COVID testing has not been reported in the SAE submitted to safety. Please submit a follow-up SAE form [#2020404788] to provide whether COVID testing was performed (yes/no) and if yes, the results.
Oct-20-2020 06:26:00	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query

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Header Text: C4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

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Form Status: Data Complete, Verified

Site No: 1231

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

Subject No: 12313193

Subject Initials: ---

Generated By:

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

(b) (4)

(UTC-03:00) City of Buenos Aires				
Oct-19-2020 08:41:35 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	SAE RECON:Bladder polyp(Onset date:18Sep2020) is not reported to Safety database but marked serious on AE CRF. Confirm seriousness and report to Pfizer immediately. If this event is not serious, downgrade the event on AE CRF
Oct-17-2020 15:20:18 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	For AE Bladder polyp: Response to "Is the adverse event serious?" is 'Yes' but "Serious Adverse Event Number" is blank.

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Form Status: Data Complete, Verified

Site No: 1231

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

Subject No: 12313193

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(b) (4)

<p>Oct-17-2020 15:20:18 (UTC-03:00) City of Buenos Aires</p>	<p>ACV0PFEINFP6000</p>	<p>(b) (4), (b) (6)</p>	<p>Data Entry: YES Is this serious event associated with congenital anomaly or birth defect? NO Did this serious event result in death? NO Did this serious event require or prolong hospitalization? YES Did this serious event result in persistent or significant disability/incapacity?</p>	<p>New Information</p>
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Subject Initials: ---

Generated By:

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(b) (4)

			NO	
			Is this serious event life threatening?	
			NO	
			Other medically important serious event	
			NO	
Oct-14-2020 12:59:02 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

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

Date	Location	User	Value	Reason
Oct-14-2020 12:59:02 (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:

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

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Subject Initials: ---

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(b) (4)

Date	Location	User	Value	Reason
Oct-14-2020 12:59:02 (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> Unknow.	Initial Entry

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Oct-14-2020 12:59:02 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NOT APPLICABLE	Initial Entry

11. Was a Concomitant Medication given?

Date	Location	User	Value	Reason
Oct-14-2020 12:59:02 (UTC-03:00)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

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Site No: 1231

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

Subject No: 12313193

Subject Initials: ---

Generated By:

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

(b) (4)

City of Buenos Aires				
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12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Oct-23-2020 15:55:10 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Oct-22-2020 17:00:28 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	New Information
Oct-22-2020 17:00:28 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	New Information
Oct-20-2020 16:42:28 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	Clinical Non-Drug Treatment is 'NO'; please confirm no surgical intervention was used as

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Header Text: C4591001

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Subject Initials: ---

Generated By:

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(b) (4)

				treatment for Bladder Polyp event
Oct-14-2020 12:59:02 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

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

Date	Location	User	Value	Reason
Dec-22-2020 10:13:20 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 8: Closed	Response satisfies query
Dec-18-2020 11:32:41 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 8: Answered	New Information
Dec-18-2020 11:32:41 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: RECOVER	New Information

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Site No: 1231

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

Subject No: 12313193

Subject Initials: ---

Generated By:

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

(b) (4)

Aires			RIN G/RE SOL VIN G	
Dec-17-2020 07:24:07 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 8: Reissued: Opened	SAE RECON: Per previous query response 'The actual status is Recovering/resolving.'. However, outcome is still recorded as recovered/resolved. Please update accordingly.
Dec-11-2020 15:24:53 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 8: Answered	Good afternoon The actual status is Recovering/resolving. The subject has now a diagnostic of low grade papilar and urothelial bladder carcinoma. Follow up will be performed every three months with cystoscopy.
Dec-11-2020 08:15:27 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 8: Opened	SAE RECON:AER#2020404788 ,outcome was updated to RECOVERED/RESOLVED on AE CRF while reported as Recovering/Resolving in Safety database.Please confirm correct outcome. If

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(b) (4)

				safety update is required, please submit a follow-up form
Dec-09-2020 16:23:10 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 7: Closed	Close Auto Query
Dec-09-2020 16:23:10 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: RECOVERED/RESOLVED	New Information
Dec-09-2020 16:22:46 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 7: Opened	For AE Bladder polyp: Response to "What was the outcome of this adverse event?" is 'Recovering/Resolving' but AE End Date/Time is present.
Nov-02-2020 10:42:20 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 6: Closed	Close Auto Query

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(b) (4)

Aires				
Nov-02-2020 10:35:32 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 6: Opened	For AE Bladder polyp: Response to "What was the outcome of this adverse event?" is 'Recovering/Resolving' but AE End Date/Time is present.
Oct-31-2020 11:48:32 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 4: Closed	Response satisfies query
Oct-30-2020 09:25:41 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 5: Closed	Close Auto Query
Oct-30-2020 09:25:41 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 4: Answered	Transcription Error
Oct-30-2020 09:25:41 (UTC-03:00)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Transcription Error

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City of Buenos Aires			REC OVE RIN G/RE SOL VIN G	
Oct-29-2020 20:03:16 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 5: Opened	For AE Bladder polyp: Response to "What was the outcome of this adverse event?" is 3 but End Date/Time is missing.
Oct-29-2020 11:34:17 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 4: Opened	SAE RECON:AER#2020404788 ,outcome is still ECOVERED/RESOLVED in AE CRF however, reported as RECOVERING/RESOLVING to Safety DB. Please confirm correct outcome. If safety update is required, please submit a follow-up form
Oct-27-2020 18:06:22 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Closed	Response satisfies query

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Oct-27-2020 13:03:34 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 3: Closed	Close Auto Query
Oct-27-2020 13:03:34 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: RECOVERED/RESOLVED	New Information
Oct-27-2020 10:26:34 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 3: Opened	For AE Bladder polyp: Response to "What was the outcome of this adverse event?" is 'Recovering/Resolving' but AE End Date/Time is present.
Oct-27-2020 10:26:34 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Answered	New Information
Oct-27-2020 10:26:34	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	New Information

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(b) (4)

(UTC-03:00) City of Buenos Aires			y: REC OVE RIN G/RE SOL VIN G	
Oct-27-2020 03:21:29 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Quer y 2: Reiss ued: Open ed	SAE RECON 1: Please confirm if a follow up AEM form was sent to update outcome in Safety database.
Oct-26-2020 15:50:56 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Quer y 2: Answ ered	Original value is correct
Oct-24-2020 12:06:46 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Quer y 2: Open ed	SAE RECON:AER#2020404788 ,outcome was updated to ECOVERED/RESOLVED in AE CRF however, reported as RECOVERING/RESOLVING to Safety DB. Please confirm correct outcome. If safety update is required, please submit a follow-up form

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Oct-23-2020 19:15:40 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Quer y 1: Close d	Close Auto Query
Oct-23-2020 19:15:40 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED] [REDACTED]	Data Entr y: REC OVE RED/ RES OLV ED	New Information
Oct-23-2020 08:17:56 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Quer y 1: Open ed	For AE Bladder polyp: Response to "What was the outcome of this adverse event?" is 'Recovering/Resolving' but AE End Date/Time is present.
Oct-14-2020 12:59:02 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Data Entr y: REC OVE RIN G/RE SOL VIN	Initial Entry

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Subject No: 12313193

Subject Initials: ---

Generated By:

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

(b) (4)

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

Date	Location	User	Value	Reason
Oct-14-2020 12:59:02 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

090177e196ae2e69\Final\Final On: 01-Apr-2021 03:12 (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: 12313193

Subject Initials: ---

Generated By:

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

(b) (4)

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15. Serious Adverse Event Number: For Pfizer Use Only

Date	Location	User	Value	Reason
Oct-20-2020 06:26:00 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 2020404788	Initial Entry

090177e196ae2e69\Final\Final On: 01-Apr-2021 03:12 (GMT)

Header Text: C4591001

Visit: Disposition - Unscheduled

Form: TREATMENT UNBLINDED - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1231

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

Subject No: 12313193

Subject Initials: ---

Generated By:

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

(b) (4)

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1. Date Treatment Unblinded :

Date	Location	User	Value	Reason
Jan-13-2021 13:13:55 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Jan/12/2021	Initial Entry

2. Primary Reason for Unblinding:

Date	Location	User	Value	Reason
Jan-13-2021 13:13:55 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: ASSESS ELIGIBILI TY FOR ADDITIO NAL VACCINATIO N	Initial Entry

090177e196ae2e69\Final\Final On: 01-Apr-2021 03:12 (GMT)

Header Text: C4591001

Visit: Subject Status - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1231

Subject No: 12313193

Generated By:

(b) (4)

Form: SUBJECT STATUS - eCRF Audit Trail History

Form Status: Data Complete, Verified

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

Subject Initials: ---

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

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1. Subject Status

Date	Location	User	Value	Reason
Oct-09-2020 19:30:23 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: FOLLOW-UP	Initial Entry
Aug-22-2020 15:23:17 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: ENROLLED/RANDO MIZED	Initial Entry
Aug-22-2020 15:22:23 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SCREENED	Initial Entry

2. Subject Status Date

Date	Location	User	Value	Reason
Oct-09-2020 19:30:23 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Oct/9/2020	Initial Entry
Aug-22-2020 15:23:17 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Aug/22/2020	Initial Entry

090177e196ae2e69\Final\Final On: 01-Apr-2021 03:12 (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: 12313193

Subject Initials: ---

Generated By:

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

(b) (4)

Aug-22-2020 15:22:23 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Aug/22/2020	Initial Entry
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Header Text: C4591001

Visit: Investigator Signature -
Unscheduled

Form Version: 22-Apr-2020 21:04

Site No: 1231

Subject No: 12313193

Generated By:

(b) (4)

Form: CASEBOOK SIGNATURE FORM - eCRF Audit
Trail History

Form Status: Data Complete, Verified

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

Subject Initials: ---

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

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1. Casebook Signature

Date	Location	User	Value	Reason
Oct-22-2020 18:11:21 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Click Here to Enable	Initial Entry

090177e196ae2e69\Final\Final On: 01-Apr-2021 03:12 (GMT)