

Header Text: C4591001

Visit: COHORT_SELECTION

Form Version: 30-Jul-2020 21:29

Site No: 1231

Subject No: 12314059

Generated By: (b) (4)

Form: COHORT_SELECTION

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Cohort Selection

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

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

Header Text: C4591001

Visit: COHORT_SELECTION

Form Version: 22-Apr-2020 21:02

Site No: 1231

Subject No: 12314059

Generated By: (b) (4)

Form: MAIN INFORMED CONSENT

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Informed Consent

1.	Consent Was:	OBTAINED Date Written Consent Obtained Aug/25/2020
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Header Text: C4591001

Visit: COHORT_SELECTION

Form Version: 06-Jul-2020 21:55

Site No: 1231

Subject No: 12314059

Generated By: (b) (4)

Form: DEMOGRAPHY

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Demography

1.	Subject ID	[12314059]
2.	Birth Date:	(b) (6) 1980
3.	Sex:	FEMALE
4.	Ethnicity:	HISPANIC OR LATINO(A) OR OF SPANISH ORIGIN
5.	Race: (Check X all that apply):	WHITE
6.	Racial Designation:	

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:02

Site No: 1231

Subject No: 12314059

Generated By: (b) (4)

Form: DATE OF VISIT

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Date of Visit

1.	Date of Visit	Aug/25/2020
2.	Erroneous Visit	

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 30-Jul-2020 21:29

Site No: 1231

Subject No: 12314059

Generated By: (b) (4)

Form: INCLUSION/EXCLUSION CRITERIA

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

Form Comments

Inclusion Criteria Not Met

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

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

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1231

Subject No: 12314059

Generated By: (b) (4)

Form: DISPOSITION - SCREENING

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Disposition - Screening

1.	Date of Completion/Discontinuation /Death	Aug/25/2020
2.	Phase of Disposition:	SCREENING
3.	Status:	COMPLETED
4.	Specify Status:	[]

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1231

Subject No: 12314059

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Medical History Details

1.a	Line/MH Number:	[1]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Hepatitis A]
	Start Date:	Jul/1/1987
	Ongoing:	NO End Date: Aug/1/1987

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 21-Aug-2020 02:51

Site No: 1231

Subject No: 12314059

Generated By: (b) (4)

Form: VITAL SIGNS - BASELINE

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Vital Signs

1.	Date:	Aug/25/2020
2.	Weight:	[90.0]
3.	Unit:	kg
4.	Height:	[156.0]
5.	Unit:	cm
6.	Body Mass Index:	[37.0]

Vital Signs Details

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

090177e196ae2ed8\Final\Final On: 01-Apr-2021 03:25 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 21-Aug-2020 02:49

Site No: 1231

Subject No: 12314059

Generated By: (b) (4)

Form: LAB URINALYSIS - PREGNANCY TEST

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Lab Urinalysis

1.	Lab Panel:	URINALYSIS
2.	Lab Sub-Panel:	PREGNANCY
3.	Collection Date:	Aug/25/2020
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:	

090177e196ae2ed8\Final\Final On: 01-Apr-2021 03:25 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1231

Subject No: 12314059

Generated By: (b) (4)

Form: RANDOMIZATION

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Disposition

1.	Randomization Date :	Aug/25/2020
2.	Randomization Number:	[67010]
3.	Randomization Group:	[]

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1231

Subject No: 12314059

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Electronic Sample Tracking

1.	Data Origin	SITE
2.	Sample Type	SERUM
3.	Sample Collected?	YES Date of Collection: Aug/25/2020
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	[BNVBNF]
5.b	Sample ID	[BNVBNH]
5.c	Sample ID	[BNVBNJ]
5.d	Sample ID	[BPT95G]
5.e	Sample ID	[BPT95H]
5.f	Sample ID	[BPT95J]

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Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1231

Subject No: 12314059

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Electronic Sample Tracking

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB
3.	Sample Collected?	YES Date of Collection: Aug/25/2020
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	[BP2FB8]
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090177e196ae2ed8\Final\Final On: 01-Apr-2021 03:25 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:04

Site No: 1231

Subject No: 12314059

Generated By: (b) (4)

Form: VACCINATION

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Vaccination

1.	Was there a temporary delay of vaccination?	NO
2.	Treatment Name	[BLINDED THERAPY]
3.	Formulation:	INJECTION
4.	Dose Date Time:	Aug/25/2020 19:20
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

090177e196ae2ed8\Final\Final On: 01-Apr-2021 03:25 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 06-Jul-2020 21:53

Site No: 1231

Subject No: 12314059

Generated By: (b) (4)

Form: REACTOGENICITY DIARY

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Reactogenicity Diary

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

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:02

Site No: 1231

Subject No: 12314059

Generated By: (b) (4)

Form: DATE OF VISIT

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Date of Visit

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

Header Text: C4591001

Visit: V2_VAX2_L

Form Version: 15-Sep-2020 21:54

Site No: 1231

Subject No: 12314059

Generated By: (b) (4)

Form: VITAL SIGNS - TEMP

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Vital Signs

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

2.a	Record Identifier:	1
	Temperature:	[36.4]
	Unit:	C
	Temperature Location:	ORAL CAVITY

Header Text: C4591001

Visit: V2_VAX2_L

Form Version: 21-Aug-2020 02:49

Site No: 1231

Subject No: 12314059

Generated By: (b) (4)

Form: LAB URINALYSIS - PREGNANCY TEST

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Lab Urinalysis

1.	Lab Panel:	URINALYSIS
2.	Lab Sub-Panel:	PREGNANCY
3.	Collection Date:	Sep/13/2020
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:	

090177e196ae2ed8\Final\Final On: 01-Apr-2021 03:25 (GMT)

Header Text: C4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:03

Site No: 1231

Subject No: 12314059

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Electronic Sample Tracking

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB
3.	Sample Collected?	YES Date of Collection: Sep/13/2020
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[]

Aliquot

Please enter barcode for each aliquot.

5.a	Sample ID	[BP2BPY]
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090177e196ae2ed8\Final\Final On: 01-Apr-2021 03:25 (GMT)

Header Text: C4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:04

Site No: 1231

Subject No: 12314059

Generated By: (b) (4)

Form: VACCINATION

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Vaccination

1.	Was there a temporary delay of vaccination?	NO
2.	Treatment Name	[BLINDED THERAPY]
3.	Formulation:	INJECTION
4.	Dose Date Time:	Sep/13/2020 10:45
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

090177e196ae2ed8\Final\Final On: 01-Apr-2021 03:25 (GMT)

Header Text: C4591001

Visit: V3_MONTH1_POSTVAX2_L

Form Version: 22-Apr-2020 21:02

Site No: 1231

Subject No: 12314059

Generated By: (b) (4)

Form: DATE OF VISIT

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Date of Visit

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

Header Text: C4591001

Visit: V3_MONTH1_POSTVAX2_L

Form Version: 22-Apr-2020 21:03

Site No: 1231

Subject No: 12314059

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Electronic Sample Tracking

1.	Data Origin	SITE
2.	Sample Type	SERUM
3.	Sample Collected?	YES Date of Collection: Oct/13/2020
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[]

Aliquot

Please enter barcode for each aliquot.

5.a	Sample ID	[BPT7PK]
5.b	Sample ID	[BRXPS0]
5.c	Sample ID	[BRXPSF]

090177e196ae2ed8\Final\Final On: 01-Apr-2021 03:25 (GMT)

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: 12314059

Subject Initials: ---

Generated By: (b) (4)

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

Date of Visit

1.	Date of Visit	//
2.	Erroneous Visit	

COVID-19 Illness Visit

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

Visit: POT_COVID_ILL - New Unscheduled Visit

Form: SIGNS AND SYMPTOMS OF POTENTIAL COVID-19

Form Version: 28-Mar-2021 02:35

Form Status: Not Started

Site No: 1231

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

Subject No: 12314059

Subject Initials: ---

Generated By: (b) (4)

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

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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090177e196ae2ed8\Final\Final On: 01-Apr-2021 03:25 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL - New Unscheduled Visit

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB SELF

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: 12314059

Subject Initials: ---

Generated By: (b) (4)

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

Electronic Sample Tracking

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

Aliquot

Please enter barcode for each aliquot.

5.	Sample ID	[]
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Header Text: C4591001

Visit: POT_COVID_ILL - New Unscheduled Visit

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1231

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

Subject No: 12314059

Subject Initials: ---

Generated By: (b) (4)

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

Electronic Sample Tracking

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

Aliquot

Please enter barcode for each aliquot.

5.	Sample ID	[]
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090177e196ae2ed8\Final\Final On: 01-Apr-2021 03:25 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL - New Unscheduled Visit

Form: HEALTH CARE UTILIZATION

Form Version: 28-Mar-2021 02:23

Form Status: Not Started

Site No: 1231

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

Subject No: 12314059

Subject Initials: ---

Generated By: (b) (4)

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

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?	
----	--	--

Header Text: C4591001

Visit: POT_COVID_ILL - New Unscheduled Visit

Form: ILLNESS DETAILS

Form Version: 06-Jul-2020 21:52

Form Status: Not Started

Site No: 1231

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

Subject No: 12314059

Subject Initials: ---

Generated By: (b) (4)

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

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 **Form:** DATE OF VISIT - ILLNESS CONVALESCENT 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: 12314059

Subject Initials: ---

Generated By: (b) (4)

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

Date of Visit

1.	Date of Visit	//
2.	Erroneous Visit	

COVID-19 Illness Visit

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

Visit: POT_COVID_CONVA - New Unscheduled **Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY Visit

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: 12314059

Subject Initials: ---

Generated By: (b) (4)

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

Electronic Sample Tracking

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

Aliquot

Please enter barcode for each aliquot.

5.	Sample ID	[]
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090177e196ae2ed8\Final\Final On: 01-Apr-2021 03:25 (GMT)

Header Text: C4591001

Visit: Unplanned - New Unscheduled Visit

Form Version: 22-Apr-2020 21:02

Site No: 1231

Subject No: 12314059

Generated By: (b) (4)

Form: DATE OF VISIT

Form Status: Not Started

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

Subject Initials: ---

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

Date of Visit

1.	Date of Visit	//
2.	Erroneous Visit	

Header Text: C4591001

Visit: 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: 12314059

Subject Initials: ---

Generated By: (b) (4)

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

Unplanned Assessments

1.	Assessments	
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Header Text: C4591001

Visit: End of Treatment - Unscheduled

Form Version: 15-Sep-2020 21:55

Site No: 1231

Subject No: 12314059

Generated By: (b) (4)

Form: DISPOSITION - TREATMENT

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Disposition - Treatment

1.	Date of Completion/Discontinuation /Death :	Oct/13/2020
2.	Phase of Disposition:	VACCINATION
3.	Status:	COMPLETED
4.	Specify Status:	[]

Header Text: C4591001

Visit: Follow-Up - Unscheduled

Form Version: 15-Sep-2020 21:53

Site No: 1231

Subject No: 12314059

Generated By: (b) (4)

Form: DISPOSITION - FOLLOW-UP

Form Status: Data Complete, Frozen, Verified

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

Subject Initials: ---

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

[Form Comments](#)
[eCRF Audit Trail History](#)

Disposition - Follow-Up

1.	Date of Completion/Discontinuation /Death :	Not Applicable _____ //	Comments
2.	Phase of Disposition:	Not Applicable _____	Comments
3.	Status:	Not Applicable _____	Comments
4.	Specify Status:	Not Applicable _____ []	Comments

090177e196ae2ed8\Final\Final On: 01-Apr-2021 03:25 (GMT)

Header Text: C4591001

Visit: POT_COVID_REPEAT_SWAB - New
Unscheduled Visit

Form: DATE OF VISIT - REPEAT SWAB

Form Version: 10-Oct-2020 15:57

Form Status: Not Started

Site No: 1231

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

Subject No: 12314059

Subject Initials: ---

Generated By: (b) (4)

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

Date of Visit

1.	Date of Visit	//
2.	Erroneous Visit	

COVID-19 Repeat Swab

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

Header Text: C4591001

Visit: POT_COVID_REPEAT_SWAB - New
Unscheduled Visit

Form: ELECTRONIC SAMPLE TRACKING - REPEAT SWAB

Form Version: 10-Oct-2020 15:57

Form Status: Not Started

Site No: 1231

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

Subject No: 12314059

Subject Initials: ---

Generated By: (b) (4)

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

Electronic Sample Tracking

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

Aliquot

Please enter barcode for each aliquot.

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

090177e196ae2ed8\Final\Final On: 01-Apr-2021 03:25 (GMT)

Header Text: C4591001

Visit: Unplanned Vaccination - Unscheduled

Form: DATE OF VISIT

Form Version: 22-Apr-2020 21:02

Form Status: Not Started

Site No: 1231

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

Subject No: 12314059

Subject Initials: ---

Generated By: (b) (4)

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

Date of Visit

1.	Date of Visit	//
2.	Erroneous Visit	

Header Text: C4591001

Visit: Unplanned Vaccination - Unscheduled

Form: VITAL SIGNS - TEMP

Form Version: 28-Mar-2021 02:28

Form Status: Not Started

Site No: 1231

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

Subject No: 12314059

Subject Initials: ---

Generated By: (b) (4)

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

Vital Signs

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

Vital Signs Details

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

090177e196ae2ed8\Final\Final On: 01-Apr-2021 03:25 (GMT)

Header Text: C4591001**Visit:** Unplanned Vaccination - Unscheduled**Form:** LAB URINALYSIS - PREGNANCY TEST**Form Version:** 20-Feb-2021 02:14**Form Status:** Not Started**Site No:** 1231**Site Name:** (1231) Hospital Militar Central Cirujano Mayor Dr. Cosme Argerich**Subject No:** 12314059**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 20:34**Lab Urinalysis**

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

Lab Result

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

Header Text: C4591001

Visit: Unplanned Vaccination - Unscheduled

Form Version: 10-Dec-2020 02:26

Site No: 1231

Subject No: 12314059

Generated By: (b) (4)

Form: VACCINATION

Form Status: Not Started

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

Subject Initials: ---

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

Vaccination

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

090177e196ae2ed8\Final\Final On: 01-Apr-2021 03:25 (GMT)

Header Text: C4591001

Visit: Unplanned Vaccination - Unscheduled

Form: CONTACT OUTCOME - MONTH 1

Form Version: 10-Oct-2020 15:57

Form Status: Not Started

Site No: 1231

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

Subject No: 12314059

Subject Initials: ---

Generated By: (b) (4)

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

Contact Outcome

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

Header Text: C4591001

Visit: Unplanned Vaccination - Unscheduled

Form: CONTACT OUTCOME - MONTH 6

Form Version: 10-Oct-2020 16:01

Form Status: Not Started

Site No: 1231

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

Subject No: 12314059

Subject Initials: ---

Generated By: (b) (4)

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

Contact Outcome

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

Header Text: C4591001

Visit: Potential ReVax Initial Contact -
Unscheduled

Form: DATE OF VISIT

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1231

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

Subject No: 12314059

Subject Initials: ---

Generated By: (b) (4)

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

[eCRF Audit Trail History](#)

Date of Visit

1.	Date of Visit	Feb/17/2021
2.	Erroneous Visit	

Header Text: C4591001

Visit: Potential ReVax Initial Contact -
Unscheduled

Form Version: 10-Dec-2020 02:25

Site No: 1231

Subject No: 12314059

Generated By: (b) (4)

Form: FURTHER VACCINATION CONFIRMATION

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Further Vaccination Confirmation

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

Header Text: C4591001

Visit: V101_VAX3

Form Version: 22-Apr-2020 21:02

Site No: 1231

Subject No: 12314059

Generated By: (b) (4)

Form: DATE OF VISIT

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Date of Visit

1.	Date of Visit	Mar/4/2021
2.	Erroneous Visit	

Header Text: C4591001

Visit: V101_VAX3

Form Version: 10-Dec-2020 02:31

Site No: 1231

Subject No: 12314059

Generated By: (b) (4)

Form: INFORMED CONSENT - FURTHER VACCINATION

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Informed Consent - Further Vaccination

1.	Consent Was:	OBTAINED Date Written Consent Obtained Mar/4/2021
----	--------------	---

090177e196ae2ed8\Final\Final On: 01-Apr-2021 03:25 (GMT)

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: 12314059

Subject Initials: ---

Generated By: (b) (4)

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

Form Comments

Inclusion Criteria Not Met

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

Exclusion Criteria Met

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

Header Text: C4591001

Visit: V101_VAX3

Form Version: 10-Dec-2020 02:31

Site No: 1231

Subject No: 12314059

Generated By: (b) (4)

Form: DISPOSITION - SCREENING FOR FURTHER VACCINATION

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Disposition - Screening for Further Vaccination

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

090177e196ae2ed8\Final\Final On: 01-Apr-2021 03:25 (GMT)

Header Text: C4591001

Visit: V101_VAX3

Form Version: 20-Feb-2021 02:14

Site No: 1231

Subject No: 12314059

Generated By: (b) (4)

Form: LAB URINALYSIS - PREGNANCY TEST

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Lab Urinalysis

1.	Lab Panel:	URINALYSIS
2.	Lab Sub-Panel:	PREGNANCY
3.	Collection Date:	Mar/4/2021
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:	

090177e196ae2ed8\Final\Final On: 01-Apr-2021 03:25 (GMT)

Header Text: C4591001

Visit: V101_VAX3

Form Version: 22-Apr-2020 21:03

Site No: 1231

Subject No: 12314059

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Electronic Sample Tracking

1.	Data Origin	SITE
2.	Sample Type	SERUM
3.	Sample Collected?	YES Date of Collection: Mar/4/2021
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	[BR21FZ]
5.b	Sample ID	[BRXJ2X]
5.c	Sample ID	[BRXJ2D]

090177e196ae2ed8\Final\Final On: 01-Apr-2021 03:25 (GMT)

Header Text: C4591001

Visit: V101_VAX3

Form Version: 22-Apr-2020 21:03

Site No: 1231

Subject No: 12314059

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Electronic Sample Tracking

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB
3.	Sample Collected?	YES Date of Collection: Mar/4/2021
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	[BR1WR6]
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090177e196ae2ed8\Final\Final On: 01-Apr-2021 03:25 (GMT)

Header Text: C4591001

Visit: V101_VAX3

Form Version: 10-Dec-2020 02:26

Site No: 1231

Subject No: 12314059

Generated By: (b) (4)

Form: VACCINATION

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Vaccination

1.	Was there a temporary delay of vaccination?	NO
2.	Treatment Name	[BNT162b2]
3.	Formulation:	INJECTION
4.	Dose Date Time:	Mar/4/2021 11:16
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

090177e196ae2ed8\Final\Final On: 01-Apr-2021 03:25 (GMT)

Header Text: C4591001

Visit: V102_VAX4

Form Version: 22-Apr-2020 21:02

Site No: 1231

Subject No: 12314059

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 20:34

[eCRF Audit Trail History](#)

Date of Visit

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

Header Text: C4591001

Visit: V102_VAX4

Form Version: 20-Feb-2021 02:14

Site No: 1231

Subject No: 12314059

Generated By: (b) (4)

Form: LAB URINALYSIS - PREGNANCY TEST

Form Status: Data Complete, Verified

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

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Lab Urinalysis

1.	Lab Panel:	URINALYSIS
2.	Lab Sub-Panel:	PREGNANCY
3.	Collection Date:	Mar/25/2021
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:	

090177e196ae2ed8\Final\Final On: 01-Apr-2021 03:25 (GMT)

Header Text: C4591001

Visit: V102_VAX4

Form Version: 22-Apr-2020 21:03

Site No: 1231

Subject No: 12314059

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB

Form Status: Data Complete, Verified

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

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Electronic Sample Tracking

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB
3.	Sample Collected?	YES Date of Collection: Mar/25/2021
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	[BPT8M6]
-----	-----------	----------

090177e196ae2ed8\Final\Final On: 01-Apr-2021 03:25 (GMT)

Header Text: C4591001

Visit: V102_VAX4

Form Version: 10-Dec-2020 02:26

Site No: 1231

Subject No: 12314059

Generated By: (b) (4)

Form: VACCINATION

Form Status: Data Complete, Verified

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

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Vaccination

1.	Was there a temporary delay of vaccination?	NO
2.	Treatment Name	[BNT162b2]
3.	Formulation:	INJECTION
4.	Dose Date Time:	Mar/25/2021 10:48
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

090177e196ae2ed8\Final\Final On: 01-Apr-2021 03:25 (GMT)

Header Text: C4591001

Visit: V103_MONTH1

Form Version: 22-Apr-2020 21:02

Site No: 1231

Subject No: 12314059

Generated By: (b) (4)

Form: DATE OF VISIT

Form Status: Not Started

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

Subject Initials: ---

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

Date of Visit

1.	Date of Visit	//
2.	Erroneous Visit	

Header Text: C4591001

Visit: V103_MONTH1

Form Version: 22-Apr-2020 21:04

Site No: 1231

Subject No: 12314059

Generated By: (b) (4)

Form: CONTACT OUTCOME

Form Status: Not Started

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

Subject Initials: ---

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

Contact Outcome

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

Header Text: C4591001

Visit: V104_MONTH6

Form Version: 22-Apr-2020 21:02

Site No: 1231

Subject No: 12314059

Generated By: (b) (4)

Form: DATE OF VISIT

Form Status: Not Started

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

Subject Initials: ---

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

Date of Visit

1.	Date of Visit	//
2.	Erroneous Visit	

Header Text: C4591001

Visit: V104_MONTH6

Form Version: 22-Apr-2020 21:04

Site No: 1231

Subject No: 12314059

Generated By: (b) (4)

Form: CONTACT OUTCOME

Form Status: Not Started

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

Subject Initials: ---

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

Contact Outcome

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

Header Text: C4591001

Visit: V105_MONTH18

Form Version: 22-Apr-2020 21:02

Site No: 1231

Subject No: 12314059

Generated By: (b) (4)

Form: DATE OF VISIT

Form Status: Not Started

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

Subject Initials: ---

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

Date of Visit

1.	Date of Visit	//
2.	Erroneous Visit	

Header Text: C4591001

Visit: V105_MONTH18

Form Version: 22-Apr-2020 21:04

Site No: 1231

Subject No: 12314059

Generated By: (b) (4)

Form: CONTACT OUTCOME

Form Status: Not Started

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

Subject Initials: ---

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

Contact Outcome

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

Header Text: C4591001

Visit: FURTHER_VACCINATION_EOT -
Unscheduled

Form Version: 20-Feb-2021 02:26

Site No: 1231

Subject No: 12314059

Generated By: (b) (4)

Form: DISPOSITION - TREATMENT

Form Status: Not Started

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

Subject Initials: ---

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

Disposition - Treatment

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

Header Text: C4591001

Visit: Logs

Form: ADVERSE EVENT REPORT

Form Version: 22-Apr-2020 21:02

Site No: 1231

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

Subject No: 12314059

Subject Initials: ---

Generated By: (b) (4)

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

#	Category	AE Identifier	Adverse Event	Start Date	Is the Adverse Event Still Ongoing	Form Instance
1.	ADVERSE EVENT	1	exposure during pregnancy	Aug/31/2020 17:30	NO End Date Time: Nov/9/2020 UNK:UNK	Repeating Pages

090177e196ae2ed8\Final\Final On: 01-Apr-2021 03:25 (GMT)

Header Text: C4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1231

Subject No: 12314059

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

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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)	[exposure during pregnancy]	
4.	Start Date Time:	Aug/31/2020 17:30	
5.	Is the adverse event still ongoing?	NO End Date Time: Nov/9/2020 UNK:UNK	
6.	Toxicity Grade:	Not Applicable	Comments
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: [unplanned pregnancy]	
10.	Latest Action Taken with Study Treatment:	NOT APPLICABLE	

090177e196ae2ed8\Final\Final On: 01-Apr-2021 03:25 (GMT)

Header Text: C4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1231

Subject No: 12314059

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

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	[]

090177e196ae2ed8\Final\Final On: 01-Apr-2021 03:25 (GMT)

Header Text: C4591001

Visit: Logs

Form: MEDICATION ERROR

Form Version: 17-Jul-2020 21:54

Site No: 1231

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

Subject No: 12314059

Subject Initials: ---

Generated By: (b) (4)

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

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

Header Text: C4591001

Visit: Logs - Unscheduled

Form Version: 17-Jul-2020 21:54

Site No: 1231

Subject No: 12314059

Generated By: (b) (4)

Form: MEDICATION ERROR

Form Status: Not Started

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

Subject Initials: ---

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

[Back to Form](#)

Medication Error

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

090177e196ae2ed8\Final\Final On: 01-Apr-2021 03:25 (GMT)

Header Text: C4591001

Visit: Logs

Form: CONCOMITANT MEDICATIONS - NON STUDY
VACCINATIONS

Form Version: 22-Apr-2020 21:03

Site No: 1231

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

Subject No: 12314059

Subject Initials: ---

Generated By: (b) (4)

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

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

Header Text: C4591001

Visit: Logs - Unscheduled

Form: CONCOMITANT MEDICATIONS - NON STUDY
VACCINATIONS

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1231

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

Subject No: 12314059

Subject Initials: ---

Generated By: (b) (4)

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

[Back to Form](#)

Concomitant Medications

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

090177e196ae2ed8\Final\Final On: 01-Apr-2021 03:25 (GMT)

Header Text: C4591001

Visit: Logs

Form: CONCOMITANT MEDICATIONS - PROHIBITED

Form Version: 22-Apr-2020 21:03

Site No: 1231

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

Subject No: 12314059

Subject Initials: ---

Generated By: (b) (4)

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

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

Header Text: C4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1231

Subject No: 12314059

Generated By: (b) (4)

Form: CONCOMITANT MEDICATIONS - PROHIBITED

Form Status: Not Started

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

Subject Initials: ---

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

[Back to Form](#)

Concomitant Medications

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

090177e196ae2ed8\Final\Final On: 01-Apr-2021 03:25 (GMT)

Header Text: C4591001

Visit: Logs

Form: RADIATION TREATMENT

Form Version: 22-Apr-2020 21:02

Site No: 1231

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

Subject No: 12314059

Subject Initials: ---

Generated By: (b) (4)

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

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

Header Text: C4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1231

Subject No: 12314059

Generated By: (b) (4)

Form: RADIATION TREATMENT

Form Status: Not Started

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

Subject Initials: ---

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

[Back to Form](#)

Radiation Treatment

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

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: 12314059

Subject Initials: ---

Generated By: (b) (4)

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

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

Header Text: C4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1231

Subject No: 12314059

Generated By: (b) (4)

Form: TRANSFUSIONS

Form Status: Not Started

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

Subject Initials: ---

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

[Back to Form](#)

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

Header Text: C4591001

Visit: Disposition - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1231

Subject No: 12314059

Generated By: (b) (4)

Form: TREATMENT UNBLINDED

Form Status: Data Complete, Frozen, Verified

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

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Treatment Unblinded

1.	Date Treatment Unblinded :	Feb/17/2021
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: 12314059

Generated By: (b) (4)

Form: WITHDRAWAL OF CONSENT

Form Status: Not Started

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

Subject Initials: ---

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

Withdrawal Of Consent

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

Visit: Disposition - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1231

Subject No: 12314059

Generated By: (b) (4)

Form: DEATH DETAILS CODED

Form Status: Not Started

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

Subject Initials: ---

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

Death Details

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

Cause of Death

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

Header Text: C4591001

Visit: Subject Status - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1231

Subject No: 12314059

Generated By: (b) (4)

Form: SUBJECT STATUS

Form Status: Data Complete, Verified

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

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Subject Status

1.	Subject Status	FOLLOW-UP
2.	Subject Status Date	Oct/13/2020

Header Text: C4591001

Visit: Investigator Signature - Unscheduled

Form Version: 22-Apr-2020 21:04

Site No: 1231

Subject No: 12314059

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 20:34

[eCRF Audit Trail History](#)

Casebook Signature Form

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

Visit: Investigator Signature - Unscheduled

Form: CASEBOOK SIGNATURE FORM

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Verified

Site No: 1231

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

Subject No: 12314059

Subject Initials: ---

Generated By: (b) (4)

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

[Audit Trail](#)

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

- CRF_Sign
- CRF_Sign_1

Name	Signature Meaning	Date	Type	Action
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Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 30-Jul-2020 21:29

Site No: 1231

Subject No: 12314059

Generated By: (b) (4)

Form: INCLUSION/EXCLUSION CRITERIA - Comments

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

[Back to Form](#)

Item	Date	User	Comment
Form	Aug-25-2020 21:19:21 (UTC-03:00) City of Buenos Aires	Martina Davalli (b) (4)	Not Applicable

Header Text: C4591001

Visit: Follow-Up - Unscheduled

Form Version: 15-Sep-2020 21:53

Site No: 1231

Subject No: 12314059

Generated By: (b) (4)

Form: DISPOSITION - FOLLOW-UP - Comments

Form Status: Data Complete, Frozen, Verified

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

Subject Initials: ---

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

[Back to Form](#)

Item	Date	User	Comment
Form	Nov-09-2020 13:12:54 (UTC-03:00) City of Buenos Aires	(b) (4), (b) (6)	Not Applicable

Header Text: C4591001

Visit: Follow-Up

Form Version: 15-Sep-2020 21:53

Site No: 1231

Subject No: 12314059

Generated By: (b) (4)

Form: DISPOSITION - FOLLOW-UP - Comments

Form Status: Data Complete, Frozen, Verified

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

Subject Initials: ---

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

[Back to Form](#)

Item	Date	User	Comment
1	Nov-09-2020 13:12:54 (UTC-03:00) City of Buenos Aires	(b) (4), (b) (6)	Not Applicable

Header Text: C4591001

Visit: Follow-Up

Form Version: 15-Sep-2020 21:53

Site No: 1231

Subject No: 12314059

Generated By: (b) (4)

Form: DISPOSITION - FOLLOW-UP - Comments

Form Status: Data Complete, Frozen, Verified

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

Subject Initials: ---

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

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Item	Date	User	Comment
2	Nov-09-2020 13:12:54 (UTC-03:00) City of Buenos Aires	(b) (4), (b) (6)	Not Applicable

Header Text: C4591001

Visit: Follow-Up

Form Version: 15-Sep-2020 21:53

Site No: 1231

Subject No: 12314059

Generated By: (b) (4)

Form: DISPOSITION - FOLLOW-UP - Comments

Form Status: Data Complete, Frozen, Verified

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

Subject Initials: ---

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

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Item	Date	User	Comment
3	Nov-09-2020 13:12:54 (UTC-03:00) City of Buenos Aires	(b) (4), (b) (6)	Not Applicable

Header Text: C4591001

Visit: Follow-Up

Form Version: 15-Sep-2020 21:53

Site No: 1231

Subject No: 12314059

Generated By: (b) (4)

Form: DISPOSITION - FOLLOW-UP - Comments

Form Status: Data Complete, Frozen, Verified

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

Subject Initials: ---

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

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Item	Date	User	Comment
4	Nov-09-2020 13:12:54 (UTC-03:00) City of Buenos Aires	(b) (4), (b) (6)	Not Applicable

090177e196ae2ed8\Final\Final On: 01-Apr-2021 03:25 (GMT)

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: 12314059

Subject Initials: ---

Generated By: (b) (4)

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

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Item	Date	User	Comment
Form	Mar-04-2021 13:43:41 (UTC-03:00) City of Buenos Aires	(b) (4), (b) (6)	Not Applicable

Header Text: C4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1231

Subject No: 12314059

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - Comments

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

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Item	Date	User	Comment
6	Nov-15-2020 10:55:05 (UTC-03:00) City of Buenos Aires	(b) (4), (b) (6)	not applicable Not Applicable
6	Nov-15-2020 10:54:24 (UTC-03:00) City of Buenos Aires	(b) (4), (b) (6)	not applicable

090177e196ae2ed8\Final\Final On: 01-Apr-2021 03:25 (GMT)

Header Text: C4591001

Visit: Investigator Signature - Unscheduled

Form: CASEBOOK SIGNATURE FORM - Signature History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Verified

Site No: 1231

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

Subject No: 12314059

Subject Initials: ---

Generated By: (b) (4)

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

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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 15:39:06 (UTC-03:00) City of Buenos Aires		Edit - All signatures invalidated

Affidavit:
N/A

Tatiana Estrada	Approved	Mar-09-2021 16:21:31 (UTC-03:00) City of Buenos Aires	BOOK	Signed
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Affidavit:

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

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

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

(b) (6)	N/A	Mar-04-2021 13:43:01 (UTC-03:00) City of Buenos Aires		Edit - All signatures invalidated
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Affidavit:
N/A

(b) (6)	Approved	Feb-22-2021 17:40:36 (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.

090177e196ae2ed8\Final\Final On: 01-Apr-2021 03:25 (GMT)

Header Text: C4591001**Visit:** Investigator Signature - Unscheduled**Form:** CASEBOOK SIGNATURE FORM - Signature History**Form Version:** 22-Apr-2020 21:04**Form Status:** Data Complete, Verified**Site No:** 1231**Site Name:** (1231) Hospital Militar Central Cirujano Mayor Dr. Cosme Argerich**Subject No:** 12314059**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 20:34

(b) (6)	N/A	Feb-17-2021 11:40:53 (UTC-03:00) City of Buenos Aires		Edit - All signatures invalidated
Affidavit: N/A				
(b) (6)	Approved	Jan-22-2021 10:49:39 (UTC-03:00) City of Buenos Aires	BOOK	Signed
Affidavit: By my dated signature below, I, (b) (6), verify that all case report form pages accurately display the results of the examinations, tests, evaluations and treatments performed on this subject. Pursuant to Section 11.100 of Title 21 of the Code of Federal Regulations, this is to certify that I intend that this electronic signature is to be the legally binding equivalent of my handwritten signature. To this I do attest by supplying my user name and password and clicking the button marked Submit below.				
(b) (6)	N/A	Dec-04-2020 13:21:14 (UTC-03:00) City of Buenos Aires		Edit - All signatures invalidated
Affidavit: N/A				
(b) (6)	Approved	Nov-15-2020 18:27:49 (UTC-03:00) City of Buenos Aires	BOOK	Signed
Affidavit: By my dated signature below, I, (b) (6) verify that all case report form pages accurately display the results of the examinations, tests, evaluations and treatments performed on this subject. Pursuant to Section 11.100 of Title 21 of the Code of Federal Regulations, this is to certify that I intend that this electronic signature is to be the legally binding equivalent of my handwritten signature. To this I do attest by supplying my user name and password and clicking the button marked Submit below.				
(b) (6)	N/A	Nov-15-2020 10:54:24 (UTC-03:00) City of Buenos Aires		Edit - All signatures invalidated
Affidavit: N/A				

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: 12314059

Subject Initials: ---

Generated By: (b) (4)

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

(b) (6)	Approved	Nov-09-2020 17:50:50 (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	Nov-09-2020 13:12:54 (UTC-03:00) City of Buenos Aires		Edit - All signatures invalidated
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Affidavit:

N/A

Fernando Polack	Approved	Nov-08-2020 21:39:55 (UTC-03:00) City of Buenos Aires	BOOK	Signed
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Affidavit:

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

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

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

Tatiana Estrada	N/A	Nov-03-2020 11:39:40 (UTC-03:00) City of Buenos Aires		Edit - All signatures invalidated
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Affidavit:

N/A

(b) (6)	Approved	Nov-02-2020 15:02:34 (UTC-03:00) City of Buenos Aires	BOOK	Signed
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090177e196ae2ed8\Final\Final On: 01-Apr-2021 03:25 (GMT)

Header Text: C4591001

Visit: Investigator Signature - Unscheduled

Form: CASEBOOK SIGNATURE FORM - Signature History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Verified

Site No: 1231

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

Subject No: 12314059

Subject Initials: ---

Generated By: (b) (4)

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

Affidavit:

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

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

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

(b) (6)	N/A	Oct-30-2020 11:12:15 (UTC-03:00) City of Buenos Aires		Edit - All signatures invalidated
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Affidavit:

N/A

(b) (6)	Approved	Oct-23-2020 14:27:41 (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.

090177e196ae2ed8\Final\Final On: 01-Apr-2021 03:25 (GMT)

Header Text: C4591001

Visit: COHORT_SELECTION

Form Version: 30-Jul-2020 21:29

Site No: 1231

Subject No: 12314059

Generated By: (b) (4)

Form: COHORT SELECTION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

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1. Select appropriate response - Protocol version

Date	Location	User	Value	Reason
Aug-25-2020 21:18:33 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	Martina Davalli (b) (4)	Data Entry: 24 JUL 2020	Initial Entry

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

Date	Location	User	Value	Reason
Aug-25-2020 21:18:33 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	Martina Davalli (b) (4)	Data Entry: STAGE 3 COHORTS	Initial Entry

Header Text: C4591001

Visit: COHORT_SELECTION

Form Version: 22-Apr-2020 21:02

Site No: 1231

Subject No: 12314059

Generated By: (b) (4)

Form: MAIN INFORMED CONSENT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

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I. Consent Was:

Date	Location	User	Value	Reason
Aug-25-2020 21:18:39 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	Martina Davalli (b) (4)	Data Entry: OBTAINED Date Written Consent Obtained Aug/25/2020	Initial Entry

090177e196ae2ed8\Final\Final On: 01-Apr-2021 03:25 (GMT)

Header Text: C4591001

Visit: COHORT_SELECTION

Form Version: 06-Jul-2020 21:55

Site No: 1231

Subject No: 12314059

Generated By: (b) (4)

Form: DEMOGRAPHY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

[Back to Form](#)

1. Subject ID

Date	Location	User	Value	Reason
Aug-25-2020 18:09:31 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 12314059	Item copied from previous form

2. Birth Date:

Date	Location	User	Value	Reason
Aug-25-2020 18:09:25 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: (b) (6)/1980	Enrollment Entry

3. Sex:

Date	Location	User	Value	Reason
Aug-25-2020 21:18:56 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	Martina Davalli (b) (4)	Data Entry: FEMALE	Initial Entry

4. Ethnicity:

Date	Location	User	Value	Reason
Aug-25-2020 21:18:56 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	Martina Davalli (b) (4)	Data Entry: HISPANIC OR LATINO(A) OR O F SPANISH ORIGIN	Initial Entry

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

Date	Location	User	Value	Reason
Aug-25-2020 21:18:56 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	Martina Davalli (b) (4)	Data Entry: WHITE	Initial Entry

090177e196ae2ed8\Final\Final On: 01-Apr-2021 03:25 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:02

Site No: 1231

Subject No: 12314059

Generated By: (b) (4)

Form: DATE OF VISIT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

[Back to Form](#)

I. Date of Visit

Date	Location	User	Value	Reason
Aug-25-2020 21:19:11 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	Martina Davalli (b) (4)	Data Entry: Aug/25/2020	Initial Entry

090177e196ae2ed8\Final\Final On: 01-Apr-2021 03:25 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1231

Subject No: 12314059

Generated By: (b) (4)

Form: DISPOSITION - SCREENING - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

[Back to Form](#)

1. Date of Completion/Discontinuation/Death

Date	Location	User	Value	Reason
Aug-25-2020 21:21:27 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	Martina Davalli (b) (4)	Data Entry: Aug/25/2020	Initial Entry

2. Phase of Disposition:

Date	Location	User	Value	Reason
Aug-25-2020 21:21:27 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SCREENING	Initial Entry

3. Status:

Date	Location	User	Value	Reason
Aug-25-2020 21:21:27 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	Martina Davalli (b) (4)	Data Entry: COMPLETED	Initial Entry

090177e196ae2ed8\Final\Final On: 01-Apr-2021 03:25 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1231

Subject No: 12314059

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

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I.a

Date	Location	User	Value	Reason
Aug-25-2020 21:22:12 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 1 Medical History Term: Hepatitis A Start Date: Jul/1/1987 Ongoing: NO End Date: Aug/1/1987	Initial Entry

I.a Line/MH Number:

Date	Location	User	Value	Reason
Aug-25-2020 21:22:12 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 1	Initial Entry

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

Date	Location	User	Value	Reason
Aug-25-2020 21:22:12 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	Martina Davalli (b) (4)	Data Entry: Hepatitis A	Initial Entry

I.a Start Date:

Date	Location	User	Value	Reason
Aug-25-2020 21:22:12 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	Martina Davalli (b) (4)	Data Entry: Jul/1/1987	Initial Entry

I.a Ongoing:

Date	Location	User	Value	Reason
Aug-25-2020 21:22:12 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	Martina Davalli	Data Entry: NO	Initial Entry

090177e196ae2ed8\Final\Final On: 01-Apr-2021 03:25 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1231

Subject No: 12314059

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

Buenos Aires	(b) (4)	End Date:	
		Aug/1/1987	

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 21-Aug-2020 02:51

Site No: 1231

Subject No: 12314059

Generated By: (b) (4)

Form: VITAL SIGNS - BASELINE - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

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1. Date:

Date	Location	User	Value	Reason
Aug-25-2020 21:22:44 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	Martina Davalli (b) (4)	Data Entry: Aug/25/2020	Initial Entry

2. Weight:

Date	Location	User	Value	Reason
Aug-25-2020 21:22:44 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	Martina Davalli (b) (4)	Data Entry: 90.0	Initial Entry

3. Unit:

Date	Location	User	Value	Reason
Aug-25-2020 21:22:44 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	Martina Davalli (b) (4)	Data Entry: kg	Initial Entry

4. Height:

Date	Location	User	Value	Reason
Aug-25-2020 21:22:44 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	Martina Davalli (b) (4)	Data Entry: 156.0	Initial Entry

5. Unit:

Date	Location	User	Value	Reason
Aug-25-2020 21:22:44 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	Martina Davalli (b) (4)	Data Entry: cm	Initial Entry

6. Body Mass Index:

Date	Location	User	Value	Reason
Aug-25-2020 21:22:44 (UTC-03:00) City of	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 37.0	Initial Entry

090177e196ae2ed8\Final\Final On: 01-Apr-2021 03:25 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 21-Aug-2020 02:51

Site No: 1231

Subject No: 12314059

Generated By: (b) (4)

Form: VITAL SIGNS - BASELINE - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

Buenos Aires			
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7.a

Date	Location	User	Value	Reason
Aug-25-2020 21:22:44 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	Martina Davalli (b) (4)	Data Entry: Record Identifier:: 1 Temperature: 37.0 Temperature Unit: C Temperature Location:: ORAL CAVITY	Initial Entry

7.a Record Identifier:

Date	Location	User	Value	Reason
Aug-25-2020 21:22:44 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	Martina Davalli (b) (4)	Data Entry: 1	Initial Entry

7.a Temperature:

Date	Location	User	Value	Reason
Aug-25-2020 21:22:44 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	Martina Davalli (b) (4)	Data Entry: 37.0	Initial Entry

7.a Unit:

Date	Location	User	Value	Reason
Aug-25-2020 21:22:44 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	Martina Davalli (b) (4)	Data Entry: C	Initial Entry

7.a Temperature Location:

Date	Location	User	Value	Reason
Aug-25-2020 21:22:44 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	Martina Davalli (b) (4)	Data Entry: ORAL CAVITY	Initial Entry

090177e196ae2ed8\Final\Final On: 01-Apr-2021 03:25 (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: 12314059

Subject Initials: ---

Generated By: (b) (4)

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

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1. Lab Panel:

Date	Location	User	Value	Reason
Aug-25-2020 21:22:54 (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-25-2020 21:22:54 (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-25-2020 21:22:54 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	Martina Davalli (b) (4)	Data Entry: Aug/25/2020	Initial Entry

4. Laboratory Name and Address (Derived)

Date	Location	User	Value	Reason
Aug-25-2020 21:22:54 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: STUDY SITE	Initial Entry

5. Specimen Type:

Date	Location	User	Value	Reason
Aug-25-2020 21:22:54 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: URINE	Initial Entry

6.a

Date	Location	User	Value	Reason
Aug-25-2020 21:22:54	ACV0PFEINFP6000	auto calc	Data Entry:	Initial Entry

090177e196ae2ed8\Final\Final On: 01-Apr-2021 03:25 (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: 12314059

Subject Initials: ---

Generated By: (b) (4)

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

(UTC-03:00) City of Buenos Aires	(autocalc)	Sponsor-Defined Identifier: 113	
		Test:: Choriogonadotropin in Beta_PX113	
		Result:: NEGATIVE	
		Not Done::	

6.a Sponsor ID:

Date	Location	User	Value	Reason
Aug-25-2020 21:22:54 (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-25-2020 21:22:54 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	Martina Davalli (b) (4)	Data Entry: Choriogonadotropin Beta_PX113	Initial Entry

6.a Result:

Date	Location	User	Value	Reason
Aug-25-2020 21:22:54 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	Martina Davalli (b) (4)	Data Entry: NEGATIVE	Initial Entry

090177e196ae2ed8\Final\Final On: 01-Apr-2021 03:25 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1231

Subject No: 12314059

Generated By: (b) (4)

Form: RANDOMIZATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

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1. Randomization Date :

Date	Location	User	Value	Reason
Aug-25-2020 21:23:02 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	Martina Davalli (b) (4)	<u>Data Entry:</u> Aug/25/2020	Initial Entry

2. Randomization Number:

Date	Location	User	Value	Reason
Aug-25-2020 21:23:02 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	Martina Davalli (b) (4)	<u>Data Entry:</u> 67010	Initial Entry

090177e196ae2ed8\Final\Final On: 01-Apr-2021 03:25 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1231

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

Subject No: 12314059

Subject Initials: ---

Generated By: (b) (4)

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

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1. Data Origin

Date	Location	User	Value	Reason
Aug-25-2020 21:23:07 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Aug-25-2020 21:23:07 (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-27-2020 12:24:24 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Aug-26-2020 02:55:31 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Aug-25-2020 21:23:07 (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-25-2020 21:23:07 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	Martina Davalli (b) (4)	Data Entry: YES Date of Collection: Aug/25/2020	Initial Entry

5.a

090177e196ae2ed8\Final\Final On: 01-Apr-2021 03:25 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1231

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

Subject No: 12314059

Subject Initials: ---

Generated By: (b) (4)

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

Date	Location	User	Value	Reason
Aug-27-2020 12:24:24 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BNVBNF	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Aug-27-2020 12:24:24 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BNVBNF	Initial Entry

5.b

Date	Location	User	Value	Reason
Aug-27-2020 12:24:33 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BNVBNH	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Aug-27-2020 12:24:33 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BNVBNH	Initial Entry

5.c

Date	Location	User	Value	Reason
Aug-27-2020 12:24:43 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BNVBNJ	Initial Entry

5.c Sample ID

Date	Location	User	Value	Reason
Aug-27-2020 12:24:43 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BNVBNJ	Initial Entry

5.d

090177e196ae2ed8\Final\Final On: 01-Apr-2021 03:25 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1231

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

Subject No: 12314059

Subject Initials: ---

Generated By: (b) (4)

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

Date	Location	User	Value	Reason
Aug-27-2020 13:15:50 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BPT95G	Initial Entry

5.d Sample ID

Date	Location	User	Value	Reason
Aug-27-2020 13:15:50 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BPT95G	Initial Entry

5.e

Date	Location	User	Value	Reason
Aug-27-2020 13:16:00 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BPT95H	Initial Entry

5.e Sample ID

Date	Location	User	Value	Reason
Aug-27-2020 13:16:00 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BPT95H	Initial Entry

5.f

Date	Location	User	Value	Reason
Aug-27-2020 13:16:39 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BPT95J	Initial Entry

5.f Sample ID

Date	Location	User	Value	Reason
Aug-27-2020 13:16:39 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BPT95J	Initial Entry

090177e196ae2ed8\Final\Final On: 01-Apr-2021 03:25 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1231

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

Subject No: 12314059

Subject Initials: ---

Generated By: (b) (4)

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

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1. Data Origin

Date	Location	User	Value	Reason
Aug-25-2020 21:23:13 (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-25-2020 21:23:13 (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-26-2020 09:11:01 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Aug-26-2020 02:55:31 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Aug-25-2020 21:23:13 (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-25-2020 21:23:13 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	Martina Davalli (b) (4)	Data Entry: YES Date of Collection: Aug/25/2020	Initial Entry

5.a

090177e196ae2ed8\Final\Final On: 01-Apr-2021 03:25 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1231

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

Subject No: 12314059

Subject Initials: ---

Generated By: (b) (4)

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

Date	Location	User	Value	Reason
Aug-26-2020 09:11:01 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BP2FB8	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Aug-26-2020 09:11:01 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BP2FB8	Initial Entry

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:04

Site No: 1231

Subject No: 12314059

Generated By: (b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

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1. Was there a temporary delay of vaccination?

Date	Location	User	Value	Reason
Aug-25-2020 21:23:31 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	Martina Davalli (b) (4)	Data Entry: NO	Initial Entry

2. Treatment Name

Date	Location	User	Value	Reason
Aug-25-2020 21:23:31 (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-25-2020 21:23:31 (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-25-2020 21:23:31 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	Martina Davalli (b) (4)	Data Entry: Aug/25/2020 19:20	Initial Entry

5. Anatomical Location:

Date	Location	User	Value	Reason
Aug-25-2020 21:23:31 (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-25-2020 21:23:31 (UTC-03:00) City of	ACV0PFEINFP6000	Martina Davalli	Data Entry: LEFT	Initial Entry

090177e196ae2ed8\Final\Final On: 01-Apr-2021 03:25 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:04

Site No: 1231

Subject No: 12314059

Generated By: (b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

Buenos Aires	(b) (4)
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7. Route:

Date	Location	User	Value	Reason
Aug-25-2020 21:23:31 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: INTRAMUSCULAR	Initial Entry

10. Timeframe Subject Was Observed

Date	Location	User	Value	Reason
Aug-25-2020 21:23:31 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: THE PROTOCOL SPECIFIED OBSERVATION PERIOD	Initial Entry

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

Date	Location	User	Value	Reason
Aug-25-2020 21:23:31 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	Martina Davalli (b) (4)	Data Entry: YES	Initial Entry

090177e196ae2ed8\Final\Final On: 01-Apr-2021 03:25 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 06-Jul-2020 21:53

Site No: 1231

Subject No: 12314059

Generated By: (b) (4)

Form: REACTOGENICITY DIARY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

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1. Select appropriate response - Reactogenicity diary collection

Date	Location	User	Value	Reason
Aug-25-2020 21:23:37 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	Martina Davalli (b) (4)	Data Entry: NO - REACTOGENICITY E-DIA RY NOT COLLECTED FOR THI S SUBJECT	Initial Entry

090177e196ae2ed8\Final\Final On: 01-Apr-2021 03:25 (GMT)

Header Text: C4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:02

Site No: 1231

Subject No: 12314059

Generated By: (b) (4)

Form: DATE OF VISIT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

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I. Date of Visit

Date	Location	User	Value	Reason
Sep-17-2020 19:15:22 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sep/13/2020	Initial Entry

Header Text: C4591001

Visit: V2_VAX2_L

Form Version: 15-Sep-2020 21:54

Site No: 1231

Subject No: 12314059

Generated By: (b) (4)

Form: VITAL SIGNS - TEMP - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

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1. Date:

Date	Location	User	Value	Reason
Sep-17-2020 19:15:38 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sep/13/2020	Initial Entry

2.a

Date	Location	User	Value	Reason
Sep-17-2020 19:15:38 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Record Identifier:: 1 Temperature: 36.4 Temperature Unit: C Temperature Location:: ORAL CAVITY	Initial Entry

2.a Record Identifier:

Date	Location	User	Value	Reason
Sep-17-2020 19:15:38 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 1	Initial Entry

2.a Temperature:

Date	Location	User	Value	Reason
Sep-17-2020 19:15:38 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 36.4	Initial Entry

2.a Unit:

Date	Location	User	Value	Reason
Sep-17-2020 19:15:38 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: C	Initial Entry

090177e196ae2ed8\Final\Final On: 01-Apr-2021 03:25 (GMT)

Header Text: C4591001

Visit: V2_VAX2_L

Form Version: 15-Sep-2020 21:54

Site No: 1231

Subject No: 12314059

Generated By: (b) (4)

Form: VITAL SIGNS - TEMP - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

		(b) (4), (b) (6)	
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2.a Temperature Location:

Date	Location	User	Value	Reason
Sep-17-2020 19:15:38 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: ORAL CAVITY	Initial Entry

Header Text: C4591001

Visit: V2_VAX2_L

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

Form Version: 21-Aug-2020 02:49

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1231

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

Subject No: 12314059

Subject Initials: ---

Generated By: (b) (4)

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

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1. Lab Panel:

Date	Location	User	Value	Reason
Sep-17-2020 19:15:49 (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-17-2020 19:15:49 (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-17-2020 19:15:49 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sep/13/2020	Initial Entry

4. Laboratory Name and Address (Derived)

Date	Location	User	Value	Reason
Sep-17-2020 19:15:49 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: STUDY SITE	Initial Entry

5. Specimen Type:

Date	Location	User	Value	Reason
Sep-17-2020 19:15:49 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: URINE	Initial Entry

6.a

Date	Location	User	Value	Reason
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090177e196ae2ed8\Final\Final On: 01-Apr-2021 03:25 (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: 12314059

Subject Initials: ---

Generated By: (b) (4)

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

Sep-17-2020 19:15:49 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sponsor-Defined Identifier: Test:: Choriogonadotropin in Beta_PX113 Result:: NEGATIVE Not Done::	Initial Entry
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6.a Sponsor ID:

Date	Location	User	Value	Reason
Sep-17-2020 19:15:49 (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-17-2020 19:15:49 (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-17-2020 19:15:49 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NEGATIVE	Initial Entry

090177e196ae2ed8\Final\Final On: 01-Apr-2021 03:25 (GMT)

Header Text: C4591001

Visit: V2_VAX2_L

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1231

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

Subject No: 12314059

Subject Initials: ---

Generated By: (b) (4)

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

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1. Data Origin

Date	Location	User	Value	Reason
Sep-13-2020 16:13:05 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Sep-13-2020 16:13:05 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: NASAL_SWAB	Initial Entry

3. Sample Collected?

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

5.a

Date	Location	User	Value	Reason
Sep-13-2020 16:13:15 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BP2BPY	Initial Entry

090177e196ae2ed8\Final\Final On: 01-Apr-2021 03:25 (GMT)

Header Text: C4591001

Visit: V2_VAX2_L

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1231

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

Subject No: 12314059

Subject Initials: ---

Generated By: (b) (4)

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

5.a Sample ID

Date	Location	User	Value	Reason
Sep-13-2020 16:13:15 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BP2BPY	Initial Entry

Header Text: C4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:04

Site No: 1231

Subject No: 12314059

Generated By: (b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

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1. Was there a temporary delay of vaccination?

Date	Location	User	Value	Reason
Sep-17-2020 19:16:10 (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-17-2020 19:16:10 (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-17-2020 19:16:10 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: INJECTION	Initial Entry

4. Dose Date Time:

Date	Location	User	Value	Reason
Sep-17-2020 19:16:10 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sep/13/2020 10:45	Initial Entry

5. Anatomical Location:

Date	Location	User	Value	Reason
Sep-17-2020 19:16:10 (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
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090177e196ae2ed8\Final\Final On: 01-Apr-2021 03:25 (GMT)

Header Text: C4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:04

Site No: 1231

Subject No: 12314059

Generated By: (b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

Sep-17-2020 19:16:10 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: LEFT	Initial Entry
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7. Route:

Date	Location	User	Value	Reason
Sep-17-2020 19:16:10 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: INTRAMUSCULAR	Initial Entry

10. Timeframe Subject Was Observed

Date	Location	User	Value	Reason
Sep-17-2020 19:16:10 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: THE PROTOCOL SPECIFIED OBSERVATION PERIOD	Initial Entry

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

Date	Location	User	Value	Reason
Sep-17-2020 19:16:10 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

090177e196ae2ed8\Final\Final On: 01-Apr-2021 03:25 (GMT)

Header Text: C4591001

Visit: V3_MONTH1_POSTVAX2_L

Form Version: 22-Apr-2020 21:02

Site No: 1231

Subject No: 12314059

Generated By: (b) (4)

Form: DATE OF VISIT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

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I. Date of Visit

Date	Location	User	Value	Reason
Oct-18-2020 03:53:09 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	edc updated.
Oct-16-2020 12:25:49 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	The information was uploaded Thank you
Oct-16-2020 05:22:19 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	DM: Patient completed the treatment phase and reached at Visit 3. Kindly consider to update EOT form with matching V3 date or else clarify. Thank you.
Oct-14-2020 13:46:24 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Oct/13/2020	Initial Entry

090177e196ae2ed8\Final\Final On: 01-Apr-2021 03:25 (GMT)

Header Text: C4591001

Visit: V3_MONTH1_POSTVAX2_L

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1231

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

Subject No: 12314059

Subject Initials: ---

Generated By: (b) (4)

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

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1. Data Origin

Date	Location	User	Value	Reason
Oct-13-2020 16:01:39 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Oct-13-2020 16:01:39 (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-13-2020 16:01:52 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Oct-13-2020 16:01:39 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Oct-13-2020 16:01:39 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Date of Collection: Oct/13/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Oct-13-2020 16:01:52 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BPT7PK	Initial Entry

090177e196ae2ed8\Final\Final On: 01-Apr-2021 03:25 (GMT)

Header Text: C4591001

Visit: V3_MONTH1_POSTVAX2_L

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1231

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

Subject No: 12314059

Subject Initials: ---

Generated By: (b) (4)

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

5.a Sample ID

Date	Location	User	Value	Reason
Oct-13-2020 16:01:52 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> BPT7PK	Initial Entry

5.b

Date	Location	User	Value	Reason
Oct-13-2020 17:20:23 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Sample ID: BRXPS0	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Oct-13-2020 17:20:23 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> BRXPS0	Initial Entry

5.c

Date	Location	User	Value	Reason
Oct-13-2020 17:23:21 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Sample ID: BRXPSF	Initial Entry

5.c Sample ID

Date	Location	User	Value	Reason
Oct-13-2020 17:23:21 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> BRXPSF	Initial Entry

090177e196ae2ed8\Final\Final On: 01-Apr-2021 03:25 (GMT)

Header Text: C4591001

Visit: End of Treatment - Unscheduled

Form Version: 15-Sep-2020 21:55

Site No: 1231

Subject No: 12314059

Generated By: (b) (4)

Form: DISPOSITION - TREATMENT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

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1. Date of Completion/Discontinuation/Death :

Date	Location	User	Value	Reason
Oct-16-2020 12:25:35 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Oct/13/2020	Initial Entry

2. Phase of Disposition:

Date	Location	User	Value	Reason
Oct-16-2020 12:25:35 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: VACCINATION	Initial Entry

3. Status:

Date	Location	User	Value	Reason
Oct-16-2020 12:25:35 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: COMPLETED	Initial Entry

090177e196ae2ed8\Final\Final On: 01-Apr-2021 03:25 (GMT)

Header Text: C4591001

Visit: Follow-Up - Unscheduled

Form Version: 15-Sep-2020 21:53

Site No: 1231

Subject No: 12314059

Generated By: (b) (4)

Form: DISPOSITION - FOLLOW-UP - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

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

Subject Initials: ---

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

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1. Date of Completion/Discontinuation/Death :

Date	Location	User	Value	Reason
Nov-09-2020 13:12:54 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry
Nov-07-2020 10:43:53 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	The subject will continue the follow up
Oct-21-2020 10:15:35 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Oct/13/2020	Initial Entry

2. Phase of Disposition:

Date	Location	User	Value	Reason
Nov-09-2020 13:12:54 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Not Applicable	Initial Entry
Nov-07-2020 10:43:53 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry:	The subject will continue the follow up
Oct-21-2020 10:15:35 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: FOLLOW-UP	Initial Entry

3. Status:

Date	Location	User	Value	Reason
Nov-09-2020 13:12:54 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry
Nov-07-2020 11:14:38 (UTC-03:00) City of	ACV0PFEINFP6000	Hayley Wyper (b) (4)	Query 3: Closed	Response satisfies query

090177e196ae2ed8\Final\Final On: 01-Apr-2021 03:25 (GMT)

Header Text: C4591001

Visit: Follow-Up - Unscheduled

Form Version: 15-Sep-2020 21:53

Site No: 1231

Subject No: 12314059

Generated By: (b) (4)

Form: DISPOSITION - FOLLOW-UP - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

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

Subject Initials: ---

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

Buenos Aires				
Nov-07-2020 10:45:00 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 3: An swere d	The subject will continue the follow up visits as per protocol
Nov-07-2020 10:45:00 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry :	The subject will continue the follow up visits as per protocol
Nov-07-2020 07:15:06 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	Hayley Wyper (b) (4)	Query 3: Rei ssued: Opene d	CLINQUERY: Please note, this page is related to end of study (not end of treatment). Please review it's completion and confirm data correct i.e. that subject will not longer take part in safety follow up
Nov-06-2020 19:45:19 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 3: An swere d	Transcription Error
Nov-06-2020 19:45:19 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry : COM PLET ED	Transcription Error
Nov-06-2020 17:09:15 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	Hayley Wyper (b) (4)	Query 3: Op ened	CLINQUERY: It is indicated on this page that the subject will no longer attend visits on the study due to pregnancy. If this is correct, then please update the AE entry for pregnancy for question 'Did AE cause subject to be discontinued from study'

090177e196ae2ed8\Final\Final On: 01-Apr-2021 03:25 (GMT)

Header Text: C4591001

Visit: Follow-Up - Unscheduled

Form Version: 15-Sep-2020 21:53

Site No: 1231

Subject No: 12314059

Generated By: (b) (4)

Form: DISPOSITION - FOLLOW-UP - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

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

Subject Initials: ---

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

Oct-23-2020 04:48:05 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Closed	Response satisfies query
Oct-22-2020 13:05:32 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Answered	pregnancy test was performed on 26/SEP/2020 at 17:30 by the volunteer at home. The result was positive.
Oct-22-2020 02:56:23 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (b) (4)	Query 2: Opened	DMW5123194;Response to 'Status' is PREGNANCY, but there is no pregnancy tests with a positive result with a 'Collection Date' on or before the disposition date. Please review and update as appropriate.
Oct-21-2020 10:16:54 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Oct-21-2020 10:15:35 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	Response to "Status" is PREGNANCY but "Specify Status" is Provided.
Oct-21-2020 10:15:35 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry : PREGNANCY	Initial Entry

4. Specify Status:

Date	Location	User	Value	Reason
Nov-09-2020 13:12:54 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

Header Text: C4591001

Visit: Follow-Up - Unscheduled

Form Version: 15-Sep-2020 21:53

Site No: 1231

Subject No: 12314059

Generated By: (b) (4)

Form: DISPOSITION - FOLLOW-UP - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

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

Subject Initials: ---

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

Oct-21-2020 10:16:54 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Transcription Error
Oct-21-2020 10:15:35 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: pregnancy test perform by subject 26/09/2020	Initial Entry

Header Text: C4591001

Visit: Potential ReVax Initial Contact -
Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1231

Subject No: 12314059

Generated By: (b) (4)

Form: DATE OF VISIT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

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I. Date of Visit

Date	Location	User	Value	Reason
Feb-17-2021 11:41:17 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Feb/17/2021	Initial Entry

090177e196ae2ed8\Final\Final On: 01-Apr-2021 03:25 (GMT)

Header Text: C4591001

Visit: Potential ReVax Initial Contact -
Unscheduled

Form Version: 10-Dec-2020 02:25

Site No: 1231

Subject No: 12314059

Generated By: (b) (4)

Form: FURTHER VACCINATION CONFIRMATION - eCRF Audit Trail
History

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

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

Date	Location	User	Value	Reason
Feb-17-2021 11:41:29 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Participant is willing to return for V accination 3 Participant is: eligible per other protocol allowa nce(s) and confirmed to have rec eived only placebo at Vaccinatio n 1/2	Initial Entry

090177e196ae2ed8\Final\Final On: 01-Apr-2021 03:25 (GMT)

Header Text: C4591001

Visit: V101_VAX3

Form Version: 22-Apr-2020 21:02

Site No: 1231

Subject No: 12314059

Generated By: (b) (4)

Form: DATE OF VISIT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

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I. Date of Visit

Date	Location	User	Value	Reason
Mar-04-2021 13:43:01 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Mar/4/2021	Initial Entry

Header Text: C4591001

Visit: V101_VAX3

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

Form Version: 10-Dec-2020 02:31

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1231

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

Subject No: 12314059

Subject Initials: ---

Generated By: (b) (4)

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

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I. Consent Was:

Date	Location	User	Value	Reason
Mar-04-2021 13:43:13 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: OBTAINED Date Written Consent Obtained Mar/4/2021	Initial Entry

Header Text: C4591001

Visit: V101_VAX3

Form Version: 10-Dec-2020 02:31

Site No: 1231

Subject No: 12314059

Generated By: (b) (4)

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

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

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1. Date of Completion/Discontinuation/Death :

Date	Location	User	Value	Reason
Mar-04-2021 13:43:57 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Mar/4/2021	Initial Entry

2. Phase of Disposition:

Date	Location	User	Value	Reason
Mar-04-2021 13:43:57 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: REPEAT SCREENING 1	Initial Entry

3. Status:

Date	Location	User	Value	Reason
Mar-04-2021 13:43:57 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: COMPLETED	Initial Entry

090177e196ae2ed8\Final\Final On: 01-Apr-2021 03:25 (GMT)

Header Text: C4591001

Visit: V101_VAX3

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

Form Version: 20-Feb-2021 02:14

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1231

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

Subject No: 12314059

Subject Initials: ---

Generated By: (b) (4)

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

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1. Lab Panel:

Date	Location	User	Value	Reason
Mar-04-2021 13:44:08 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: URINALYSIS	Initial Entry

2. Lab Sub-Panel:

Date	Location	User	Value	Reason
Mar-04-2021 13:44:08 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: PREGNANCY	Initial Entry

3. Collection Date:

Date	Location	User	Value	Reason
Mar-04-2021 13:44:08 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Mar/4/2021	Initial Entry

4. Laboratory Name and Address (Derived)

Date	Location	User	Value	Reason
Mar-04-2021 13:44:08 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: STUDY SITE	Initial Entry

5. Specimen Type:

Date	Location	User	Value	Reason
Mar-04-2021 13:44:08 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: URINE	Initial Entry

6.a

Date	Location	User	Value	Reason
Mar-04-2021 13:44:08	ACV0PFEINFP6000	auto calc	Data Entry:	Initial Entry

090177e196ae2ed8\Final\Final On: 01-Apr-2021 03:25 (GMT)

Header Text: C4591001

Visit: V101_VAX3

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

Form Version: 20-Feb-2021 02:14

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1231

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

Subject No: 12314059

Subject Initials: ---

Generated By: (b) (4)

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

(UTC-03:00) City of Buenos Aires	(autocalc)	Sponsor-Defined Identifier: 113	
		Test:: Choriogonadotropin in Beta_PX113	
		Result:: NEGATIVE	
		Not Done::	

6.a Sponsor ID:

Date	Location	User	Value	Reason
Mar-04-2021 13:44:08 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 113	Initial Entry

6.a Test:

Date	Location	User	Value	Reason
Mar-04-2021 13:44:08 (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
Mar-04-2021 13:44:08 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NEGATIVE	Initial Entry

090177e196ae2ed8\Final\Final On: 01-Apr-2021 03:25 (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: 12314059

Subject Initials: ---

Generated By: (b) (4)

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

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1. Data Origin

Date	Location	User	Value	Reason
Mar-04-2021 13:44:19 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Mar-04-2021 13:44:19 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SERUM	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Mar-04-2021 15:01:22 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Mar-04-2021 13:44:19 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Mar-04-2021 13:44:19 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Date of Collection: Mar/4/2021	Initial Entry

5.a

Date	Location	User	Value	Reason
Mar-04-2021 15:01:22 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BR21FZ	Initial Entry

090177e196ae2ed8\Final\Final On: 01-Apr-2021 03:25 (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: 12314059

Subject Initials: ---

Generated By: (b) (4)

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

5.a Sample ID

Date	Location	User	Value	Reason
Mar-04-2021 15:01:22 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> BR21FZ	Initial Entry

5.b

Date	Location	User	Value	Reason
Mar-04-2021 15:02:16 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Sample ID: BRXJ2X	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Mar-04-2021 15:02:16 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> BRXJ2X	Initial Entry

5.c

Date	Location	User	Value	Reason
Mar-04-2021 15:31:55 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	Alan Colombo (b) (4)	<u>Data Entry:</u> Sample ID: BRXJ2D	Initial Entry

5.c Sample ID

Date	Location	User	Value	Reason
Mar-04-2021 15:31:55 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	Alan Colombo (b) (4)	<u>Data Entry:</u> BRXJ2D	Initial Entry

090177e196ae2ed8\Final\Final On: 01-Apr-2021 03:25 (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: 12314059

Subject Initials: ---

Generated By: (b) (4)

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

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1. Data Origin

Date	Location	User	Value	Reason
Mar-04-2021 13:44:31 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Mar-04-2021 13:44:31 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: NASAL_SWAB	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Mar-04-2021 15:25:35 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Mar-04-2021 13:44:31 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Mar-04-2021 13:44:31 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Date of Collection: Mar/4/2021	Initial Entry

5.a

Date	Location	User	Value	Reason
Mar-04-2021 15:25:35 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BR1WR6	Initial Entry

090177e196ae2ed8\Final\Final On: 01-Apr-2021 03:25 (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: 12314059

Subject Initials: ---

Generated By: (b) (4)

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

5.a Sample ID

Date	Location	User	Value	Reason
Mar-04-2021 15:25:35 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BR1WR6	Initial Entry

Header Text: C4591001

Visit: V101_VAX3

Form Version: 10-Dec-2020 02:26

Site No: 1231

Subject No: 12314059

Generated By: (b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

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1. Was there a temporary delay of vaccination?

Date	Location	User	Value	Reason
Mar-04-2021 13:44:55 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2. Treatment Name

Date	Location	User	Value	Reason
Mar-04-2021 13:44:55 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: BNT162b2	Initial Entry

3. Formulation:

Date	Location	User	Value	Reason
Mar-04-2021 13:44:55 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: INJECTION	Initial Entry

4. Dose Date Time:

Date	Location	User	Value	Reason
Mar-04-2021 13:44:55 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Mar/4/2021 11:16	Initial Entry

5. Anatomical Location:

Date	Location	User	Value	Reason
Mar-04-2021 13:44:55 (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
Mar-04-2021 13:44:55 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: LEFT	Initial Entry

090177e196ae2ed8\Final\Final On: 01-Apr-2021 03:25 (GMT)

Header Text: C4591001

Visit: V101_VAX3

Form Version: 10-Dec-2020 02:26

Site No: 1231

Subject No: 12314059

Generated By: (b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

Buenos Aires				
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7. Route:

Date	Location	User	Value	Reason
Mar-04-2021 13:44:55 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: INTRAMUSCULAR	Initial Entry

8. Actual Dose:

Date	Location	User	Value	Reason
Mar-04-2021 13:44:55 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 30.0	Initial Entry

9. Unit:

Date	Location	User	Value	Reason
Mar-04-2021 13:44:55 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: ug	Initial Entry

10. Timeframe Subject Was Observed

Date	Location	User	Value	Reason
Mar-04-2021 13:44:55 (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
Mar-04-2021 13:44:55 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

090177e196ae2ed8\Final\Final On: 01-Apr-2021 03:25 (GMT)

Header Text: C4591001

Visit: V102_VAX4

Form Version: 22-Apr-2020 21:02

Site No: 1231

Subject No: 12314059

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 20:34

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I. Date of Visit

Date	Location	User	Value	Reason
Mar-25-2021 15:39:06 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Mar/25/2021	Initial Entry

Header Text: C4591001

Visit: V102_VAX4

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

Form Version: 20-Feb-2021 02:14

Form Status: Data Complete, Verified

Site No: 1231

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

Subject No: 12314059

Subject Initials: ---

Generated By: (b) (4)

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

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1. Lab Panel:

Date	Location	User	Value	Reason
Mar-25-2021 15:39:20 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: URINALYSIS	Initial Entry

2. Lab Sub-Panel:

Date	Location	User	Value	Reason
Mar-25-2021 15:39:20 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: PREGNANCY	Initial Entry

3. Collection Date:

Date	Location	User	Value	Reason
Mar-25-2021 15:39:20 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Mar/25/2021	Initial Entry

4. Laboratory Name and Address (Derived)

Date	Location	User	Value	Reason
Mar-25-2021 15:39:20 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: STUDY SITE	Initial Entry

5. Specimen Type:

Date	Location	User	Value	Reason
Mar-25-2021 15:39:20 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: URINE	Initial Entry

6.a

Date	Location	User	Value	Reason
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090177e196ae2ed8\Final\Final On: 01-Apr-2021 03:25 (GMT)

Header Text: C4591001

Visit: V102_VAX4

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

Form Version: 20-Feb-2021 02:14

Form Status: Data Complete, Verified

Site No: 1231

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

Subject No: 12314059

Subject Initials: ---

Generated By: (b) (4)

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

Mar-25-2021 15:39:20 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sponsor-Defined Identifier: Test:: Choriogonadotropin in Beta_PX113 Result:: NEGATIVE Not Done::	Initial Entry
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6.a Sponsor ID:

Date	Location	User	Value	Reason
Mar-25-2021 15:39:20 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 113	Initial Entry

6.a Test:

Date	Location	User	Value	Reason
Mar-25-2021 15:39:20 (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
Mar-25-2021 15:39:20 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NEGATIVE	Initial Entry

090177e196ae2ed8\Final\Final On: 01-Apr-2021 03:25 (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, Verified

Site No: 1231

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

Subject No: 12314059

Subject Initials: ---

Generated By: (b) (4)

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

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1. Data Origin

Date	Location	User	Value	Reason
Mar-25-2021 15:39:36 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Mar-25-2021 15:39:36 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: NASAL_SWAB	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Mar-26-2021 10:39:01 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Mar-26-2021 08:22:27 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Mar-25-2021 15:39:36 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Mar-25-2021 15:39:36 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Date of Collection: Mar/25/2021	Initial Entry

5.a

090177e196ae2ed8\Final\Final On: 01-Apr-2021 03:25 (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, Verified

Site No: 1231

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

Subject No: 12314059

Subject Initials: ---

Generated By: (b) (4)

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

Date	Location	User	Value	Reason
Mar-26-2021 10:39:01 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	Agustin Morato Cabral (b) (4)	Data Entry: Sample ID: BPT8M6	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Mar-26-2021 10:39:01 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	Agustin Morato Cabral (b) (4)	Data Entry: BPT8M6	Initial Entry

Header Text: C4591001

Visit: V102_VAX4

Form Version: 10-Dec-2020 02:26

Site No: 1231

Subject No: 12314059

Generated By: (b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Verified

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

Subject Initials: ---

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

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1. Was there a temporary delay of vaccination?

Date	Location	User	Value	Reason
Mar-25-2021 15:40:06 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2. Treatment Name

Date	Location	User	Value	Reason
Mar-25-2021 15:40:06 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: BNT162b2	Initial Entry

3. Formulation:

Date	Location	User	Value	Reason
Mar-25-2021 15:40:06 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: INJECTION	Initial Entry

4. Dose Date Time:

Date	Location	User	Value	Reason
Mar-25-2021 15:40:06 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Mar/25/2021 10:48	Initial Entry

5. Anatomical Location:

Date	Location	User	Value	Reason
Mar-25-2021 15:40:06 (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
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090177e196ae2ed8\Final\Final On: 01-Apr-2021 03:25 (GMT)

Header Text: C4591001

Visit: V102_VAX4

Form: VACCINATION - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:26

Form Status: Data Complete, Verified

Site No: 1231

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

Subject No: 12314059

Subject Initials: ---

Generated By: (b) (4)

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

Mar-25-2021 15:40:06 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: LEFT	Initial Entry
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7. Route:

Date	Location	User	Value	Reason
Mar-25-2021 15:40:06 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: INTRAMUSCULAR	Initial Entry

8. Actual Dose:

Date	Location	User	Value	Reason
Mar-25-2021 15:40:06 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 30.0	Initial Entry

9. Unit:

Date	Location	User	Value	Reason
Mar-25-2021 15:40:06 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: ug	Initial Entry

10. Timeframe Subject Was Observed

Date	Location	User	Value	Reason
Mar-25-2021 15:40:06 (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
Mar-25-2021 15:40:06 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

090177e196ae2ed8\Final\Final On: 01-Apr-2021 03:25 (GMT)

Header Text: C4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1231

Subject No: 12314059

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: ---

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Date	Location	User	Value	Reason
Oct-13-2020 16:52:48 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Created	

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Visit: Logs - Unscheduled

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Site No: 1231

Subject No: 12314059

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

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1. Category:

Date	Location	User	Value	Reason
Oct-13-2020 16:52:48 (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-13-2020 16:52:48 (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
Nov-03-2020 17:29:47 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	change was made
Nov-03-2020 11:39:40 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Changed Information
Nov-03-2020 11:39:40 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	Tatiana Estrada (b) (4)	Data Entry: exposure during pregnancy	Changed Information
Nov-03-2020 11:02:01 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	SAE RECON:AER#2020398247, the term was reported as pregnancy. Based on the latest EDP guidance,term should be reported as 'EXPOSURE DURING PREGNANCY. Please confirm and update accordingly
Oct-13-2020 16:52:48 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: pregnancy	Initial Entry

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Subject No: 12314059

Generated By: (b) (4)

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4. Start Date Time:

Date	Location	User	Value	Reason
Dec-09-2020 11:36:52 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 4: Closed	Response satisfies query
Dec-08-2020 13:04:17 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	Santiago Corradetti (b) (4)	Query 4: Answered	The subject had an induced abortion, therefore the end date and outcome are correct. Thank you.
Dec-07-2020 11:27:01 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 4: Opened	ClinQuery: Stop date O3Dec20 entered for exposure during pregnancy. Please verify if subject is no longer pregnant and confirm outcome.
Nov-08-2020 11:28:18 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Closed	Clinical - Query closed; will follow for Pregnancy safety update with the requested onset date info
Nov-07-2020 13:22:40 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Reissued:Candidate	To check next SAE listing
Nov-07-2020 13:10:09 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Answered	Serious adverse event follow-up form was sent on 5-11-2020. Thank you
Nov-07-2020 12:58:24 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Reissued:Opened	SAE RECON 2: Onset date was updated to 31Aug2020 in AE CRF. Please confirm if a follow up AEM form was submitted to update onset date in Safety database.
Nov-06-2020 11:57:22	ACV0PFEINFP6000	auto query	Query 3: Answered	New Information

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(UTC-03:00) City of Buenos Aires		(autoquery)		
Nov-06-2020 11:57:22 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Aug/31/2020 17:30	New Information
Nov-05-2020 18:32:53 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Reissued:Opened	CLINICAL - Preg onset of 8/25 (study day 1) is not c/w neg urine PG tests then and 2 (9/13); nor with 9/28 GYN US stating '4 week gestation'. Please report PG onset as 4 wks prior to 9/28 US or conception date estimate
Nov-05-2020 02:59:33 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Reissued:Candidate	SAE RECON:For Clinical review
Nov-04-2020 08:49:35 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Answered	I clarify that estimate date of conception is unknown. Ultrasound is still pending. Further follow-up will be provided. This information is in a follow-up SAE form.
Nov-04-2020 08:30:49 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Reissued:Opened	SAE RECON 1: Onset date was updated however, Per Clinical 'he correct date of conception is 05 Sep 2020. Please confirm and update. Also, please submit a follow up AEM form to update onset date in Safety.
Nov-04-2020 08:25:20 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 3: Answered	New Information

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Nov-04-2020 08:25:20 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Aug/25/2020 17:30	New Information
Nov-03-2020 17:32:06 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Reissued:Opened	Clinical - Reported PG Onset date of 26Sep20 is date of 2nd + urine test/2 days prior to GYN US on 28Sep stating "4 weeks". Please update onset of exposure during pregnancy to estimated conception date 05Sep20 or 4 weeks before 28Sep20
Nov-03-2020 11:44:34 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 3: Answered	Transcription Error
Nov-03-2020 11:44:34 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sep/26/2020 17:30	Transcription Error
Nov-03-2020 08:27:54 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Opened	SAE RECON: AER#2020398247 , onset date was updated to 05Sep2020 in AE CRF while retained as 26Sep2020 in Safety. Per Clinical 'he correct date of conception is 05 Sep 2020.Please submit a follow up AEM form to update SDB onset date
Oct-30-2020 22:31:09 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Closed	Response satisfies query
Oct-30-2020 11:12:15 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Answered	Transcription Error

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Oct-30-2020 11:12:15 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sep/5/2020 17:30	Transcription Error
Oct-29-2020 12:18:41 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Opened	Clinical - please review AE/SAE start date - with urine PG test positive on 26 Sep 2020, her date of conception cannot be 05 OCT 2020. SAE report has date of conception as 05 SEP 2020.
Oct-26-2020 14:48:00 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Clinical - please review again - with urine PG test positive on 26 Sep 2020, her date of conception cannot be 05 OCT 2020. SAE report has date of conception as 05 SEP 2020.
Oct-21-2020 09:03:33 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	According with data collected, date of conception can be estimated on 5 OCT 2020, approximately, as date of last menstruation is 22 AGO 2020 and date of first pregnancy test is 26 SEP 2020.
Oct-21-2020 09:03:33 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	Maria Beretta (b) (4)	Data Entry: Oct/5/2020 17:30	According with data collected, date of conception can be estimated on 5 OCT 2020, approximately, as date of last menstruation is 22 AGO 2020 and date of first pregnancy test is 26 SEP 2020.
Oct-16-2020 16:11:00	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	CLINICAL Date of

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(UTC-03:00) City of Buenos Aires		(b) (4), (b) (6)		onset for pregnancy would not be the date of the visit 3 urine pregnancy test; please enter calculated conception onset date of 05 SEP 2020
Oct-13-2020 16:52:48 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sep/26/2020 17:30	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Jan-19-2021 16:26:27 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Closed	Response satisfies query
Jan-15-2021 13:00:39 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Answered	This information was sent on the SAE FU form on 28DEC20
Jan-12-2021 23:57:03 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Reissued:Opened	Clinical Followup for Drug Exposed Pregnancy STOP date shows no date entered in the Event section under STOP DATE/TIME (most recent SAE 28Dec20). Please submit the end date to the event STOP DATE.
Dec-29-2020 10:31:49 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO End Date Time: Nov/9/2020 UNK:UNK	New Information
Dec-26-2020 10:19:07 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Answered	17 Dec 2020 EDP and event update form sent to sponsor. Thank you.

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Dec-22-2020 13:11:24 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Reissued:Opened	CLINICAL Thank you. End date is reported in text; however, please add End Date in the Event section (under Drug Exposed pregnancy)
Dec-18-2020 11:05:13 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Answered	Follow-up SAE form was sent with this information.
Dec-17-2020 12:55:59 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Reissued:Opened	Clinical Thank you. The most recent SAE update (03Dec20) does not report an end date in the event section for the end of 'drug exposed pregnancy'
Dec-15-2020 17:10:03 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Answered	The end date is correct. In turn, it was indicated that the event was resolved. On 12/04/2020 an update was sent to the sponsor.
Dec-15-2020 02:35:32 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Opened	CLINICAL Event end date is 03Dec20; per SAE, an elective termination with misoprostol. However, SAE event is ongoing. Please review, harmonize reporting and update in the applicable location
Dec-04-2020 13:21:14 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO End Date Time: Dec/3/2020 UNK:UNK	New Information

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Oct-22-2020 17:49:56 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Oct-22-2020 13:07:37 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	yes the sujet is still pregnant
Oct-21-2020 10:15:35 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	'Disposition Follow-up form is completed and this Adverse Event is still ongoing. Please review and update as appropriate.
Oct-13-2020 16:52:48 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

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6. Toxicity Grade:

Date	Location	User	Value	Reason
Nov-15-2020 12:26:00 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Nov-15-2020 10:55:05 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry
Nov-15-2020 10:54:49 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Transcription Error
Nov-15-2020 10:54:49 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Transcription Error
Nov-15-2020 03:37:52 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	Balaji Prabu R (b) (4)	Query 1: Opened	Toxicity grade is not expected for pregnancy related adverse events, hence please remove the toxicity and add item level comment as NOT APPLICABLE.
Oct-13-2020 16:52:48 (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-17-2020 10:04:32 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 3: Deleted	Close Auto Query

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Oct-17-2020 10:03:08 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Closed	Response satisfies query
Oct-16-2020 09:11:33 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 3: Candidate	For AE pregnancy: Response to "Is the adverse event serious?" is 'No' but "Serious Adverse Event Number" is present.
Oct-16-2020 09:11:33 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Answered	New Information
Oct-16-2020 09:11:33 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	New Information
Oct-16-2020 07:08:18 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Opened	SAE RECON: Per Clinical,The pregnancy was appropriately reported to safety; however, seriousness criteria is met only if there is an abnormal pregnancy outcome/protocol section 8.3.5.1. Please update seriousness criteria accordingly.
Oct-15-2020 07:46:42 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Oct-14-2020 08:03:36 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	SAE RECON:pregnancy(Onset date:26Sep2020) 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

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Oct-13-2020 16:52:48 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	For AE pregnancy: Response to "Is the adverse event serious?" is 'Yes' but "Serious Adverse Event Number" is blank.
Oct-13-2020 16:52:48 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<p>Data Entry:</p> <p>YES</p> <p>Is this serious event associated with congenital anomaly or birth defect?</p> <p>NO</p> <p>Did this serious event result in death?</p> <p>NO</p> <p>Did this serious event require or prolong hospitalization?</p> <p>NO</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> <p>NO</p> <p>Other medically important serious event</p> <p>YES</p>	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-13-2020 16:52:48	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Initial Entry

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(UTC-03:00) City of Buenos Aires		(b) (4), (b) (6)	NO	
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9. Is this event related to study treatment:

Date	Location	User	Value	Reason
Oct-13-2020 16:52:48 (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 If Other, specify: unplanned pregnancy	Initial Entry

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Oct-13-2020 16:52:48 (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-13-2020 16:52:48 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Oct-13-2020 16:52:48 (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-04-2020 13:21:49 (UTC-03:00) City of	ACV0PFEINFP6000	auto query (autoquery)	Query 3: Closed	Close Auto Query

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Buenos Aires				
Dec-04-2020 13:21:49 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: RECOVERED/RESOLVED	New Information
Dec-04-2020 13:21:14 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 3: Opened	For AE exposure during pregnancy: Response to "What was the outcome of this adverse event?" is 'Unknown' but End Date/Time is provided or "Is the adverse event still ongoing?" is marked "Yes".
Nov-04-2020 08:24:31 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Nov-04-2020 07:14:26 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Closed	Data ok as is
Nov-04-2020 06:00:39 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Reissued:Opened	DM: Thank you for response. If AE is still ongoing then please review and update response to 'What was the outcome of this adverse event?' as appropriate.
Nov-03-2020 19:01:19 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Answered	is still on going
Nov-03-2020 15:32:31 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Opened	For AE exposure during pregnancy: Response to "What was the outcome of this adverse event?" is 'Unknown' but End Date/Time is provided or "Is the adverse event still ongoing?" is marked "Yes".

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Header Text: C4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1231

Subject No: 12314059

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

Nov-03-2020 15:32:31 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	New Information
Nov-03-2020 15:32:31 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: UNKNOWN	New Information
Nov-03-2020 12:08:28 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	SAE RECON: AER2020398247, the outcome in AE CRF was reported as NOT RECOVERED/NOT RESOLVED. Based on the latest EDP guidance, outcome should be recorded as UNKNOWN. Please confirm and update accordingly.
Oct-13-2020 16:52:48 (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-26-2020 14:41:20 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Closed	Response satisfies query
Oct-22-2020 13:18:57 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Closed	Response satisfies query
Oct-22-2020 13:02:51 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 4: Deleted	Close Auto Query
Oct-22-2020 13:02:51 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Answered	Transcription Error
Oct-22-2020 13:02:51 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Transcription Error

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Header Text: C4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1231

Subject No: 12314059

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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Oct-22-2020 06:36:53 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Clinical query raised already.
Oct-21-2020 10:15:35 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 4: Candidate	'Did the adverse event cause the subject to be discontinued from the study?' is Yes but neither DISPOSITION - TREATMENT form nor DISPOSITION - FOLLOW-UP has Status as "ADVERSE EVENT". Please review and update as appropriate.
Oct-21-2020 09:00:24 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Answered	The answer is correct, the volunteer is discontinued (due to pregnancy) but must continue with the corresponding controls. Discontinuing does not imply leaving the follow-up.
Oct-21-2020 08:59:15 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	The answer is correct, the volunteer is discontinued (due to pregnancy) but must continue with the corresponding controls. Discontinuing does not imply leaving the follow-up.
Oct-16-2020 16:05:24 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Opened	CLINICAL If the subject remains in the clinical trial for safety followup, the

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Header Text: C4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1231

Subject No: 12314059

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

				answer to this question would be 'NO'
Oct-15-2020 15:31:59 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	'Did the adverse event cause the subject to be discontinued from the study?' is Yes but neither DISPOSITION - TREATMENT form nor DISPOSITION - FOLLOW-UP has Status as "ADVERSE EVENT". Please review and update as appropriate.
Oct-15-2020 14:42:37 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Opened	According to the AE record, subject discontinued study due to pregnancy. Please update all appropriate records to indicate that the subject has discontinued from the study.
Oct-13-2020 16:52:48 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Did the adverse event cause the subject to be discontinued from the study?' is Yes but neither DISPOSITION - TREATMENT form nor DISPOSITION - FOLLOW-UP has Status as "ADVERSE EVENT". Please review and update as appropriate.

090177e196ae2ed8\Final\Final On: 01-Apr-2021 03:25 (GMT)

Header Text: C4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1231

Subject No: 12314059

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

Oct-13-2020 16:52:48 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry
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15. Serious Adverse Event Number: For Pfizer Use Only

Date	Location	User	Value	Reason
Oct-17-2020 10:04:32 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	event seriousness downgraded to no
Oct-15-2020 07:46:42 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 2020398247	Initial Entry

Header Text: C4591001

Visit: Disposition - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1231

Subject No: 12314059

Generated By: (b) (4)

Form: TREATMENT UNBLINDED - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

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

Subject Initials: ---

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

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1. Date Treatment Unblinded :

Date	Location	User	Value	Reason
Feb-17-2021 11:40:53 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Feb/17/2021	Initial Entry

2. Primary Reason for Unblinding:

Date	Location	User	Value	Reason
Feb-17-2021 11:40:53 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: ASSESS ELIGIBILITY FOR ADDITIONAL VACCINATION	Initial Entry

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Header Text: C4591001

Visit: Subject Status - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1231

Subject No: 12314059

Generated By: (b) (4)

Form: SUBJECT STATUS - eCRF Audit Trail History

Form Status: Data Complete, Verified

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

Subject Initials: ---

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

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I. Subject Status

Date	Location	User	Value	Reason
Nov-07-2020 10:45:00 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: FOLLOW-UP	The subject will continue the follow up visits as per protocol
Nov-06-2020 19:45:19 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: COMPLETED	Transcription Error
Oct-21-2020 10:15:35 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: DISCONTINUED	Initial Entry
Oct-16-2020 12:25:35 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: FOLLOW-UP	Initial Entry
Aug-25-2020 21:23:02 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: ENROLLED/RANDOMIZED	Initial Entry
Aug-25-2020 21:21:27 (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
Nov-07-2020 10:45:00 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Oct/13/2020	The subject will continue the follow up visits as per protocol
Nov-07-2020 10:43:53 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Oct/13/2020	The subject will continue the follow up
Nov-06-2020 19:45:19 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Oct/13/2020	Transcription Error
Oct-21-2020 10:15:35	ACV0PFEINFP6000	auto calc	Data Entry:	Initial Entry

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Header Text: C4591001

Visit: Subject Status - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1231

Subject No: 12314059

Generated By: (b) (4)

Form: SUBJECT STATUS - eCRF Audit Trail History

Form Status: Data Complete, Verified

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

Subject Initials: ---

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

(UTC-03:00) City of Buenos Aires		(autocalc)	Oct/13/2020	
Oct-16-2020 12:25:35 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Oct/13/2020	Initial Entry
Aug-25-2020 21:23:02 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Aug/25/2020	Initial Entry
Aug-25-2020 21:21:27 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Aug/25/2020	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: 12314059

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 20:34

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I. Casebook Signature

Date	Location	User	Value	Reason
Oct-22-2020 20:58:47 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Click Here to Enable	Initial Entry