

Header Text: c4591001

Visit: COHORT_SELECTION

Form Version: 15-Sep-2020 21:55

Site No: 4444

Subject No: 44441035

Generated By: (b) (4)

Form: COHORT_SELECTION

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

Generated Time (GMT): 19-Apr-2021 21:04

[eCRF Audit Trail History](#)

Cohort Selection

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

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

Header Text: c4591001

Visit: COHORT_SELECTION

Form Version: 22-Apr-2020 21:02

Site No: 4444

Subject No: 44441035

Generated By: (b) (4)

Form: MAIN INFORMED CONSENT

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

Generated Time (GMT): 19-Apr-2021 21:04

[eCRF Audit Trail History](#)

Informed Consent

1.	Consent Was:	OBTAINED Date Written Consent Obtained Sep/21/2020
----	--------------	--

Header Text: c4591001

Visit: COHORT_SELECTION

Form Version: 15-Sep-2020 21:54

Site No: 4444

Subject No: 44441035

Generated By: (b) (4)

Form: DEMOGRAPHY

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

Generated Time (GMT): 19-Apr-2021 21:04

[eCRF Audit Trail History](#)

Demography

1.	Subject ID	[44441035]
2.	Birth Date:	(b) (6)/1960
3.	Sex:	MALE
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: 4444

Subject No: 44441035

Generated By: (b) (4)

Form: DATE OF VISIT

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

Generated Time (GMT): 19-Apr-2021 21:04

[eCRF Audit Trail History](#)

Date of Visit

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

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 15-Sep-2020 21:53

Site No: 4444

Subject No: 44441035

Generated By: (b) (4)

Form: INCLUSION/EXCLUSION CRITERIA

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

Generated Time (GMT): 19-Apr-2021 21:04

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: V1_DAY1_VAX1_L

Form Version: 15-Sep-2020 21:52

Site No: 4444

Subject No: 44441035

Generated By: (b) (4)

Form: DISPOSITION - SCREENING

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

Generated Time (GMT): 19-Apr-2021 21:04

[eCRF Audit Trail History](#)

Disposition - Screening

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

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 4444

Subject No: 44441035

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

Generated Time (GMT): 19-Apr-2021 21:04

Form Comments

Medical History Details

1.	Line/MH Number:	Not Applicable _____
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	Not Applicable _____
	Start Date:	Not Applicable _____ //
	Ongoing:	Not Applicable _____

090177e196d6f289\Final\Final On: 22-Apr-2021 02:12 (GMT)

Header Text: c4591001	Form: HIV STATUS
Visit: V1_DAY1_VAX1_L	Form Status: Data Complete, Locked, Frozen, Verified
Form Version: 15-Sep-2020 21:57	Site Name: (4444) Hospital Militar Central Cirujano Mayor Dr Cosme Argerich
Site No: 4444	Subject Initials: ---
Subject No: 44441035	Generated Time (GMT): 19-Apr-2021 21:04
Generated By: (b) (4)	

[eCRF Audit Trail History](#)

HIV Status		
1.	Select appropriate response - What is the subject HIV status?	The subject is NOT known to be HIV POSITIVE

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 15-Sep-2020 21:56

Site No: 4444

Subject No: 44441035

Generated By: (b) (4)

Form: VITAL SIGNS - BASELINE

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

Generated Time (GMT): 19-Apr-2021 21:04

[eCRF Audit Trail History](#)

Vital Signs

1.	Date:	Sep/21/2020
2.	Weight:	[84.0]
3.	Unit:	kg
4.	Height:	[169.0]
5.	Unit:	cm
6.	Body Mass Index:	[29.4]

Vital Signs Details

7.a	Record Identifier:	1
	Temperature:	[36.1]
	Unit:	C
	Temperature Location:	ORAL CAVITY

090177e196d6f289\Final\Final On: 22-Apr-2021 02:12 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 4444

Subject No: 44441035

Generated By: (b) (4)

Form: RANDOMIZATION

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

Generated Time (GMT): 19-Apr-2021 21:04

[eCRF Audit Trail History](#)

Disposition

1.	Randomization Date :	Sep/21/2020
2.	Randomization Number:	[262428]
3.	Randomization Group:	[]

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 4444

Subject No: 44441035

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

Generated Time (GMT): 19-Apr-2021 21:04

[eCRF Audit Trail History](#)

Electronic Sample Tracking

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

Aliquot

Please enter barcode for each aliquot.

5.a	Sample ID	[BRXSL8]
5.b	Sample ID	[BRXSKY]
5.c	Sample ID	[BHXFVK]

090177e196d6f289\Final\Final On: 22-Apr-2021 02:12 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 4444

Subject No: 44441035

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

Generated Time (GMT): 19-Apr-2021 21:04

[eCRF Audit Trail History](#)

Electronic Sample Tracking

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

Aliquot

Please enter barcode for each aliquot.

5.a	Sample ID	[BPWF5F]
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090177e196d6f289\Final\Final On: 22-Apr-2021 02:12 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:04

Site No: 4444

Subject No: 44441035

Generated By: (b) (4)

Form: VACCINATION

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

Generated Time (GMT): 19-Apr-2021 21:04

eCRF Audit Trail History

Vaccination		
1.	Was there a temporary delay of vaccination?	NO
2.	Treatment Name	[BLINDED THERAPY]
3.	Formulation:	INJECTION
4.	Dose Date Time:	Sep/21/2020 13:45
5.	Anatomical Location:	DELTOID MUSCLE
6.	Body Side:	RIGHT
7.	Route:	INTRAMUSCULAR
8.	Actual Dose:	[]
9.	Unit:	
10.	Timeframe Subject Was Observed	THE PROTOCOL SPECIFIED OBSERVATION PERIOD
11.	Was the subject observed for at least the protocol specified observation period after investigational product administration?	YES

090177e196d6f289\Final\Final On: 22-Apr-2021 02:12 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 06-Jul-2020 21:53

Site No: 4444

Subject No: 44441035

Generated By: (b) (4)

Form: REACTOGENICITY DIARY

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

Generated Time (GMT): 19-Apr-2021 21:04

[eCRF Audit Trail History](#)

Reactogenicity Diary

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

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:02

Site No: 4444

Subject No: 44441035

Generated By: (b) (4)

Form: DATE OF VISIT

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

Generated Time (GMT): 19-Apr-2021 21:04

[eCRF Audit Trail History](#)

Date of Visit

1.	Date of Visit	Oct/12/2020
2.	Erroneous Visit	

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 10-Oct-2020 16:01

Site No: 4444

Subject No: 44441035

Generated By: (b) (4)

Form: VITAL SIGNS - TEMP

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

Generated Time (GMT): 19-Apr-2021 21:04

[eCRF Audit Trail History](#)

Vital Signs

1.	Date:	Oct/12/2020
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Vital Signs Details

2.a	Record Identifier:	1
	Temperature:	[36.9]
	Unit:	C
	Temperature Location:	ORAL CAVITY

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:03

Site No: 4444

Subject No: 44441035

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

Generated Time (GMT): 19-Apr-2021 21:04

[eCRF Audit Trail History](#)

Electronic Sample Tracking

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB
3.	Sample Collected?	YES Date of Collection: Oct/12/2020
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	[BPXX2G]
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090177e196d6f289\Final\Final On: 22-Apr-2021 02:12 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:04

Site No: 4444

Subject No: 44441035

Generated By: (b) (4)

Form: VACCINATION

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

Generated Time (GMT): 19-Apr-2021 21:04

eCRF Audit Trail History

Vaccination

1.	Was there a temporary delay of vaccination?	NO
2.	Treatment Name	[BLINDED THERAPY]
3.	Formulation:	INJECTION
4.	Dose Date Time:	Oct/12/2020 13:30
5.	Anatomical Location:	DELTOID MUSCLE
6.	Body Side:	RIGHT
7.	Route:	INTRAMUSCULAR
8.	Actual Dose:	[]
9.	Unit:	
10.	Timeframe Subject Was Observed	THE PROTOCOL SPECIFIED OBSERVATION PERIOD
11.	Was the subject observed for at least the protocol specified observation period after investigational product administration?	YES

090177e196d6f289\Final\Final On: 22-Apr-2021 02:12 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form Version: 22-Apr-2020 21:02

Site No: 4444

Subject No: 44441035

Generated By: (b) (4)

Form: DATE OF VISIT

Form Status: Data Complete, Frozen, Verified

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

Subject Initials: ---

Generated Time (GMT): 19-Apr-2021 21:04

[eCRF Audit Trail History](#)

Date of Visit

1.	Date of Visit	Nov/18/2020
2.	Erroneous Visit	

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form Version: 22-Apr-2020 21:03

Site No: 4444

Subject No: 44441035

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Status: Data Complete, Frozen, Verified

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

Subject Initials: ---

Generated Time (GMT): 19-Apr-2021 21:04

[eCRF Audit Trail History](#)

Electronic Sample Tracking

1.	Data Origin	SITE
2.	Sample Type	SERUM
3.	Sample Collected?	YES Date of Collection: Nov/18/2020
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	[BRVRF2]
5.b	Sample ID	[BRVRDM]
5.c	Sample ID	[BPXJ9P]

090177e196d6f289\Final\Final On: 22-Apr-2021 02:12 (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: 4444

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

Subject No: 44441035

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 19-Apr-2021 21:04

Date of Visit

1.	Date of Visit	//
2.	Erroneous Visit	

COVID-19 Illness Visit

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

Header Text: c4591001

Visit: POT_COVID_ILL - New Unscheduled Visit

Form: SIGNS AND SYMPTOMS OF POTENTIAL COVID-19

Form Version: 20-Feb-2021 02:17

Form Status: Not Started

Site No: 4444

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

Subject No: 44441035

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 19-Apr-2021 21:04

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

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: 4444

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

Subject No: 44441035

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 19-Apr-2021 21:04

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: 4444

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

Subject No: 44441035

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 19-Apr-2021 21:04

Electronic Sample Tracking

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

Aliquot

Please enter barcode for each aliquot.

5.	Sample ID	[]
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Header Text: c4591001

Visit: POT_COVID_ILL - New Unscheduled Visit **Form:** HEALTH CARE UTILIZATION

Form Version: 20-Feb-2021 02:19 **Form Status:** Not Started

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

Subject No: 44441035 **Subject Initials:** ---

Generated By: (b) (4) **Generated Time (GMT):** 19-Apr-2021 21:04

Health Care Utilization

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

Health Care Utilization Other

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

Health Care Utilization

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

Header Text: c4591001

Visit: POT_COVID_ILL - New Unscheduled Visit **Form:** ILLNESS DETAILS

Form Version: 06-Jul-2020 21:52

Form Status: Not Started

Site No: 4444

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

Subject No: 44441035

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 19-Apr-2021 21:04

Illness Details

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

Header Text: c4591001

Visit: POT_COVID_CONVA - New Unscheduled Visit

Form: DATE OF VISIT - ILLNESS CONVALESCENT

Form Version: 22-Apr-2020 21:04

Form Status: Not Started

Site No: 4444

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

Subject No: 44441035

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 19-Apr-2021 21:04

Date of Visit

1.	Date of Visit	//
2.	Erroneous Visit	

COVID-19 Illness Visit

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

090177e196d6f289\Final\Final On: 22-Apr-2021 02:12 (GMT)

Header Text: c4591001

Visit: POT_COVID_CONVA - New Unscheduled Visit

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 4444

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

Subject No: 44441035

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 19-Apr-2021 21:04

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_REPEAT_SWAB - New
Unscheduled Visit

Form: DATE OF VISIT - REPEAT SWAB

Form Version: 10-Oct-2020 15:57

Form Status: Not Started

Site No: 4444

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

Subject No: 44441035

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 19-Apr-2021 21:04

Date of Visit

1.	Date of Visit	//
2.	Erroneous Visit	

COVID-19 Repeat Swab

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

Header Text: c4591001

Visit: POT_COVID_REPEAT_SWAB - New
Unscheduled Visit

Form: ELECTRONIC SAMPLE TRACKING - REPEAT SWAB

Form Version: 10-Oct-2020 15:57

Form Status: Not Started

Site No: 4444

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

Subject No: 44441035

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 19-Apr-2021 21:04

Electronic Sample Tracking

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

Aliquot

Please enter barcode for each aliquot.

5.	Sample ID	[]
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Header Text: c4591001

Visit: Unplanned - New Unscheduled Visit

Form: DATE OF VISIT

Form Version: 22-Apr-2020 21:02

Form Status: Not Started

Site No: 4444

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

Subject No: 44441035

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 19-Apr-2021 21:04

Date of Visit

1.	Date of Visit	//
2.	Erroneous Visit	

Header Text: c4591001

Visit: Unplanned - New Unscheduled Visit

Form: UNPLANNED VISIT

Form Version: 22-Apr-2020 21:04

Form Status: Not Started

Site No: 4444

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

Subject No: 44441035

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 19-Apr-2021 21:04

Unplanned Assessments

1.	Assessments	
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Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 4444

Subject No: 44441035

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Not Started

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

Subject Initials: ---

Generated Time (GMT): 19-Apr-2021 21:04

Adverse Event Report

1.	Category:	
2.	AE ID:	[]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[]
4.	Start Date Time:	//
5.	Is the adverse event still ongoing?	
6.	Toxicity Grade:	
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).	
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.	
9.	Is this event related to study treatment:	
10.	Latest Action Taken with Study Treatment:	
11.	Was a Concomitant Medication given?	
12.	Was a Non-Drug Treatment given?	
13.	What was the outcome of this adverse event?:	
14.	Did the adverse event cause the subject to be discontinued from the study?	
15.	Serious Adverse Event Number: For Pfizer Use Only	[]

090177e196d6f289\Final\Final On: 22-Apr-2021 02:12 (GMT)

Header Text: c4591001

Visit: Logs

Form: MEDICATION ERROR

Form Version: 17-Jul-2020 21:54

Site No: 4444

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

Subject No: 44441035

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 19-Apr-2021 21:04

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

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 17-Jul-2020 21:54

Site No: 4444

Subject No: 44441035

Generated By: (b) (4)

Form: MEDICATION ERROR

Form Status: Not Started

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

Subject Initials: ---

Generated Time (GMT): 19-Apr-2021 21:04

[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	[]

090177e196d6f289\Final\Final On: 22-Apr-2021 02:12 (GMT)

Header Text: c4591001

Visit: Logs

Form: CONCOMITANT MEDICATIONS - NON STUDY VACCINATIONS

Form Version: 22-Apr-2020 21:03

Site No: 4444

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

Subject No: 44441035

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 19-Apr-2021 21:04

#	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 Version: 22-Apr-2020 21:03

Site No: 4444

Subject No: 44441035

Generated By: (b) (4)

Form: CONCOMITANT MEDICATIONS - NON STUDY VACCINATIONS

Form Status: Not Started

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

Subject Initials: ---

Generated Time (GMT): 19-Apr-2021 21:04

[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:	//

090177e196d6f289\Final\Final On: 22-Apr-2021 02:12 (GMT)

Header Text: c4591001

Visit: Logs

Form: CONCOMITANT MEDICATIONS - PROHIBITED

Form Version: 22-Apr-2020 21:03

Site No: 4444

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

Subject No: 44441035

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 19-Apr-2021 21:04

#	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: 4444

Subject No: 44441035

Generated By: (b) (4)

Form: CONCOMITANT MEDICATIONS - PROHIBITED

Form Status: Not Started

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

Subject Initials: ---

Generated Time (GMT): 19-Apr-2021 21:04

[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?	

090177e196d6f289\Final\Final On: 22-Apr-2021 02:12 (GMT)

Header Text: c4591001

Visit: Logs

Form: RADIATION TREATMENT

Form Version: 22-Apr-2020 21:02

Site No: 4444

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

Subject No: 44441035

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 19-Apr-2021 21:04

#	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: 4444

Subject No: 44441035

Generated By: (b) (4)

Form: RADIATION TREATMENT

Form Status: Not Started

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

Subject Initials: ---

Generated Time (GMT): 19-Apr-2021 21:04

[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: 4444

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

Subject No: 44441035

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 19-Apr-2021 21:04

#	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: 4444

Subject No: 44441035

Generated By: (b) (4)

Form: TRANSFUSIONS

Form Status: Not Started

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

Subject Initials: ---

Generated Time (GMT): 19-Apr-2021 21:04

[Back to Form](#)

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

Header Text: c4591001

Visit: End of Treatment - Unscheduled

Form Version: 15-Sep-2020 21:55

Site No: 4444

Subject No: 44441035

Generated By: (b) (4)

Form: DISPOSITION - TREATMENT

Form Status: Data Complete, Frozen, Verified

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

Subject Initials: ---

Generated Time (GMT): 19-Apr-2021 21:04

[eCRF Audit Trail History](#)

Disposition - Treatment

1.	Date of Completion/Discontinuation /Death :	Nov/18/2020
2.	Phase of Disposition:	VACCINATION
3.	Status:	COMPLETED
4.	Specify Status:	[]

Header Text: c4591001

Visit: Unplanned Vaccination - Unscheduled

Form: DATE OF VISIT

Form Version: 22-Apr-2020 21:02

Form Status: Not Started

Site No: 4444

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

Subject No: 44441035

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 19-Apr-2021 21:04

Date of Visit

1.	Date of Visit	//
2.	Erroneous Visit	

Header Text: c4591001

Visit: Unplanned Vaccination - Unscheduled

Form: VITAL SIGNS - TEMP

Form Version: 20-Feb-2021 02:16

Form Status: Not Started

Site No: 4444

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

Subject No: 44441035

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 19-Apr-2021 21:04

Vital Signs

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

Vital Signs Details

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

Header Text: c4591001

Visit: Unplanned Vaccination - Unscheduled

Form: VACCINATION

Form Version: 10-Dec-2020 02:26

Form Status: Not Started

Site No: 4444

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

Subject No: 44441035

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 19-Apr-2021 21:04

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?	

090177e196d6f289\Final\Final On: 22-Apr-2021 02:12 (GMT)

Header Text: c4591001

Visit: Unplanned Vaccination - Unscheduled

Form Version: 10-Oct-2020 15:57

Site No: 4444

Subject No: 44441035

Generated By: (b) (4)

Form: CONTACT OUTCOME - MONTH 1

Form Status: Not Started

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

Subject Initials: ---

Generated Time (GMT): 19-Apr-2021 21:04

Contact Outcome

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

Header Text: c4591001

Visit: Unplanned Vaccination - Unscheduled

Form: CONTACT OUTCOME - MONTH 6

Form Version: 10-Oct-2020 16:01

Form Status: Not Started

Site No: 4444

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

Subject No: 44441035

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 19-Apr-2021 21:04

Contact Outcome

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

Header Text: c4591001

Visit: Follow-Up - Unscheduled

Form Version: 15-Sep-2020 21:53

Site No: 4444

Subject No: 44441035

Generated By: (b) (4)

Form: DISPOSITION - FOLLOW-UP

Form Status: Not Started

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

Subject Initials: ---

Generated Time (GMT): 19-Apr-2021 21:04

Disposition - Follow-Up

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

Header Text: c4591001

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

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen, Verified

Site No: 4444

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

Subject No: 44441035

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 19-Apr-2021 21:04

[eCRF Audit Trail History](#)

Date of Visit

1.	Date of Visit	Jan/28/2021
2.	Erroneous Visit	

Header Text: c4591001

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

Form Version: 10-Dec-2020 02:25

Form Status: Data Complete, Frozen, Verified

Site No: 4444

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

Subject No: 44441035

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 19-Apr-2021 21:04

[eCRF Audit Trail History](#)

Further Vaccination Confirmation

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

Header Text: c4591001

Visit: Disposition - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 4444

Subject No: 44441035

Generated By: (b) (4)

Form: TREATMENT UNBLINDED

Form Status: Data Complete, Frozen, Verified

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

Subject Initials: ---

Generated Time (GMT): 19-Apr-2021 21:04

[eCRF Audit Trail History](#)

Treatment Unblinded

1.	Date Treatment Unblinded :	Jan/28/2021
2.	Primary Reason for Unblinding:	ASSESS ELIGIBILITY FOR ADDITIONAL VACCINATION

Header Text: c4591001

Visit: Disposition - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 4444

Subject No: 44441035

Generated By: (b) (4)

Form: WITHDRAWAL OF CONSENT

Form Status: Not Started

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

Subject Initials: ---

Generated Time (GMT): 19-Apr-2021 21:04

Withdrawal Of Consent

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

Header Text: c4591001

Visit: Disposition - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 4444

Subject No: 44441035

Generated By: (b) (4)

Form: DEATH DETAILS CODED

Form Status: Not Started

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

Subject Initials: ---

Generated Time (GMT): 19-Apr-2021 21:04

Death Details

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

Cause of Death

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

Header Text: c4591001

Visit: V101_VAX3

Form Version: 22-Apr-2020 21:02

Site No: 4444

Subject No: 44441035

Generated By: (b) (4)

Form: DATE OF VISIT

Form Status: Data Complete, Frozen, Verified

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

Subject Initials: ---

Generated Time (GMT): 19-Apr-2021 21:04

[eCRF Audit Trail History](#)

Date of Visit

1.	Date of Visit	Jan/29/2021
2.	Erroneous Visit	

Header Text: c4591001

Visit: V101_VAX3

Form Version: 10-Dec-2020 02:31

Site No: 4444

Subject No: 44441035

Generated By: (b) (4)

Form: INFORMED CONSENT - FURTHER VACCINATION

Form Status: Data Complete, Frozen, Verified

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

Subject Initials: ---

Generated Time (GMT): 19-Apr-2021 21:04

[eCRF Audit Trail History](#)

Informed Consent - Further Vaccination

1.	Consent Was:	OBTAINED Date Written Consent Obtained Jan/29/2021
----	--------------	--

Header Text: c4591001

Visit: V101_VAX3

Form Version: 10-Dec-2020 02:30

Site No: 4444

Subject No: 44441035

Generated By: (b) (4)

Form: INCLUSION/EXCLUSION CRITERIA - FURTHER VACCINATION

Form Status: Data Complete, Frozen, Verified

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

Subject Initials: ---

Generated Time (GMT): 19-Apr-2021 21:04

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: 4444

Subject No: 44441035

Generated By: (b) (4)

Form: DISPOSITION - SCREENING FOR FURTHER VACCINATION

Form Status: Data Complete, Frozen, Verified

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

Subject Initials: ---

Generated Time (GMT): 19-Apr-2021 21:04

[eCRF Audit Trail History](#)

Disposition - Screening for Further Vaccination

1.	Date of Completion/Discontinuation /Death :	Jan/29/2021
2.	Phase of Disposition:	REPEAT SCREENING 1
3.	Status:	COMPLETED
4.	Specify Status:	[]

Header Text: c4591001

Visit: V101_VAX3

Form Version: 22-Apr-2020 21:03

Site No: 4444

Subject No: 44441035

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Status: Data Complete, Frozen, Verified

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

Subject Initials: ---

Generated Time (GMT): 19-Apr-2021 21:04

[eCRF Audit Trail History](#)

Electronic Sample Tracking

1.	Data Origin	SITE
2.	Sample Type	SERUM
3.	Sample Collected?	YES Date of Collection: Jan/29/2021
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	[BS423B]
5.b	Sample ID	[BPWFSV]
5.c	Sample ID	[BRYWPK]

090177e196d6f289\Final\Final On: 22-Apr-2021 02:12 (GMT)

Header Text: c4591001

Visit: V101_VAX3

Form Version: 22-Apr-2020 21:03

Site No: 4444

Subject No: 44441035

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB

Form Status: Data Complete, Frozen, Verified

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

Subject Initials: ---

Generated Time (GMT): 19-Apr-2021 21:04

[eCRF Audit Trail History](#)

Electronic Sample Tracking

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB
3.	Sample Collected?	YES Date of Collection: Jan/29/2021
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	[BPFWF1]
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090177e196d6f289\Final\Final On: 22-Apr-2021 02:12 (GMT)

Header Text: c4591001

Visit: V101_VAX3

Form Version: 10-Dec-2020 02:26

Site No: 4444

Subject No: 44441035

Generated By: (b) (4)

Form: VACCINATION

Form Status: Data Complete, Frozen, Verified

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

Subject Initials: ---

Generated Time (GMT): 19-Apr-2021 21:04

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:	Jan/29/2021 15:20
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

090177e196d6f289\Final\Final On: 22-Apr-2021 02:12 (GMT)

Header Text: c4591001

Visit: V102_VAX4

Form Version: 22-Apr-2020 21:02

Site No: 4444

Subject No: 44441035

Generated By: (b) (4)

Form: DATE OF VISIT

Form Status: Data Complete, Frozen, Verified

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

Subject Initials: ---

Generated Time (GMT): 19-Apr-2021 21:04

[eCRF Audit Trail History](#)

Date of Visit

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

Header Text: c4591001

Visit: V102_VAX4

Form Version: 22-Apr-2020 21:03

Site No: 4444

Subject No: 44441035

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB

Form Status: Data Complete, Frozen, Verified

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

Subject Initials: ---

Generated Time (GMT): 19-Apr-2021 21:04

[eCRF Audit Trail History](#)

Electronic Sample Tracking

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB
3.	Sample Collected?	YES Date of Collection: Feb/17/2021
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	[BR287D]
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090177e196d6f289\Final\Final On: 22-Apr-2021 02:12 (GMT)

Header Text: c4591001

Visit: V102_VAX4

Form Version: 10-Dec-2020 02:26

Site No: 4444

Subject No: 44441035

Generated By: (b) (4)

Form: VACCINATION

Form Status: Data Complete, Frozen, Verified

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

Subject Initials: ---

Generated Time (GMT): 19-Apr-2021 21:04

eCRF Audit Trail History

Vaccination

1.	Was there a temporary delay of vaccination?	NO
2.	Treatment Name	[BNT162b2]
3.	Formulation:	INJECTION
4.	Dose Date Time:	Feb/17/2021 16:25
5.	Anatomical Location:	DELTOID MUSCLE
6.	Body Side:	LEFT
7.	Route:	INTRAMUSCULAR
8.	Actual Dose:	[30.0]
9.	Unit:	ug
10.	Timeframe Subject Was Observed	30 MINUTES
11.	Was the subject observed for at least the protocol specified observation period after investigational product administration?	YES

090177e196d6f289\Final\Final On: 22-Apr-2021 02:12 (GMT)

Header Text: c4591001

Visit: V103_MONTH1

Form Version: 22-Apr-2020 21:02

Site No: 4444

Subject No: 44441035

Generated By: (b) (4)

Form: DATE OF VISIT

Form Status: Not Started

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

Subject Initials: ---

Generated Time (GMT): 19-Apr-2021 21:04

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: 4444

Subject No: 44441035

Generated By: (b) (4)

Form: CONTACT OUTCOME

Form Status: Not Started

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

Subject Initials: ---

Generated Time (GMT): 19-Apr-2021 21:04

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: 4444

Subject No: 44441035

Generated By: (b) (4)

Form: DATE OF VISIT

Form Status: Not Started

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

Subject Initials: ---

Generated Time (GMT): 19-Apr-2021 21:04

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: 4444

Subject No: 44441035

Generated By: (b) (4)

Form: CONTACT OUTCOME

Form Status: Not Started

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

Subject Initials: ---

Generated Time (GMT): 19-Apr-2021 21:04

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: 4444

Subject No: 44441035

Generated By: (b) (4)

Form: DATE OF VISIT

Form Status: Not Started

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

Subject Initials: ---

Generated Time (GMT): 19-Apr-2021 21:04

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: 4444

Subject No: 44441035

Generated By: (b) (4)

Form: CONTACT OUTCOME

Form Status: Not Started

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

Subject Initials: ---

Generated Time (GMT): 19-Apr-2021 21:04

Contact Outcome

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

Header Text: c4591001

Visit: FURTHER_VACCINATION_EOT -
Unscheduled

Form: DISPOSITION - TREATMENT

Form Version: 20-Feb-2021 02:26

Form Status: Not Started

Site No: 4444

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

Subject No: 44441035

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 19-Apr-2021 21:04

Disposition - Treatment

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

Header Text: c4591001

Visit: Subject Status - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 4444

Subject No: 44441035

Generated By: (b) (4)

Form: SUBJECT STATUS

Form Status: Data Complete, Verified

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

Subject Initials: ---

Generated Time (GMT): 19-Apr-2021 21:04

[eCRF Audit Trail History](#)

Subject Status

1.	Subject Status	FOLLOW-UP
2.	Subject Status Date	Nov/18/2020

Header Text: c4591001

Visit: Investigator Signature - Unscheduled

Form Version: 22-Apr-2020 21:04

Site No: 4444

Subject No: 44441035

Generated By: (b) (4)

Form: CASEBOOK SIGNATURE FORM

Form Status: Data Complete, Signed, Verified

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

Subject Initials: ---

Generated Time (GMT): 19-Apr-2021 21:04

[eCRF Audit Trail History](#)

Casebook Signature Form

1.	Casebook Signature	Click Here to Enable
----	--------------------	--------------------------------------

Header Text: c4591001

Visit: Investigator Signature - Unscheduled

Form Version: 22-Apr-2020 21:04

Site No: 4444

Subject No: 44441035

Generated By: (b) (4)

Form: CASEBOOK SIGNATURE FORM

Form Status: Data Complete, Signed, Verified

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

Subject Initials: ---

Generated Time (GMT): 19-Apr-2021 21:04

[Audit Trail](#)

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

- CRF_Sign

Name	Signature Meaning	Date	Type	Action
Tatiana Estrada	Approved	Feb-19-2021 19:19:56 (UTC-03:00) City of Buenos Aires	BOOK	Signed

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.

090177e196d6f289\Final\Final On: 22-Apr-2021 02:12 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 15-Sep-2020 21:53

Site No: 4444

Subject No: 44441035

Generated By: (b) (4)

Form: INCLUSION/EXCLUSION CRITERIA - Comments

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

Generated Time (GMT): 19-Apr-2021 21:04

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Item	Date	User	Comment
Form	Sep-21-2020 18:30:43 (UTC-03:00) City of Buenos Aires	(b) (4), (b) (6)	Not Applicable

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 4444

Subject No: 44441035

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - Comments

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

Generated Time (GMT): 19-Apr-2021 21:04

[Back to Form](#)

Item	Date	User	Comment
Form	Sep-21-2020 18:31:21 (UTC-03:00) City of Buenos Aires	(b) (4), (b) (6)	Not Applicable

Header Text: c4591001

Visit: V101_VAX3

Form Version: 10-Dec-2020 02:30

Site No: 4444

Subject No: 44441035

Generated By: (b) (4)

Form: INCLUSION/EXCLUSION CRITERIA - FURTHER VACCINATION - Comments

Form Status: Data Complete, Frozen, Verified

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

Subject Initials: ---

Generated Time (GMT): 19-Apr-2021 21:04

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Item	Date	User	Comment
Form	Jan-30-2021 11:11:54 (UTC-03:00) City of Buenos Aires	(b) (4), (b) (6)	Not Applicable

Header Text: c4591001

Visit: Investigator Signature - Unscheduled

Form: CASEBOOK SIGNATURE FORM - Signature History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Signed, Verified

Site No: 4444

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

Subject No: 44441035

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 19-Apr-2021 21:04

[Back to Form](#)

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

- CRF_Sign

Name	Signature Meaning	Date	Type	Action
Tatiana Estrada	Approved	Feb-19-2021 19:19:56 (UTC-03:00) City of Buenos Aires	BOOK	Signed

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	Feb-17-2021 17:43:29 (UTC-03:00) City of Buenos Aires		Edit - All signatures invalidated
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Affidavit:

N/A

(b) (6)	Approved	Feb-05-2021 11:36:47 (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	Jan-30-2021 11:11:13 (UTC-03:00) City of Buenos Aires		Edit - All signatures invalidated
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Affidavit:

N/A

(b) (6)	Approved	Jan-29-2021 16:37:08 (UTC-03:00) City of Buenos Aires	BOOK	Signed
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090177e196d6f289\Final\Final On: 22-Apr-2021 02:12 (GMT)

Header Text: c4591001

Visit: Investigator Signature - Unscheduled

Form: CASEBOOK SIGNATURE FORM - Signature History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Signed, Verified

Site No: 4444

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

Subject No: 44441035

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 19-Apr-2021 21:04

Affidavit:

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

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

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

(b) (6)	N/A	Jan-28-2021 12:25:54 (UTC-03:00) City of Buenos Aires		Edit - All signatures invalidated
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Affidavit:

N/A

(b) (6)	Approved	Nov-25-2020 18:27:33 (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)	Approved	Nov-25-2020 18:27:32 (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)	Approved	Nov-25-2020 18:27:27 (UTC-03:00) City of Buenos Aires	BOOK	Signed
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090177e196d6f289\Final\Final On: 22-Apr-2021 02:12 (GMT)

Header Text: c4591001

Visit: Investigator Signature - Unscheduled

Form: CASEBOOK SIGNATURE FORM - Signature History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Signed, Verified

Site No: 4444

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

Subject No: 44441035

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 19-Apr-2021 21:04

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-18-2020 10:39:07 (UTC-03:00) City of Buenos Aires		Edit - All signatures invalidated
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Affidavit:

N/A

Fernando Polack	Approved	Nov-10-2020 11:11:17 (UTC-03:00) City of Buenos Aires	BOOK	Signed
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Affidavit:

By my dated signature below, I, FernandoPolack, 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.

090177e196d6f289\Final\Final On: 22-Apr-2021 02:12 (GMT)

Header Text: c4591001

Visit: COHORT_SELECTION

Form Version: 15-Sep-2020 21:55

Site No: 4444

Subject No: 44441035

Generated By: (b) (4)

Form: COHORT_SELECTION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

Generated Time (GMT): 19-Apr-2021 21:04

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1. Select appropriate response - Protocol version

Date	Location	User	Value	Reason
Sep-21-2020 18:29:30 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 08 SEP 2020	Initial Entry

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

Date	Location	User	Value	Reason
Sep-21-2020 18:29:30 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: STAGE 3 COHORTS	Initial Entry

090177e196d6f289\Final\Final On: 22-Apr-2021 02:12 (GMT)

Header Text: c4591001

Visit: COHORT_SELECTION

Form Version: 22-Apr-2020 21:02

Site No: 4444

Subject No: 44441035

Generated By: (b) (4)

Form: MAIN INFORMED CONSENT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

Generated Time (GMT): 19-Apr-2021 21:04

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I. Consent Was:

Date	Location	User	Value	Reason
Sep-21-2020 18:29:59 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: OBTAINED Date Written Consent Obtained Sep/21/2020	Initial Entry

Header Text: c4591001

Visit: COHORT_SELECTION

Form Version: 15-Sep-2020 21:54

Site No: 4444

Form: DEMOGRAPHY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject No: 44441035

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 19-Apr-2021 21:04

[Back to Form](#)

1. Subject ID

Date	Location	User	Value	Reason
Sep-21-2020 18:29:23 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> 44441035	Item copied from previous form

2. Birth Date:

Date	Location	User	Value	Reason
Sep-21-2020 18:29:18 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> (b) (6)/1960	Enrollment Entry

3. Sex:

Date	Location	User	Value	Reason
Sep-21-2020 18:30:13 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> MALE	Initial Entry

4. Ethnicity:

Date	Location	User	Value	Reason
Sep-21-2020 18:30:13 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> HISPANIC OR LATINO(A) OR OF SPANISH ORIGIN	Initial Entry

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

Date	Location	User	Value	Reason
Sep-21-2020 18:30:13 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> WHITE	Initial Entry

090177e196d6f289\Final\Final On: 22-Apr-2021 02:12 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:02

Site No: 4444

Subject No: 44441035

Generated By: (b) (4)

Form: DATE OF VISIT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

Generated Time (GMT): 19-Apr-2021 21:04

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1. Date of Visit

Date	Location	User	Value	Reason
Sep-21-2020 18:30:25 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sep/21/2020	Initial Entry

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 15-Sep-2020 21:52

Site No: 4444

Subject No: 44441035

Generated By: (b) (4)

Form: DISPOSITION - SCREENING - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

Generated Time (GMT): 19-Apr-2021 21:04

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1. Date of Completion/Discontinuation/Death

Date	Location	User	Value	Reason
Sep-21-2020 18:31:08 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sep/21/2020	Initial Entry

2. Phase of Disposition:

Date	Location	User	Value	Reason
Sep-21-2020 18:31:08 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SCREENING	Initial Entry

3. Status:

Date	Location	User	Value	Reason
Sep-21-2020 18:31:08 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: COMPLETED	Initial Entry

090177e196d6f289\Final\Final On: 22-Apr-2021 02:12 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 15-Sep-2020 21:57

Site No: 4444

Subject No: 44441035

Generated By: (b) (4)

Form: HIV STATUS - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

Generated Time (GMT): 19-Apr-2021 21:04

[Back to Form](#)

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

Date	Location	User	Value	Reason
Sep-21-2020 18:31:34 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: The subject is NOT known to be HIV POSITIVE	Initial Entry

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 15-Sep-2020 21:56

Site No: 4444

Subject No: 44441035

Generated By: (b) (4)

Form: VITAL SIGNS - BASELINE - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

Generated Time (GMT): 19-Apr-2021 21:04

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1. Date:

Date	Location	User	Value	Reason
Sep-21-2020 18:32:03 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Sep/21/2020	Initial Entry

2. Weight:

Date	Location	User	Value	Reason
Sep-21-2020 18:32:03 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> 84.0	Initial Entry

3. Unit:

Date	Location	User	Value	Reason
Sep-21-2020 18:32:03 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> kg	Initial Entry

4. Height:

Date	Location	User	Value	Reason
Sep-21-2020 18:32:03 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> 169.0	Initial Entry

5. Unit:

Date	Location	User	Value	Reason
Sep-21-2020 18:32:03 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> cm	Initial Entry

6. Body Mass Index:

Date	Location	User	Value	Reason
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090177e196d6f289\Final\Final On: 22-Apr-2021 02:12 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 15-Sep-2020 21:56

Site No: 4444

Form: VITAL SIGNS - BASELINE - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject No: 44441035

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 19-Apr-2021 21:04

Sep-21-2020 18:32:03 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 29.4	Initial Entry
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7.a

Date	Location	User	Value	Reason
Sep-21-2020 18:32:03 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Record Identifier:: 1 Temperature: 36.1 Temperature Unit: C Temperature Location:: ORAL CAVITY	Initial Entry

7.a Record Identifier:

Date	Location	User	Value	Reason
Sep-21-2020 18:32:03 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 1	Initial Entry

7.a Temperature:

Date	Location	User	Value	Reason
Sep-21-2020 18:32:03 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 36.1	Initial Entry

7.a Unit:

Date	Location	User	Value	Reason
Sep-21-2020 18:32:03 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: C	Initial Entry

7.a Temperature Location:

Date	Location	User	Value	Reason
Sep-21-2020 18:32:03 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: ORAL CAVITY	Initial Entry

090177e196d6f289\Final\Final On: 22-Apr-2021 02:12 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 4444

Subject No: 44441035

Generated By: (b) (4)

Form: RANDOMIZATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

Generated Time (GMT): 19-Apr-2021 21:04

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1. Randomization Date :

Date	Location	User	Value	Reason
Sep-21-2020 18:32:21 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Sep/21/2020	Initial Entry

2. Randomization Number:

Date	Location	User	Value	Reason
Sep-21-2020 18:32:21 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> 262428	Initial Entry

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 4444

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

Subject No: 44441035

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 19-Apr-2021 21:04

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1. Data Origin

Date	Location	User	Value	Reason
Sep-21-2020 18:32:41 (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-21-2020 18:32:41 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SERUM	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Sep-22-2020 10:48:52 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Sep-22-2020 03:43:19 (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.
Sep-21-2020 18:32:41 (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-21-2020 18:32:41 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Date of Collection: Sep/21/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Sep-22-2020 10:48:52 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BRXSL8	Initial Entry

090177e196d6f289\Final\Final On: 22-Apr-2021 02:12 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 4444

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

Subject No: 44441035

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 19-Apr-2021 21:04

5.a Sample ID

Date	Location	User	Value	Reason
Sep-22-2020 10:48:52 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BRXSL8	Initial Entry

5.b

Date	Location	User	Value	Reason
Sep-22-2020 11:22:33 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BRXSKY	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Sep-22-2020 11:22:33 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BRXSKY	Initial Entry

5.c

Date	Location	User	Value	Reason
Sep-23-2020 12:18:44 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BHXFWK	Initial Entry

5.c Sample ID

Date	Location	User	Value	Reason
Sep-23-2020 12:18:44 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BHXFWK	Initial Entry

090177e196d6f289\Final\Final On: 22-Apr-2021 02:12 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 4444

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

Subject No: 44441035

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 19-Apr-2021 21:04

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1. Data Origin

Date	Location	User	Value	Reason
Sep-21-2020 18:32:48 (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-21-2020 18:32:48 (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-22-2020 08:46:17 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Sep-22-2020 03:43:19 (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.
Sep-21-2020 18:32:48 (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-21-2020 18:32:48 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Date of Collection: Sep/21/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Sep-22-2020 08:46:17 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BPWF5F	Initial Entry

090177e196d6f289\Final\Final On: 22-Apr-2021 02:12 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 4444

Subject No: 44441035

Generated By: (b) (4)

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

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

Generated Time (GMT): 19-Apr-2021 21:04

5.a Sample ID

Date	Location	User	Value	Reason
Sep-22-2020 08:46:17 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> BPWF5F	Initial Entry

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:04

Site No: 4444

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject No: 44441035

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 19-Apr-2021 21:04

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1. Was there a temporary delay of vaccination?

Date	Location	User	Value	Reason
Sep-21-2020 18:33:08 (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-21-2020 18:33:08 (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-21-2020 18:33:08 (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-21-2020 18:33:08 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sep/21/2020 13:45	Initial Entry

5. Anatomical Location:

Date	Location	User	Value	Reason
Sep-21-2020 18:33:08 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: DELTOID MUSCLE	Initial Entry

6. Body Side:

Date	Location	User	Value	Reason
Sep-21-2020 18:33:08 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: RIGHT	Initial Entry

090177e196d6f289\Final\Final On: 22-Apr-2021 02:12 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:04

Site No: 4444

Subject No: 44441035

Generated By: (b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

Generated Time (GMT): 19-Apr-2021 21:04

7. Route:

Date	Location	User	Value	Reason
Sep-21-2020 18:33:08 (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-21-2020 18:33:08 (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-21-2020 18:33:08 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

090177e196d6f289\Final\Final On: 22-Apr-2021 02:12 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 06-Jul-2020 21:53

Site No: 4444

Subject No: 44441035

Generated By: (b) (4)

Form: REACTOGENICITY DIARY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

Generated Time (GMT): 19-Apr-2021 21:04

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1. Select appropriate response - Reactogenicity diary collection

Date	Location	User	Value	Reason
Sep-21-2020 18:33:14 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO - REACTOGENICITY E-DIARY NOT COLLECTED FOR THIS SUBJECT	Initial Entry

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:02

Site No: 4444

Subject No: 44441035

Generated By: (b) (4)

Form: DATE OF VISIT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

Generated Time (GMT): 19-Apr-2021 21:04

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1. Date of Visit

Date	Location	User	Value	Reason
Oct-12-2020 21:10:08 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Oct/12/2020	Initial Entry

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 10-Oct-2020 16:01

Site No: 4444

Subject No: 44441035

Generated By: (b) (4)

Form: VITAL SIGNS - TEMP - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

Generated Time (GMT): 19-Apr-2021 21:04

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1. Date:

Date	Location	User	Value	Reason
Oct-12-2020 21:10:23 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Oct/12/2020	Initial Entry

2.a

Date	Location	User	Value	Reason
Oct-12-2020 21:10:23 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Record Identifier:: 1 Temperature: 36.9 Temperature Unit: C Temperature Location: ORAL CAVITY	Initial Entry

2.a Record Identifier:

Date	Location	User	Value	Reason
Oct-12-2020 21:10:23 (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
Oct-12-2020 21:10:23 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 36.9	Initial Entry

2.a Unit:

Date	Location	User	Value	Reason
Oct-12-2020 21:10:23 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: C	Initial Entry

2.a Temperature Location:

090177e196d6f289\Final\Final On: 22-Apr-2021 02:12 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 10-Oct-2020 16:01

Site No: 4444

Subject No: 44441035

Generated By: (b) (4)

Form: VITAL SIGNS - TEMP - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

Generated Time (GMT): 19-Apr-2021 21:04

Date	Location	User	Value	Reason
Oct-12-2020 21:10:23 (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: ELECTRONIC SAMPLE TRACKING - NASAL SWAB - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 4444

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

Subject No: 44441035

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 19-Apr-2021 21:04

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1. Data Origin

Date	Location	User	Value	Reason
Oct-12-2020 18:24:02 (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-12-2020 18:24:02 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: NASAL_SWAB	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Oct-12-2020 18:24:19 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Oct-12-2020 18:24:02 (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-12-2020 18:24:02 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Date of Collection: Oct/12/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Oct-12-2020 18:24:19 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BPXX2G	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
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090177e196d6f289\Final\Final On: 22-Apr-2021 02:12 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:03

Site No: 4444

Subject No: 44441035

Generated By: (b) (4)

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

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

Generated Time (GMT): 19-Apr-2021 21:04

Oct-12-2020 18:24:19 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Data Entry: BPXX2G	Initial Entry
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Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:04

Site No: 4444

Subject No: 44441035

Generated By: (b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

Generated Time (GMT): 19-Apr-2021 21:04

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1. Was there a temporary delay of vaccination?

Date	Location	User	Value	Reason
Oct-12-2020 21:10:47 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NO	Initial Entry

2. Treatment Name

Date	Location	User	Value	Reason
Oct-12-2020 21:10:47 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> BLINDED THERAPY	Initial Entry

3. Formulation:

Date	Location	User	Value	Reason
Oct-12-2020 21:10:47 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> INJECTION	Initial Entry

4. Dose Date Time:

Date	Location	User	Value	Reason
Oct-12-2020 21:10:47 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Oct/12/2020 13:30	Initial Entry

5. Anatomical Location:

Date	Location	User	Value	Reason
Oct-12-2020 21:10:47 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> DELTOID MUSCLE	Initial Entry

6. Body Side:

Date	Location	User	Value	Reason
Oct-12-2020 21:10:47 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> RIGHT	Initial Entry

090177e196d6f289\Final\Final On: 22-Apr-2021 02:12 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:04

Site No: 4444

Subject No: 44441035

Generated By: (b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

Generated Time (GMT): 19-Apr-2021 21:04

7. Route:

Date	Location	User	Value	Reason
Oct-12-2020 21:10:47 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: INTRAMUSCULAR	Initial Entry

10. Timeframe Subject Was Observed

Date	Location	User	Value	Reason
Oct-12-2020 21:10:47 (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
Oct-12-2020 21:10:47 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

090177e196d6f289\Final\Final On: 22-Apr-2021 02:12 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form: DATE OF VISIT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen, Verified

Site No: 4444

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

Subject No: 44441035

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 19-Apr-2021 21:04

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I. Date of Visit

Date	Location	User	Value	Reason
Nov-20-2020 03:06:14 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Closed per SITE response, added to PD tracker for Clinical Review
Nov-19-2020 09:03:32 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Original value is correct. The v3 was out of window because of personal reasons.
Nov-19-2020 03:13:02 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000.InFormAdapter.Discrepancy	PFE SDQ PROD (b) (4)	Query 1: Opened	PDQ: Date of visit at V3_MONTH1_POSTVAX2_L is out of window for 2 days from V2_VAX2_L DOV or V2 Vaccination date. Please verify and update. Else, confirm in query response appropriately. (b) (4)
Nov-18-2020 10:39:07 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry : Nov/18/2020	Initial Entry

090177e196d6f289\Final\Final On: 22-Apr-2021 02:12 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 4444

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

Subject No: 44441035

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 19-Apr-2021 21:04

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1. Data Origin

Date	Location	User	Value	Reason
Nov-18-2020 10:39:17 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Nov-18-2020 10:39:17 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SERUM	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Nov-18-2020 13:43:52 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Nov-18-2020 10:39:17 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Nov-18-2020 10:39:17 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Date of Collection: Nov/18/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Nov-18-2020 13:43:52 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	Agustin Morato Cabral (b) (4)	Data Entry: Sample ID: BRVRF2	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
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090177e196d6f289\Final\Final On: 22-Apr-2021 02:12 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 4444

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

Subject No: 44441035

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 19-Apr-2021 21:04

Nov-18-2020 13:43:52 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	Agustin Morato Cabral (b) (4)	Data Entry: BRVRF2	Initial Entry
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5.b

Date	Location	User	Value	Reason
Nov-19-2020 09:48:29 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BRVRDM	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Nov-19-2020 09:48:29 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BRVRDM	Initial Entry

5.c

Date	Location	User	Value	Reason
Nov-19-2020 10:06:36 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BPXJ9P	Initial Entry

5.c Sample ID

Date	Location	User	Value	Reason
Nov-19-2020 10:06:36 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BPXJ9P	Initial Entry

090177e196d6f289\Final\Final On: 22-Apr-2021 02:12 (GMT)

Header Text: c4591001

Visit: End of Treatment - Unscheduled

Form Version: 15-Sep-2020 21:55

Site No: 4444

Subject No: 44441035

Generated By: (b) (4)

Form: DISPOSITION - TREATMENT - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

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

Subject Initials: ---

Generated Time (GMT): 19-Apr-2021 21:04

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1. Date of Completion/Discontinuation/Death :

Date	Location	User	Value	Reason
Nov-18-2020 10:39:37 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Nov/18/2020	Initial Entry

2. Phase of Disposition:

Date	Location	User	Value	Reason
Nov-18-2020 10:39:37 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: VACCINATION	Initial Entry

3. Status:

Date	Location	User	Value	Reason
Nov-18-2020 10:39:37 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: COMPLETED	Initial Entry

090177e196dd6f289\Final\Final On: 22-Apr-2021 02:12 (GMT)

Header Text: c4591001

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

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen, Verified

Site No: 4444

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

Subject No: 44441035

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 19-Apr-2021 21:04

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1. Date of Visit

Date	Location	User	Value	Reason
Jan-28-2021 12:25:54 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Jan/28/2021	Initial Entry

Header Text: c4591001

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

Form Version: 10-Dec-2020 02:25

Form Status: Data Complete, Frozen, Verified

Site No: 4444

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

Subject No: 44441035

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 19-Apr-2021 21:04

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

Date	Location	User	Value	Reason
Jan-28-2021 12:26:14 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Jan-28-2021 12:26:03 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	The response indicates participant was unblinded, however the TREATMENT UNBLINDED date is missing in the DISP visit. Please complete this date.
Jan-28-2021 12:26:03 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Participant is willing to return for Vaccination 3 Participant is: eligible per local/national recommendations and confirmed to have received only placebo at Vaccination 1 /2	Initial Entry

090177e196d6f289\Final\Final On: 22-Apr-2021 02:12 (GMT)

Header Text: c4591001

Visit: Disposition - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 4444

Subject No: 44441035

Generated By: (b) (4)

Form: TREATMENT UNBLINDED - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

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

Subject Initials: ---

Generated Time (GMT): 19-Apr-2021 21:04

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1. Date Treatment Unblinded :

Date	Location	User	Value	Reason
Jan-28-2021 12:26:14 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Jan/28/2021	Initial Entry

2. Primary Reason for Unblinding:

Date	Location	User	Value	Reason
Jan-28-2021 12:26:14 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: ASSESS ELIGIBILITY FOR ADDITIONAL VACCINATION	Initial Entry

Header Text: c4591001

Visit: V101_VAX3

Form Version: 22-Apr-2020 21:02

Site No: 4444

Subject No: 44441035

Generated By: (b) (4)

Form: DATE OF VISIT - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

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

Subject Initials: ---

Generated Time (GMT): 19-Apr-2021 21:04

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1. Date of Visit

Date	Location	User	Value	Reason
Jan-30-2021 11:11:13 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Jan/29/2021	Initial Entry

Header Text: c4591001

Visit: V101_VAX3

Form Version: 10-Dec-2020 02:31

Site No: 4444

Subject No: 44441035

Generated By: (b) (4)

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

Form Status: Data Complete, Frozen, Verified

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

Subject Initials: ---

Generated Time (GMT): 19-Apr-2021 21:04

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I. Consent Was:

Date	Location	User	Value	Reason
Jan-30-2021 11:11:36 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: OBTAINED Date Written Consent Obtained Jan/29/2021	Initial Entry

Header Text: c4591001

Visit: V101_VAX3

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

Form Version: 10-Dec-2020 02:31

Form Status: Data Complete, Frozen, Verified

Site No: 4444

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

Subject No: 44441035

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 19-Apr-2021 21:04

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1. Date of Completion/Discontinuation/Death :

Date	Location	User	Value	Reason
Jan-30-2021 11:12:13 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Jan/29/2021	Initial Entry

2. Phase of Disposition:

Date	Location	User	Value	Reason
Jan-30-2021 11:12:13 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: REPEAT SCREENING 1	Initial Entry

3. Status:

Date	Location	User	Value	Reason
Jan-30-2021 11:12:13 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: COMPLETED	Initial Entry

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, Frozen, Verified

Site No: 4444

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

Subject No: 44441035

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 19-Apr-2021 21:04

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1. Data Origin

Date	Location	User	Value	Reason
Jan-30-2021 11:12:39 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Jan-30-2021 11:12:39 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SERUM	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Feb-01-2021 10:52:26 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Jan-31-2021 23:58:04 (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.
Jan-30-2021 11:12:39 (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.
Jan-30-2021 11:12:39 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Date of Collection: Jan/29/2021	Initial Entry

5.a

Date	Location	User	Value	Reason
Feb-01-2021 10:52:26 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BS423B	Initial Entry

090177e196d6f289\Final\Final On: 22-Apr-2021 02:12 (GMT)

Header Text: c4591001

Visit: V101_VAX3

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 4444

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

Subject No: 44441035

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 19-Apr-2021 21:04

5.a Sample ID

Date	Location	User	Value	Reason
Feb-01-2021 10:52:26 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> BS423B	Initial Entry

5.b

Date	Location	User	Value	Reason
Feb-01-2021 12:23:41 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Sample ID: BPWFSV	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Feb-01-2021 12:23:41 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> BPWFSV	Initial Entry

5.c

Date	Location	User	Value	Reason
Feb-01-2021 12:42:43 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Sample ID: BRYWPK	Initial Entry

5.c Sample ID

Date	Location	User	Value	Reason
Feb-01-2021 12:42:43 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> BRYWPK	Initial Entry

090177e196d6f289\Final\Final On: 22-Apr-2021 02:12 (GMT)

Header Text: c4591001

Visit: V101_VAX3

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 4444

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

Subject No: 44441035

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 19-Apr-2021 21:04

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1. Data Origin

Date	Location	User	Value	Reason
Jan-30-2021 11:12:55 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Jan-30-2021 11:12:55 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: NASAL_SWAB	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Feb-01-2021 12:49:56 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Jan-31-2021 23:58:04 (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.
Jan-30-2021 11:12:55 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Jan-30-2021 11:12:55 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Date of Collection: Jan/29/2021	Initial Entry

5.a

Date	Location	User	Value	Reason
Feb-01-2021 12:49:56 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BPFWF1	Initial Entry

090177e196d6f289\Final\Final On: 22-Apr-2021 02:12 (GMT)

Header Text: c4591001

Visit: V101_VAX3

Form Version: 22-Apr-2020 21:03

Site No: 4444

Subject No: 44441035

Generated By: (b) (4)

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

Form Status: Data Complete, Frozen, Verified

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

Subject Initials: ---

Generated Time (GMT): 19-Apr-2021 21:04

5.a Sample ID

Date	Location	User	Value	Reason
Feb-01-2021 12:49:56 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> BPWFW1	Initial Entry

Header Text: c4591001

Visit: V101_VAX3

Form Version: 10-Dec-2020 02:26

Site No: 4444

Subject No: 44441035

Generated By: (b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

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

Subject Initials: ---

Generated Time (GMT): 19-Apr-2021 21:04

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1. Was there a temporary delay of vaccination?

Date	Location	User	Value	Reason
Jan-30-2021 11:13:18 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NO	Initial Entry

2. Treatment Name

Date	Location	User	Value	Reason
Jan-30-2021 11:13:18 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> BNT162b2	Initial Entry

3. Formulation:

Date	Location	User	Value	Reason
Jan-30-2021 11:13:18 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> INJECTION	Initial Entry

4. Dose Date Time:

Date	Location	User	Value	Reason
Jan-30-2021 11:13:18 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Jan/29/2021 15:20	Initial Entry

5. Anatomical Location:

Date	Location	User	Value	Reason
Jan-30-2021 11:13:18 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> DELTOID MUSCLE	Initial Entry

6. Body Side:

Date	Location	User	Value	Reason
Jan-30-2021 11:13:18 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> LEFT	Initial Entry

090177e196d6f289\Final\Final On: 22-Apr-2021 02:12 (GMT)

Header Text: c4591001

Visit: V101_VAX3

Form Version: 10-Dec-2020 02:26

Site No: 4444

Subject No: 44441035

Generated By: (b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

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

Subject Initials: ---

Generated Time (GMT): 19-Apr-2021 21:04

7. Route:

Date	Location	User	Value	Reason
Jan-30-2021 11:13:18 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> INTRAMUSCULAR	Initial Entry

8. Actual Dose:

Date	Location	User	Value	Reason
Jan-30-2021 11:13:18 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> 30.0	Initial Entry

9. Unit:

Date	Location	User	Value	Reason
Jan-30-2021 11:13:18 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> ug	Initial Entry

10. Timeframe Subject Was Observed

Date	Location	User	Value	Reason
Jan-30-2021 11:13:18 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> 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
Jan-30-2021 11:13:18 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> YES	Initial Entry

090177e196d6f289\Final\Final On: 22-Apr-2021 02:12 (GMT)

Header Text: c4591001

Visit: V102_VAX4

Form Version: 22-Apr-2020 21:02

Site No: 4444

Subject No: 44441035

Generated By: (b) (4)

Form: DATE OF VISIT - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

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

Subject Initials: ---

Generated Time (GMT): 19-Apr-2021 21:04

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1. Date of Visit

Date	Location	User	Value	Reason
Feb-17-2021 17:43:29 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Feb/17/2021	Initial Entry

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, Frozen, Verified

Site No: 4444

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

Subject No: 44441035

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 19-Apr-2021 21:04

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1. Data Origin

Date	Location	User	Value	Reason
Feb-17-2021 17:43:45 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Feb-17-2021 17:43:45 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: NASAL_SWAB	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Feb-18-2021 10:40:02 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Feb-18-2021 09:43:44 (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.
Feb-17-2021 17:43:45 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Feb-17-2021 17:43:45 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Date of Collection: Feb/17/2021	Initial Entry

5.a

Date	Location	User	Value	Reason
Feb-18-2021 10:40:02 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BR287D	Initial Entry

090177e196d6f289\Final\Final On: 22-Apr-2021 02:12 (GMT)

Header Text: c4591001

Visit: V102_VAX4

Form Version: 22-Apr-2020 21:03

Site No: 4444

Subject No: 44441035

Generated By: (b) (4)

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

Form Status: Data Complete, Frozen, Verified

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

Subject Initials: ---

Generated Time (GMT): 19-Apr-2021 21:04

5.a Sample ID

Date	Location	User	Value	Reason
Feb-18-2021 10:40:02 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> BR287D	Initial Entry

Header Text: c4591001

Visit: V102_VAX4

Form Version: 10-Dec-2020 02:26

Site No: 4444

Subject No: 44441035

Generated By: (b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

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

Subject Initials: ---

Generated Time (GMT): 19-Apr-2021 21:04

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1. Was there a temporary delay of vaccination?

Date	Location	User	Value	Reason
Feb-17-2021 17:44:17 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2. Treatment Name

Date	Location	User	Value	Reason
Feb-17-2021 17:44:17 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: BNT162b2	Initial Entry

3. Formulation:

Date	Location	User	Value	Reason
Feb-17-2021 17:44:17 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: INJECTION	Initial Entry

4. Dose Date Time:

Date	Location	User	Value	Reason
Feb-17-2021 17:44:17 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Feb/17/2021 16:25	Initial Entry

5. Anatomical Location:

Date	Location	User	Value	Reason
Feb-17-2021 17:44:17 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: DELTOID MUSCLE	Initial Entry

6. Body Side:

Date	Location	User	Value	Reason
Feb-17-2021 17:44:17 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: LEFT	Initial Entry

090177e196d6f289\Final\Final On: 22-Apr-2021 02:12 (GMT)

Header Text: c4591001

Visit: V102_VAX4

Form Version: 10-Dec-2020 02:26

Site No: 4444

Subject No: 44441035

Generated By: (b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

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

Subject Initials: ---

Generated Time (GMT): 19-Apr-2021 21:04

7. Route:

Date	Location	User	Value	Reason
Feb-17-2021 17:44:17 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: INTRAMUSCULAR	Initial Entry

8. Actual Dose:

Date	Location	User	Value	Reason
Feb-17-2021 17:44:17 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 30.0	Initial Entry

9. Unit:

Date	Location	User	Value	Reason
Feb-17-2021 17:44:17 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: ug	Initial Entry

10. Timeframe Subject Was Observed

Date	Location	User	Value	Reason
Feb-17-2021 17:44:17 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 30 MINUTES	Initial Entry

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

Date	Location	User	Value	Reason
Feb-17-2021 17:44:17 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

090177e196d6f289\Final\Final On: 22-Apr-2021 02:12 (GMT)

Header Text: c4591001

Visit: Subject Status - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 4444

Subject No: 44441035

Generated By: (b) (4)

Form: SUBJECT STATUS - eCRF Audit Trail History

Form Status: Data Complete, Verified

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

Subject Initials: ---

Generated Time (GMT): 19-Apr-2021 21:04

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1. Subject Status

Date	Location	User	Value	Reason
Nov-18-2020 10:39:37 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: FOLLOW-UP	Initial Entry
Sep-21-2020 18:32:21 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: ENROLLED/RANDOMIZED	Initial Entry
Sep-21-2020 18:31:08 (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-18-2020 10:39:37 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Nov/18/2020	Initial Entry
Sep-21-2020 18:32:21 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sep/21/2020	Initial Entry
Sep-21-2020 18:31:08 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sep/21/2020	Initial Entry

090177e196d6f289\Final\Final On: 22-Apr-2021 02:12 (GMT)

Header Text: c4591001

Visit: Investigator Signature - Unscheduled

Form Version: 22-Apr-2020 21:04

Site No: 4444

Subject No: 44441035

Generated By: (b) (4)

Form: CASEBOOK SIGNATURE FORM - eCRF Audit Trail History

Form Status: Data Complete, Signed, Verified

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

Subject Initials: ---

Generated Time (GMT): 19-Apr-2021 21:04

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I. Casebook Signature

Date	Location	User	Value	Reason
Nov-10-2020 11:11:08 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	Fernando Polack (b) (4)	Data Entry: Click Here to Enable	Initial Entry