

Header Text: c4591001

Visit: COHORT_SELECTION

Form: COHORT_SELECTION

Form Version: 15-Sep-2020 21:55

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 4444

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

Subject No: 44441385

Subject Initials: ---

Generated By: (b) (4)

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

[eCRF Audit Trail History](#)

Cohort Selection

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

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

Header Text: c4591001

Visit: COHORT_SELECTION

Form: MAIN INFORMED CONSENT

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 4444

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

Subject No: 44441385

Subject Initials: ---

Generated By: (b) (4)

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

[eCRF Audit Trail History](#)

Informed Consent

1.	Consent Was:	OBTAINED Date Written Consent Obtained Sep/22/2020
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Header Text: c4591001

Visit: COHORT_SELECTION

Form: DEMOGRAPHY

Form Version: 15-Sep-2020 21:54

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 4444

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

Subject No: 44441385

Subject Initials: ---

Generated By: (b) (4)

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

[eCRF Audit Trail History](#)

Demography

1.	Subject ID	[44441385]
2.	Birth Date:	(b) (6)/1951
3.	Sex:	MALE
4.	Ethnicity:	HISPANIC OR LATINO(A) OR OF SPANISH ORIGIN
5.	Race: (Check X all that apply):	WHITE
6.	Racial Designation:	

090177e196ae2e6b\Final\Final On: 01-Apr-2021 03:12 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:02

Site No: 4444

Subject No: 44441385

Generated By: (b) (4)

Form: DATE OF VISIT

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Date of Visit

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

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 15-Sep-2020 21:53

Site No: 4444

Subject No: 44441385

Generated By: (b) (4)

Form: INCLUSION/EXCLUSION CRITERIA

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

Form Comments

Inclusion Criteria Not Met

1.	Description of Inclusion Criterion Not Met	Not Applicable
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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: 44441385

Generated By: (b) (4)

Form: DISPOSITION - SCREENING

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Disposition - Screening

1.	Date of Completion/Discontinuation /Death	Sep/22/2020
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: 44441385

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): 29-Mar-2021 17:38

[eCRF Audit Trail History](#)

Medical History Details

1.a	Line/MH Number:	[1]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Resolved prostate cancer]
	Start Date:	Mar/1/2012
	Ongoing:	NO End Date: Dec/1/2012
1.b	Line/MH Number:	[2]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Hypercholesterolemia]
	Start Date:	Sep/22/2019
	Ongoing:	YES
1.c	Line/MH Number:	[3]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Horton migraine]
	Start Date:	Feb/1/1980
	Ongoing:	YES

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Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 15-Sep-2020 21:57

Site No: 4444

Subject No: 44441385

Generated By: (b) (4)

Form: HIV STATUS

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

[eCRF Audit Trail History](#)

HIV Status

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

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 15-Sep-2020 21:56

Site No: 4444

Subject No: 44441385

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): 29-Mar-2021 17:38

[eCRF Audit Trail History](#)

Vital Signs

1.	Date:	Sep/22/2020
2.	Weight:	[81.0]
3.	Unit:	kg
4.	Height:	[170.0]
5.	Unit:	cm
6.	Body Mass Index:	[28.0]

Vital Signs Details

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

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Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 4444

Subject No: 44441385

Generated By: (b) (4)

Form: RANDOMIZATION

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Disposition

1.	Randomization Date :	Sep/22/2020
2.	Randomization Number:	[263528]
3.	Randomization Group:	[]

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 4444

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

Subject No: 44441385

Subject Initials: ---

Generated By: (b) (4)

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

[eCRF Audit Trail History](#)

Electronic Sample Tracking

1.	Data Origin	SITE
2.	Sample Type	SERUM
3.	Sample Collected?	YES Date of Collection: Sep/22/2020
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[]

Aliquot

Please enter barcode for each aliquot.

5.a	Sample ID	[BRVM6H]
5.b	Sample ID	[BRVM65]
5.c	Sample ID	[BHXGY8]

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Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 4444

Subject No: 44441385

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): 29-Mar-2021 17:38

[eCRF Audit Trail History](#)

Electronic Sample Tracking

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB
3.	Sample Collected?	YES Date of Collection: Sep/22/2020
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[]

Aliquot

Please enter barcode for each aliquot.

5.a	Sample ID	[BPWBT6]
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090177e196ae2e6b\Final\Final On: 01-Apr-2021 03:12 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:04

Site No: 4444

Subject No: 44441385

Generated By: (b) (4)

Form: VACCINATION

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

eCRF Audit Trail History

Vaccination

1.	Was there a temporary delay of vaccination?	NO
2.	Treatment Name	[BLINDED THERAPY]
3.	Formulation:	INJECTION
4.	Dose Date Time:	Sep/22/2020 13:47
5.	Anatomical Location:	DELTOID MUSCLE
6.	Body Side:	LEFT
7.	Route:	INTRAMUSCULAR
8.	Actual Dose:	[]
9.	Unit:	
10.	Timeframe Subject Was Observed	THE PROTOCOL SPECIFIED OBSERVATION PERIOD
11.	Was the subject observed for at least the protocol specified observation period after investigational product administration?	YES

090177e196ae2e6b\Final\Final On: 01-Apr-2021 03:12 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 06-Jul-2020 21:53

Site No: 4444

Subject No: 44441385

Generated By: (b) (4)

Form: REACTOGENICITY DIARY

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Reactogenicity Diary

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

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:02

Site No: 4444

Subject No: 44441385

Generated By: (b) (4)

Form: DATE OF VISIT

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Date of Visit

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

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 10-Oct-2020 16:01

Site No: 4444

Subject No: 44441385

Generated By: (b) (4)

Form: VITAL SIGNS - TEMP

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Vital Signs

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

2.a	Record Identifier:	1
	Temperature:	[36.7]
	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: 44441385

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): 29-Mar-2021 17:38

[eCRF Audit Trail History](#)

Electronic Sample Tracking

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

Aliquot

Please enter barcode for each aliquot.

5.a	Sample ID	[BP1V6L]
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090177e196ae2e6b\Final\Final On: 01-Apr-2021 03:12 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:04

Site No: 4444

Subject No: 44441385

Generated By: (b) (4)

Form: VACCINATION

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

eCRF Audit Trail History

Vaccination		
1.	Was there a temporary delay of vaccination?	NO
2.	Treatment Name	[BLINDED THERAPY]
3.	Formulation:	INJECTION
4.	Dose Date Time:	Oct/13/2020 11:48
5.	Anatomical Location:	DELTOID MUSCLE
6.	Body Side:	LEFT
7.	Route:	INTRAMUSCULAR
8.	Actual Dose:	[]
9.	Unit:	
10.	Timeframe Subject Was Observed	THE PROTOCOL SPECIFIED OBSERVATION PERIOD
11.	Was the subject observed for at least the protocol specified observation period after investigational product administration?	YES

090177e196ae2e6b\Final\Final On: 01-Apr-2021 03:12 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form Version: 22-Apr-2020 21:02

Site No: 4444

Subject No: 44441385

Generated By: (b) (4)

Form: DATE OF VISIT

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Date of Visit

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

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 4444

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

Subject No: 44441385

Subject Initials: ---

Generated By: (b) (4)

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

[eCRF Audit Trail History](#)

Electronic Sample Tracking

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

Aliquot

Please enter barcode for each aliquot.

5.a	Sample ID	[BPTCBS]
5.b	Sample ID	[BJ5NTL]
5.c	Sample ID	[BJ5NTD]

Header Text: c4591001

Visit: POT_COVID_ILL - New Unscheduled **Form:** DATE OF VISIT - ILLNESS ONSET Visit

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: 44441385

Subject Initials: ---

Generated By: (b) (4)

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

Date of Visit

1.	Date of Visit	//
2.	Erroneous Visit	

COVID-19 Illness Visit

3.	COVID-19 Illness Visit:	
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090177e196ae2e6b\Final\Final On: 01-Apr-2021 03:12 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL - New Unscheduled **Form:** SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 Visit

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: 44441385

Subject Initials: ---

Generated By: (b) (4)

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

Signs and Symptoms

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

Symptoms

4.	Symptoms:	
	Was symptom present?	

Symptoms - Other

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

090177e196ae2e6b\Final\Final On: 01-Apr-2021 03:12 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL - New Unscheduled Visit

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB SELF

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 4444

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

Subject No: 44441385

Subject Initials: ---

Generated By: (b) (4)

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

Electronic Sample Tracking

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

Aliquot

Please enter barcode for each aliquot.

5.	Sample ID	[]
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090177e196ae2e6b\Final\Final On: 01-Apr-2021 03:12 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL - New Unscheduled **Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB Visit

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: 44441385

Subject Initials: ---

Generated By: (b) (4)

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

Electronic Sample Tracking

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

Aliquot

Please enter barcode for each aliquot.

5.	Sample ID	[]
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090177e196ae2e6b\Final\Final On: 01-Apr-2021 03:12 (GMT)

Header Text: c4591001

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

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: 44441385

Subject Initials: ---

Generated By: (b) (4)

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

Health Care Utilization

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

Health Care Utilization Other

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

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

090177e196ae2e6b\Final\Final On: 01-Apr-2021 03:12 (GMT)

Header Text: c4591001

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

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: 44441385

Subject Initials: ---

Generated By: (b) (4)

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

Illness Details

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

Header Text: c4591001

Visit: POT_COVID_CONVA - New
Unscheduled Visit

Form Version: 22-Apr-2020 21:04

Site No: 4444

Subject No: 44441385

Generated By: (b) (4)

Form: DATE OF VISIT - ILLNESS CONVALESCENT

Form Status: Not Started

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

Subject Initials: ---

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

Date of Visit

1.	Date of Visit	//
2.	Erroneous Visit	

COVID-19 Illness Visit

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

090177e196ae2e6b\Final\Final On: 01-Apr-2021 03:12 (GMT)

Header Text: c4591001

Visit: POT_COVID_CONVA - New
Unscheduled Visit

Form Version: 22-Apr-2020 21:03

Site No: 4444

Subject No: 44441385

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING -
IMMUNOGENICITY

Form Status: Not Started

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

Subject Initials: ---

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

Electronic Sample Tracking

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

Aliquot

Please enter barcode for each aliquot.

5.	Sample ID	[]
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090177e196ae2e6b\Final\Final On: 01-Apr-2021 03:12 (GMT)

Header Text: c4591001

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

Form Version: 10-Oct-2020 15:57

Form Status: Not Started

Site No: 4444

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

Subject No: 44441385

Subject Initials: ---

Generated By: (b) (4)

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

Date of Visit

1.	Date of Visit	//
2.	Erroneous Visit	

COVID-19 Repeat Swab

3.	COVID-19 Repeat Swab:	
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090177e196ae2e6b\Final\Final On: 01-Apr-2021 03:12 (GMT)

Header Text: c4591001

Visit: POT_COVID_REPEAT_SWAB - New **Form:** ELECTRONIC SAMPLE TRACKING - REPEAT SWAB
Unscheduled Visit

Form Version: 10-Oct-2020 15:57

Form Status: Not Started

Site No: 4444

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

Subject No: 44441385

Subject Initials: ---

Generated By: (b) (4)

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

Electronic Sample Tracking

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

Aliquot

Please enter barcode for each aliquot.

5.	Sample ID	[]
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Header Text: c4591001

Visit: Unplanned - New Unscheduled 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: 44441385

Subject Initials: ---

Generated By: (b) (4)

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

Date of Visit

1.	Date of Visit	//
2.	Erroneous Visit	

Header Text: c4591001

Visit: Unplanned - New Unscheduled Visit

Form: UNPLANNED VISIT

Form Version: 22-Apr-2020 21:04

Form Status: Not Started

Site No: 4444

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

Subject No: 44441385

Subject Initials: ---

Generated By: (b) (4)

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

Unplanned Assessments

1.	Assessments	
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Header Text: c4591001

Visit: Logs

Form: ADVERSE EVENT REPORT

Form Version: 22-Apr-2020 21:02

Site No: 4444

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

Subject No: 44441385

Subject Initials: ---

Generated By: (b) (4)

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

#	Category	AE Identifier	Adverse Event	Start Date	Is the Adverse Event Still Ongoing	Form Instance
1.	ADVERSE EVENT	1	Ischemic myocardopathy worsening	Feb/5/2021 12:00	NO End Date Time: Mar/9/2021 19:00	Repeating Pages
2.	ADVERSE EVENT	2	Severe Aortic Stenosis	Jan/27/2021 12:00	NO End Date Time: Mar/9/2021 19:00	Repeating Pages
3.	ADVERSE EVENT	3	Abdominal Aortic Aneurysm	Feb/8/2021 10:50	NO End Date Time: Feb/26/2021 16:30	Repeating Pages

090177e196ae2e6b\Final\Final On: 01-Apr-2021 03:12 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 4444

Subject No: 44441385

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete

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

Subject Initials: ---

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

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Adverse Event Report

1.	Category:	ADVERSE EVENT
2.	AE ID:	[1]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[Ischemic cardiomyopathy worsening]
4.	Start Date Time:	Feb/5/2021 12:00
5.	Is the adverse event still ongoing?	NO End Date Time: Mar/9/2021 19:00
6.	Toxicity Grade:	3
7.	Is the adverse event serious? If Yes, NOTIFY PFIZER IMMEDIATELY. Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).	YES Is this serious event associated with congenital anomaly or birth defect? NO Did this serious event result in death? NO Did this serious event require or prolong hospitalization? YES Did this serious event result in persistent or significant disability/incapacity? NO Is this serious event life threatening? NO Other medically important serious event YES

090177e196ae2e6b\Final\Final On: 01-Apr-2021 03:12 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 4444

Subject No: 44441385

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete

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

Subject Initials: ---

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

8.	Is this adverse event the result of a study Medication Error? If Yes, record the type of medication error on the Medication Error Log.	NO
9.	Is this event related to study treatment:	NOT RELATED If Not Related to study treatment(s), this event is due to: OTHER If Other, specify: [unknown]
10.	Latest Action Taken with Study Treatment:	NOT APPLICABLE
11.	Was a Concomitant Medication given?	YES
12.	Was a Non-Drug Treatment given?	YES
13.	What was the outcome of this adverse event?:	RECOVERED/RESOLVED
14.	Did the adverse event cause the subject to be discontinued from the study?	NO
15.	Serious Adverse Event Number: For Pfizer Use Only	[2021161548]

090177e196ae2e6b\Final\Final On: 01-Apr-2021 03:12 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 4444

Subject No: 44441385

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Answered Queries

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

Subject Initials: ---

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

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Adverse Event Report

1.	Category:	ADVERSE EVENT
2.	AE ID:	[2]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[Severe Aortic Stenosis]
4.	Start Date Time:	Jan/27/2021 12:00
5.	Is the adverse event still ongoing?	NO End Date Time: Mar/9/2021 19:00
6.	Toxicity Grade:	3
7.	Is the adverse event serious? If Yes, NOTIFY PFIZER IMMEDIATELY. Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).	YES Is this serious event associated with congenital anomaly or birth defect? NO Did this serious event result in death? NO Did this serious event require or prolong hospitalization? YES Did this serious event result in persistent or significant disability/incapacity? NO Is this serious event life threatening? NO Other medically important serious event YES

090177e196ae2e6b\Final\Final On: 01-Apr-2021 03:12 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 4444

Subject No: 44441385

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Answered Queries

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

Subject Initials: ---

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

8.	Is this adverse event the result of a study Medication Error? If Yes, record the type of medication error on the Medication Error Log.	NO
9.	Is this event related to study treatment:	NOT RELATED If Not Related to study treatment(s), this event is due to: OTHER If Other, specify: [unknown]
10.	Latest Action Taken with Study Treatment:	NOT APPLICABLE
11.	Was a Concomitant Medication given?	YES
12.	Was a Non-Drug Treatment given?	YES
13.	What was the outcome of this adverse event?:	RECOVERED/RESOLVED
14.	Did the adverse event cause the subject to be discontinued from the study?	NO
15.	Serious Adverse Event Number: For Pfizer Use Only	[2021161580]

090177e196ae2e6b\Final\Final On: 01-Apr-2021 03:12 (GMT)

Header Text: c4591001**Visit:** Logs - Unscheduled**Form Version:** 22-Apr-2020 21:02**Site No:** 4444**Subject No:** 44441385**Generated By:** (b) (4)**Form:** ADVERSE EVENT REPORT**Form Status:** Data Complete, Frozen**Site Name:** (4444) Hospital Militar Central Cirujano Mayor Dr Cosme Argerich**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 17:38[Back to Form](#)[eCRF Audit Trail History](#)[Form Audit Trail](#)**Adverse Event Report**

1.	Category:	ADVERSE EVENT
2.	AE ID:	[3]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[Abdominal Aortic Aneurysm]
4.	Start Date Time:	Feb/8/2021 10:50
5.	Is the adverse event still ongoing?	NO End Date Time: Feb/26/2021 16:30
6.	Toxicity Grade:	1
7.	Is the adverse event serious? If Yes, NOTIFY PFIZER IMMEDIATELY. Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).	NO
8.	Is this adverse event the result of a study Medication Error? If Yes, record the type of medication error on the Medication Error Log.	NO

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 4444

Subject No: 44441385

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Frozen

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

Subject Initials: ---

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

9.	Is this event related to study treatment:	NOT RELATED If Not Related to study treatment(s), this event is due to: OTHER If Other, specify: [unknown]
10.	Latest Action Taken with Study Treatment:	NOT APPLICABLE
11.	Was a Concomitant Medication given?	YES
12.	Was a Non-Drug Treatment given?	NO
13.	What was the outcome of this adverse event?:	RECOVERED/RESOLVED
14.	Did the adverse event cause the subject to be discontinued from the study?	NO
15.	Serious Adverse Event Number: For Pfizer Use Only	[]

090177e196ae2e6b\Final\Final On: 01-Apr-2021 03:12 (GMT)

Header Text: c4591001

Visit: Logs

Form: MEDICATION ERROR

Form Version: 17-Jul-2020 21:54

Site No: 4444

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

Subject No: 44441385

Subject Initials: ---

Generated By: (b) (4)

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

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

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 17-Jul-2020 21:54

Site No: 4444

Subject No: 44441385

Generated By: (b) (4)

Form: MEDICATION ERROR

Form Status: Not Started

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

Subject Initials: ---

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

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Medication Error

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

090177e196ae2e6b\Final\Final On: 01-Apr-2021 03:12 (GMT)

Header Text: c4591001

Visit: Logs

Form: CONCOMITANT MEDICATIONS - NON STUDY VACCINATIONS

Form Version: 22-Apr-2020 21:03

Site No: 4444

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

Subject No: 44441385

Subject Initials: ---

Generated By: (b) (4)

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

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

Header Text: c4591001

Visit: Logs - Unscheduled

Form: CONCOMITANT MEDICATIONS - NON STUDY VACCINATIONS

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 4444

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

Subject No: 44441385

Subject Initials: ---

Generated By: (b) (4)

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

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Concomitant Medications

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

090177e196ae2e6b\Final\Final On: 01-Apr-2021 03:12 (GMT)

Header Text: c4591001

Visit: Logs

Form: CONCOMITANT MEDICATIONS - PROHIBITED

Form Version: 22-Apr-2020 21:03

Site No: 4444

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

Subject No: 44441385

Subject Initials: ---

Generated By: (b) (4)

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

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

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 4444

Subject No: 44441385

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): 29-Mar-2021 17:38

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Concomitant Medications

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

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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: 44441385

Subject Initials: ---

Generated By: (b) (4)

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

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

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 4444

Subject No: 44441385

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): 29-Mar-2021 17:38

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Radiation Treatment

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

090177e196ae2e6b\Final\Final On: 01-Apr-2021 03:12 (GMT)

Header Text: c4591001

Visit: Logs

Form: TRANSFUSIONS

Form Version: 22-Apr-2020 21:03

Site No: 4444

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

Subject No: 44441385

Subject Initials: ---

Generated By: (b) (4)

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

#	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: 44441385

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): 29-Mar-2021 17:38

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

Header Text: c4591001

Visit: End of Treatment - Unscheduled

Form: DISPOSITION - TREATMENT

Form Version: 15-Sep-2020 21:55

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 4444

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

Subject No: 44441385

Subject Initials: ---

Generated By: (b) (4)

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

[eCRF Audit Trail History](#)

Disposition - Treatment

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

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: 44441385

Subject Initials: ---

Generated By: (b) (4)

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

Date of Visit

1.	Date of Visit	//
2.	Erroneous Visit	

Header Text: c4591001

Visit: Unplanned Vaccination - Unscheduled **Form:** VITAL SIGNS - TEMP

Form Version: 20-Feb-2021 02:16 **Form Status:** Not Started

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

Subject No: 44441385 **Subject Initials:** ---

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

Vital Signs

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

Vital Signs Details

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

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: 44441385

Subject Initials: ---

Generated By: (b) (4)

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

Vaccination

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

090177e196ae2e6b\Final\Final On: 01-Apr-2021 03:12 (GMT)

Header Text: c4591001

Visit: Unplanned Vaccination - Unscheduled

Form: CONTACT OUTCOME - MONTH 1

Form Version: 10-Oct-2020 15:57

Form Status: Not Started

Site No: 4444

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

Subject No: 44441385

Subject Initials: ---

Generated By: (b) (4)

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

Contact Outcome

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

Header Text: c4591001

Visit: Unplanned Vaccination - Unscheduled

Form: CONTACT OUTCOME - MONTH 6

Form Version: 10-Oct-2020 16:01

Form Status: Not Started

Site No: 4444

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

Subject No: 44441385

Subject Initials: ---

Generated By: (b) (4)

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

Contact Outcome

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

Header Text: c4591001

Visit: Follow-Up - Unscheduled

Form Version: 15-Sep-2020 21:53

Site No: 4444

Subject No: 44441385

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): 29-Mar-2021 17:38

Disposition - Follow-Up

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

Header Text: c4591001

Visit: Potential ReVax Initial Contact -
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: 44441385

Subject Initials: ---

Generated By: (b) (4)

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

[eCRF Audit Trail History](#)

Date of Visit

1.	Date of Visit	Jan/29/2021
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: 44441385

Subject Initials: ---

Generated By: (b) (4)

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

[eCRF Audit Trail History](#)

Further Vaccination Confirmation

1.	Select appropriate response - Is participant willing to return for Vaccination 3?	Participant is willing to return for Vaccination 3 Participant is: eligible 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: 44441385

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): 29-Mar-2021 17:38

[eCRF Audit Trail History](#)

Treatment Unblinded

1.	Date Treatment Unblinded :	Jan/29/2021
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: 44441385

Generated By: (b) (4)

Form: WITHDRAWAL OF CONSENT

Form Status: Not Started

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

Subject Initials: ---

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

Withdrawal Of Consent

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

Visit: Disposition - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 4444

Subject No: 44441385

Generated By: (b) (4)

Form: DEATH DETAILS CODED

Form Status: Not Started

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

Subject Initials: ---

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

Death Details

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

Cause of Death

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

Header Text: c4591001

Visit: V101_VAX3

Form Version: 22-Apr-2020 21:02

Site No: 4444

Subject No: 44441385

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): 29-Mar-2021 17:38

[eCRF Audit Trail History](#)

Date of Visit

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

Header Text: c4591001

Visit: V101_VAX3

Form Version: 10-Dec-2020 02:31

Site No: 4444

Subject No: 44441385

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): 29-Mar-2021 17:38

[eCRF Audit Trail History](#)

Informed Consent - Further Vaccination

1.	Consent Was:	OBTAINED Date Written Consent Obtained Feb/3/2021
----	--------------	---

090177e196ae2e6b\Final\Final On: 01-Apr-2021 03:12 (GMT)

Header Text: c4591001

Visit: V101_VAX3

Form: INCLUSION/EXCLUSION CRITERIA - FURTHER VACCINATION

Form Version: 10-Dec-2020 02:30

Form Status: Data Complete, Frozen, Verified

Site No: 4444

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

Subject No: 44441385

Subject Initials: ---

Generated By: (b) (4)

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

[Form Comments](#)

Inclusion Criteria Not Met

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

Exclusion Criteria Met

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

Header Text: c4591001

Visit: V101_VAX3

Form: DISPOSITION - SCREENING FOR FURTHER VACCINATION

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: 44441385

Subject Initials: ---

Generated By: (b) (4)

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

[eCRF Audit Trail History](#)

Disposition - Screening for Further Vaccination

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

Header Text: c4591001

Visit: V101_VAX3

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

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: 44441385

Subject Initials: ---

Generated By: (b) (4)

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

[eCRF Audit Trail History](#)

Electronic Sample Tracking

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

Aliquot

Please enter barcode for each aliquot.

5.a	Sample ID	[BPWC4C]
5.b	Sample ID	[BS43C5]
5.c	Sample ID	[BS43ML]

Header Text: c4591001

Visit: V101_VAX3

Form Version: 22-Apr-2020 21:03

Site No: 4444

Subject No: 44441385

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): 29-Mar-2021 17:38

[eCRF Audit Trail History](#)

Electronic Sample Tracking

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

Aliquot

Please enter barcode for each aliquot.

5.a	Sample ID	[BPWCMV]
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090177e196ae2e6b\Final\Final On: 01-Apr-2021 03:12 (GMT)

Header Text: c4591001

Visit: V101_VAX3

Form Version: 10-Dec-2020 02:26

Site No: 4444

Subject No: 44441385

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): 29-Mar-2021 17:38

[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/3/2021 15:14
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

090177e196ae2e6b\Final\Final On: 01-Apr-2021 03:12 (GMT)

Header Text: c4591001

Visit: V102_VAX4

Form Version: 22-Apr-2020 21:02

Site No: 4444

Subject No: 44441385

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): 29-Mar-2021 17:38

[eCRF Audit Trail History](#)

Date of Visit

1.	Date of Visit	Mar/8/2021
2.	Erroneous Visit	

Header Text: c4591001

Visit: V102_VAX4

Form Version: 22-Apr-2020 21:03

Site No: 4444

Subject No: 44441385

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): 29-Mar-2021 17:38

[eCRF Audit Trail History](#)

Electronic Sample Tracking

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB
3.	Sample Collected?	YES Date of Collection: Mar/8/2021
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	[BR233Y]
-----	-----------	----------

090177e196ae2e6b\Final\Final On: 01-Apr-2021 03:12 (GMT)

Header Text: c4591001

Visit: V102_VAX4

Form Version: 10-Dec-2020 02:26

Site No: 4444

Subject No: 44441385

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): 29-Mar-2021 17:38

[eCRF Audit Trail History](#)

Vaccination

1.	Was there a temporary delay of vaccination?	NO
2.	Treatment Name	[BNT162b2]
3.	Formulation:	INJECTION
4.	Dose Date Time:	Mar/8/2021 10:30
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

090177e196ae2e6b\Final\Final On: 01-Apr-2021 03:12 (GMT)

Header Text: c4591001

Visit: V103_MONTH1

Form Version: 22-Apr-2020 21:02

Site No: 4444

Subject No: 44441385

Generated By: (b) (4)

Form: DATE OF VISIT

Form Status: Not Started

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

Subject Initials: ---

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

Date of Visit

1.	Date of Visit	//
2.	Erroneous Visit	

Header Text: c4591001

Visit: V103_MONTH1

Form Version: 22-Apr-2020 21:04

Site No: 4444

Subject No: 44441385

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): 29-Mar-2021 17:38

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: 44441385

Generated By: (b) (4)

Form: DATE OF VISIT

Form Status: Not Started

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

Subject Initials: ---

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

Date of Visit

1.	Date of Visit	//
2.	Erroneous Visit	

Header Text: c4591001

Visit: V104_MONTH6

Form Version: 22-Apr-2020 21:04

Site No: 4444

Subject No: 44441385

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): 29-Mar-2021 17:38

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: 44441385

Generated By: (b) (4)

Form: DATE OF VISIT

Form Status: Not Started

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

Subject Initials: ---

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

Date of Visit

1.	Date of Visit	//
2.	Erroneous Visit	

Header Text: c4591001

Visit: V105_MONTH18

Form Version: 22-Apr-2020 21:04

Site No: 4444

Subject No: 44441385

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): 29-Mar-2021 17:38

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: 44441385

Subject Initials: ---

Generated By: (b) (4)

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

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: 44441385

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): 29-Mar-2021 17:38

[eCRF Audit Trail History](#)

Subject Status

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

Header Text: c4591001

Visit: Investigator Signature - Unscheduled

Form: CASEBOOK SIGNATURE FORM

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Verified

Site No: 4444

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

Subject No: 44441385

Subject Initials: ---

Generated By: (b) (4)

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

[eCRF Audit Trail History](#)

Casebook Signature Form

1.	Casebook Signature	Click Here to Enable
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Header Text: c4591001

Visit: Investigator Signature - Unscheduled

Form: CASEBOOK SIGNATURE FORM

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Verified

Site No: 4444

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

Subject No: 44441385

Subject Initials: ---

Generated By: (b) (4)

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

[Audit Trail](#)

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

- CRF_Sign
- CRF_Sign_1

Name	Signature Meaning	Date	Type	Action
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Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 15-Sep-2020 21:53

Site No: 4444

Subject No: 44441385

Generated By: (b) (4)

Form: INCLUSION/EXCLUSION CRITERIA - Comments

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

[Back to Form](#)

Item	Date	User	Comment
Form	Sep-23-2020 08:13:11 (UTC-03:00) City of Buenos Aires	(b) (4), (b) (6) [Redacted] [Redacted]	Not Applicable

Header Text: c4591001

Visit: V101_VAX3

Form: INCLUSION/EXCLUSION CRITERIA - FURTHER VACCINATION - Comments

Form Version: 10-Dec-2020 02:30

Form Status: Data Complete, Frozen, Verified

Site No: 4444

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

Subject No: 44441385

Subject Initials: ---

Generated By: (b) (4)

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

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Item	Date	User	Comment
Form	Feb-03-2021 16:08:41 (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, Verified

Site No: 4444

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

Subject No: 44441385

Subject Initials: ---

Generated By: (b) (4)

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

[Back to Form](#)

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

- CRF_Sign
- CRF_Sign_1

Name	Signature Meaning	Date	Type	Action
(b) (6)	N/A	Feb-16-2021 22:22:26 (UTC-03:00) City of Buenos Aires		Edit - All signatures invalidated

Affidavit:

N/A

(b) (6)	Approved	Feb-16-2021 12:46:55 (UTC-03:00) City of Buenos Aires	BOOK	Signed
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Affidavit:

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

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

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

(b) (6)	N/A	Feb-14-2021 18:42:35 (UTC-03:00) City of Buenos Aires		Edit - All signatures invalidated
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Affidavit:

N/A

Gonzalo Perez Marc	Approved	Feb-06-2021 10:15:28 (UTC-03:00) City of Buenos Aires	BOOK	Signed
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090177e196ae2e6b\Final\Final On: 01-Apr-2021 03:12 (GMT)

Header Text: c4591001

Visit: Investigator Signature - Unscheduled

Form: CASEBOOK SIGNATURE FORM - Signature History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Verified

Site No: 4444

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

Subject No: 44441385

Subject Initials: ---

Generated By: (b) (4)

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

Affidavit:

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

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

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

(b) (6)	N/A	Jan-29-2021 14:21:46 (UTC-03:00) City of Buenos Aires		Edit - All signatures invalidated
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Affidavit:

N/A

(b) (6)	Approved	Nov-12-2020 09:43:17 (UTC-03:00) City of Buenos Aires	BOOK	Signed
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Affidavit:

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

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

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

(b) (6)	N/A	Nov-11-2020 12:21:06 (UTC-03:00) City of Buenos Aires		Edit - All signatures invalidated
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Affidavit:

N/A

(b) (6)	Approved	Nov-10-2020 11:54:26 (UTC-03:00) City of Buenos Aires	BOOK	Signed
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090177e196ae2e6b\Final\Final On: 01-Apr-2021 03:12 (GMT)

Header Text: c4591001

Visit: Investigator Signature - Unscheduled

Form: CASEBOOK SIGNATURE FORM - Signature History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Verified

Site No: 4444

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

Subject No: 44441385

Subject Initials: ---

Generated By: (b) (4)

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

Affidavit:

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

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

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

Header Text: c4591001

Visit: COHORT_SELECTION

Form Version: 15-Sep-2020 21:55

Site No: 4444

Subject No: 44441385

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): 29-Mar-2021 17:38

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1. Select appropriate response - Protocol version

Date	Location	User	Value	Reason
Sep-23-2020 08:09:37 (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-23-2020 08:09:37 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: STAGE 3 COHORTS	Initial Entry

090177e196ae2e6b\Final\Final On: 01-Apr-2021 03:12 (GMT)

Header Text: c4591001

Visit: COHORT_SELECTION

Form Version: 22-Apr-2020 21:02

Site No: 4444

Subject No: 44441385

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): 29-Mar-2021 17:38

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I. Consent Was:

Date	Location	User	Value	Reason
Sep-23-2020 08:11:40 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: OBTAINED Date Written Consent Obtained Sep/22/2020	Initial Entry

Header Text: c4591001

Visit: COHORT_SELECTION

Form Version: 15-Sep-2020 21:54

Site No: 4444

Subject No: 44441385

Generated By: (b) (4)

Form: DEMOGRAPHY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

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1. Subject ID

Date	Location	User	Value	Reason
Sep-22-2020 14:34:33 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 44441385	Item copied from previous form

2. Birth Date:

Date	Location	User	Value	Reason
Sep-22-2020 14:34:28 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: (b) (6)/1951	Enrollment Entry

3. Sex:

Date	Location	User	Value	Reason
Sep-23-2020 08:11:54 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: MALE	Initial Entry

4. Ethnicity:

Date	Location	User	Value	Reason
Sep-23-2020 08:11:54 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: HISPANIC OR LATINO(A) OR OF SPANISH ORIGIN	Initial Entry

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

Date	Location	User	Value	Reason
Sep-23-2020 08:11:54 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: WHITE	Initial Entry

090177e196ae2e6b\Final\Final On: 01-Apr-2021 03:12 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:02

Site No: 4444

Subject No: 44441385

Generated By: (b) (4)

Form: DATE OF VISIT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

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1. Date of Visit

Date	Location	User	Value	Reason
Sep-23-2020 08:12:36 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sep/22/2020	Initial Entry

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 15-Sep-2020 21:52

Site No: 4444

Subject No: 44441385

Generated By: (b) (4)

Form: DISPOSITION - SCREENING - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

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1. Date of Completion/Discontinuation/Death

Date	Location	User	Value	Reason
Sep-23-2020 08:13:51 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sep/22/2020	Initial Entry

2. Phase of Disposition:

Date	Location	User	Value	Reason
Sep-23-2020 08:13:51 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SCREENING	Initial Entry

3. Status:

Date	Location	User	Value	Reason
Sep-23-2020 08:13:51 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: COMPLETED	Initial Entry

090177e196ae2e6b\Final\Final On: 01-Apr-2021 03:12 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 4444

Subject No: 44441385

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

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1.a

Date	Location	User	Value	Reason
Sep-23-2020 08:16:28 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 1 Medical History Term: Resolved prostate cancer Start Date: Mar/1/2012 Ongoing: NO End Date: Dec/1/2012	Initial Entry

1.a Line/MH Number:

Date	Location	User	Value	Reason
Sep-23-2020 08:16:28 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 1	Initial Entry

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

Date	Location	User	Value	Reason
Sep-23-2020 08:16:28 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Resolved prostate cancer	Initial Entry

1.a Start Date:

Date	Location	User	Value	Reason
Sep-23-2020 08:16:28 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Mar/1/2012	Initial Entry

1.a Ongoing:

090177e196ae2e6b\Final\Final On: 01-Apr-2021 03:12 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 4444

Subject No: 44441385

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

Date	Location	User	Value	Reason
Sep-23-2020 08:16:28 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO End Date: Dec/1/2012	Initial Entry

1.b

Date	Location	User	Value	Reason
Sep-23-2020 08:17:33 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Num 2 ber: Medical Histor Hypercholeste y Term: rolemia Start Date: Sep/22/2019 Ongoing: YES	Initial Entry

090177e196ae2e6b\Final\Final On: 01-Apr-2021 03:12 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 4444

Subject No: 44441385

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

I.b Line/MH Number:

Date	Location	User	Value	Reason
Sep-23-2020 08:17:33 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 2	Initial Entry

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

Date	Location	User	Value	Reason
Sep-23-2020 08:17:33 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Hypercholesterolemia	Initial Entry

I.b Start Date:

Date	Location	User	Value	Reason
Sep-23-2020 08:17:33 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sep/22/2019	Initial Entry

I.b Ongoing:

Date	Location	User	Value	Reason
Sep-23-2020 08:17:33 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

I.c

Date	Location	User	Value	Reason
Sep-23-2020 08:18:23 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 3 Medical History Term: Horton migraine Start Date: Feb/1/1980 Ongoing: YES	Initial Entry

090177e196ae2e6b\Final\Final On: 01-Apr-2021 03:12 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 4444

Subject No: 44441385

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

I.c Line/MH Number:

Date	Location	User	Value	Reason
Sep-23-2020 08:18:23 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 3	Initial Entry

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

Date	Location	User	Value	Reason
Sep-23-2020 08:18:23 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Horton migraine	Initial Entry

I.c Start Date:

Date	Location	User	Value	Reason
Sep-23-2020 08:18:23 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Feb/1/1980	Initial Entry

I.c Ongoing:

Date	Location	User	Value	Reason
Sep-23-2020 08:18:23 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

090177e196ae2e6b\Final\Final On: 01-Apr-2021 03:12 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 15-Sep-2020 21:57

Site No: 4444

Subject No: 44441385

Generated By: (b) (4)

Form: HIV STATUS - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

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

Date	Location	User	Value	Reason
Sep-23-2020 08:18:37 (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: 44441385

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): 29-Mar-2021 17:38

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1. Date:

Date	Location	User	Value	Reason
Sep-23-2020 08:19:10 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Sep/22/2020	Initial Entry

2. Weight:

Date	Location	User	Value	Reason
Sep-23-2020 08:19:10 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> 81.0	Initial Entry

3. Unit:

Date	Location	User	Value	Reason
Sep-23-2020 08:19:10 (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-23-2020 08:19:10 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> 170.0	Initial Entry

5. Unit:

Date	Location	User	Value	Reason
Sep-23-2020 08:19:10 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> cm	Initial Entry

6. Body Mass Index:

090177e196ae2e6b\Final\Final On: 01-Apr-2021 03:12 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 15-Sep-2020 21:56

Site No: 4444

Subject No: 44441385

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): 29-Mar-2021 17:38

Date	Location	User	Value	Reason
Sep-23-2020 08:19:10 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 28.0	Initial Entry

7.a

Date	Location	User	Value	Reason
Sep-23-2020 08:19:10 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Record Identifier 1 :: Temperature: 36.8 Temperature Unit: Temperature Location: ORAL CAVITY	Initial Entry

7.a Record Identifier:

Date	Location	User	Value	Reason
Sep-23-2020 08:19:10 (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-23-2020 08:19:10 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 36.8	Initial Entry

7.a Unit:

Date	Location	User	Value	Reason
Sep-23-2020 08:19:10 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: C	Initial Entry

7.a Temperature Location:

090177e196ae2e6b\Final\Final On: 01-Apr-2021 03:12 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 15-Sep-2020 21:56

Site No: 4444

Subject No: 44441385

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): 29-Mar-2021 17:38

Date	Location	User	Value	Reason
Sep-23-2020 08:19:10 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: ORAL CAVITY	Initial Entry

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 4444

Subject No: 44441385

Generated By: (b) (4)

Form: RANDOMIZATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

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1. Randomization Date :

Date	Location	User	Value	Reason
Sep-23-2020 08:19:29 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sep/22/2020	Initial Entry

2. Randomization Number:

Date	Location	User	Value	Reason
Sep-23-2020 08:19:29 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 263528	Initial Entry

090177e196ae2e6b\Final\Final On: 01-Apr-2021 03:12 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 4444

Subject No: 44441385

Generated By: (b) (4)

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

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

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1. Data Origin

Date	Location	User	Value	Reason
Sep-23-2020 08:19:38 (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-23-2020 08:19:38 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SERUM	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Sep-23-2020 14:17:27 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Sep-23-2020 08:19:38 (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-23-2020 08:19:38 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Date of Collection: Sep/22/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
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090177e196ae2e6b\Final\Final On: 01-Apr-2021 03:12 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 4444

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

Subject No: 44441385

Subject Initials: ---

Generated By: (b) (4)

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

Sep-23-2020 14:17:27 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BRVM6H	Initial Entry
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5.a Sample ID

Date	Location	User	Value	Reason
Sep-23-2020 14:17:27 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BRVM6H	Initial Entry

5.b

Date	Location	User	Value	Reason
Sep-23-2020 14:43:35 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	Alan Colombo (b) (4)	Data Entry: Sample ID: BRVM65	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Sep-23-2020 14:43:35 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	Alan Colombo (b) (4)	Data Entry: BRVM65	Initial Entry

5.c

Date	Location	User	Value	Reason
Sep-23-2020 17:28:47 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BHXGY8	Initial Entry

5.c Sample ID

Date	Location	User	Value	Reason
Sep-23-2020 17:28:47 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BHXGY8	Initial Entry

090177e196ae2e6b\Final\Final On: 01-Apr-2021 03:12 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 4444

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

Subject No: 44441385

Subject Initials: ---

Generated By: (b) (4)

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

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1. Data Origin

Date	Location	User	Value	Reason
Sep-23-2020 08:19:51 (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-23-2020 08:19:51 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: NASAL_SWAB	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Sep-23-2020 08:36:26 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Sep-23-2020 08:19:51 (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-23-2020 08:19:51 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Date of Collection: Sep/22/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
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090177e196ae2e6b\Final\Final On: 01-Apr-2021 03:12 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 4444

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

Subject No: 44441385

Subject Initials: ---

Generated By: (b) (4)

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

Sep-23-2020 08:36:26 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BPWBT6	Initial Entry
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5.a Sample ID

Date	Location	User	Value	Reason
Sep-23-2020 08:36:26 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BPWBT6	Initial Entry

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:04

Site No: 4444

Subject No: 44441385

Generated By: (b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

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1. Was there a temporary delay of vaccination?

Date	Location	User	Value	Reason
Sep-23-2020 08:20:35 (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-23-2020 08:20:16 (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-23-2020 08:20:16 (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-23-2020 08:20:16 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sep/22/2020 13:47	Initial Entry

5. Anatomical Location:

Date	Location	User	Value	Reason
Sep-23-2020 08:20:16 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: DELTOID MUSCLE	Initial Entry

6. Body Side:

090177e196ae2e6b\Final\Final On: 01-Apr-2021 03:12 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:04

Site No: 4444

Subject No: 44441385

Generated By: (b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

Date	Location	User	Value	Reason
Sep-23-2020 08:20:16 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: LEFT	Initial Entry

7. Route:

Date	Location	User	Value	Reason
Sep-23-2020 08:20:16 (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-23-2020 08:20:16 (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-23-2020 08:20:16 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

090177e196ae2e6b\Final\Final On: 01-Apr-2021 03:12 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 06-Jul-2020 21:53

Site No: 4444

Subject No: 44441385

Generated By: (b) (4)

Form: REACTOGENICITY DIARY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

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1. Select appropriate response - Reactogenicity diary collection

Date	Location	User	Value	Reason
Sep-23-2020 08:20:26 (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: 44441385

Generated By: (b) (4)

Form: DATE OF VISIT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

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1. Date of Visit

Date	Location	User	Value	Reason
Oct-13-2020 16:41:56 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Oct/13/2020	Initial Entry

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 10-Oct-2020 16:01

Site No: 4444

Subject No: 44441385

Generated By: (b) (4)

Form: VITAL SIGNS - TEMP - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

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1. Date:

Date	Location	User	Value	Reason
Oct-13-2020 16:42:24 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Oct/13/2020	Initial Entry

2.a

Date	Location	User	Value	Reason
Oct-13-2020 16:42:24 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Record Identifier: 1 Temperature: 36.7 Temperature Unit: Temperature Location: ORAL CAVITY	Initial Entry

2.a Record Identifier:

Date	Location	User	Value	Reason
Oct-13-2020 16:42:24 (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-13-2020 16:42:24 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 36.7	Initial Entry

2.a Unit:

090177e196ae2e6b\Final\Final On: 01-Apr-2021 03:12 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 10-Oct-2020 16:01

Site No: 4444

Subject No: 44441385

Generated By: (b) (4)

Form: VITAL SIGNS - TEMP - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

Date	Location	User	Value	Reason
Oct-13-2020 16:42:24 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: C	Initial Entry

2.a Temperature Location:

Date	Location	User	Value	Reason
Oct-13-2020 16:42:24 (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:** 44441385**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 17:38[Back to Form](#)**1. Data Origin**

Date	Location	User	Value	Reason
Oct-13-2020 13:34:29 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Oct-13-2020 13:34:29 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: NASAL_SWAB	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Oct-13-2020 13:34:44 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Oct-13-2020 13:34:29 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Oct-13-2020 13:34:29 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Date of Collection: Oct/13/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
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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: 44441385

Subject Initials: ---

Generated By: (b) (4)

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

Oct-13-2020 13:34:44 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BP1V6L	Initial Entry
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5.a Sample ID

Date	Location	User	Value	Reason
Oct-13-2020 13:34:44 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BP1V6L	Initial Entry

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:04

Site No: 4444

Subject No: 44441385

Generated By: (b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

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1. Was there a temporary delay of vaccination?

Date	Location	User	Value	Reason
Oct-13-2020 16:45:35 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2. Treatment Name

Date	Location	User	Value	Reason
Oct-13-2020 16:45:35 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: BLINDED THERAPY	Initial Entry

3. Formulation:

Date	Location	User	Value	Reason
Oct-13-2020 16:45:35 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: INJECTION	Initial Entry

4. Dose Date Time:

Date	Location	User	Value	Reason
Oct-13-2020 16:45:35 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Oct/13/2020 11:48	Initial Entry

5. Anatomical Location:

Date	Location	User	Value	Reason
Oct-13-2020 16:45:35 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: DELTOID MUSCLE	Initial Entry

090177e196ae2e6b\Final\Final On: 01-Apr-2021 03:12 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:04

Site No: 4444

Subject No: 44441385

Generated By: (b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

6. Body Side:

Date	Location	User	Value	Reason
Oct-13-2020 16:45:35 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: LEFT	Initial Entry

7. Route:

Date	Location	User	Value	Reason
Oct-13-2020 16:45:35 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: INTRAMUSCULAR	Initial Entry

10. Timeframe Subject Was Observed

Date	Location	User	Value	Reason
Oct-13-2020 16:45:35 (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-13-2020 16:45:35 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

090177e196ae2e6b\Final\Final On: 01-Apr-2021 03:12 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form Version: 22-Apr-2020 21:02

Site No: 4444

Subject No: 44441385

Generated By: (b) (4)

Form: DATE OF VISIT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

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1. Date of Visit

Date	Location	User	Value	Reason
Nov-11-2020 12:21:06 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Nov/11/2020	Initial Entry

Header Text: c4591001**Visit:** V3_MONTH1_POSTVAX2_L**Form Version:** 22-Apr-2020 21:03**Site No:** 4444**Subject No:** 44441385**Generated By:** (b) (4)**Form:** ELECTRONIC SAMPLE TRACKING -
IMMUNOGENICITY - eCRF Audit Trail History**Form Status:** Data Complete, Locked, Frozen, Verified**Site Name:** (4444) Hospital Militar Central Cirujano Mayor Dr
Cosme Argerich**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 17:38[Back to Form](#)**1. Data Origin**

Date	Location	User	Value	Reason
Nov-11-2020 12:21:22 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Nov-11-2020 12:21:22 (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-11-2020 16:25:33 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Nov-11-2020 12:21:22 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Nov-11-2020 12:21:22 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Date of Collection: Nov/11/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
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Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 4444

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

Subject No: 44441385

Subject Initials: ---

Generated By: (b) (4)

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Nov-11-2020 16:25:33 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BPTCBS	Initial Entry
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5.a Sample ID

Date	Location	User	Value	Reason
Nov-11-2020 16:25:33 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BPTCBS	Initial Entry

5.b

Date	Location	User	Value	Reason
Nov-11-2020 16:43:09 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	Alan Colombo (b) (4)	Data Entry: Sample ID: BJ5NTL	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Nov-11-2020 16:43:09 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	Alan Colombo (b) (4)	Data Entry: BJ5NTL	Initial Entry

5.c

Date	Location	User	Value	Reason
Nov-11-2020 16:43:15 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BJ5NTD	Initial Entry

5.c Sample ID

Date	Location	User	Value	Reason
Nov-11-2020 16:43:15 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BJ5NTD	Initial Entry

090177e196ae2e6b\Final\Final On: 01-Apr-2021 03:12 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 4444

Subject No: 44441385

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - Audit Trail

Form Status:

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Date	Location	User	Value	Reason
Feb-14-2021 18:42:35 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Created	

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 4444

Subject No: 44441385

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - Audit Trail

Form Status:

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

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Date	Location	User	Value	Reason
Feb-14-2021 18:45:24 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Created	

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 4444

Subject No: 44441385

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - Audit Trail

Form Status:

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

Subject Initials: ---

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Date	Location	User	Value	Reason
Feb-23-2021 16:23:47 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6) [Redacted] [Redacted]	Form Created	

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 4444

Subject No: 44441385

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete

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

Subject Initials: ---

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1. Category:

Date	Location	User	Value	Reason
Feb-14-2021 18:42:35 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: ADVERSE EVENT	Initial Entry

2. AE ID:

Date	Location	User	Value	Reason
Feb-14-2021 18:42:35 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 1	Initial Entry

3. Adverse Event:

(If possible specify diagnosis, not individual symptoms)

Date	Location	User	Value	Reason
Mar-02-2021 16:36:08 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Closed	Response satisfies query
Mar-02-2021 07:55:02 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	term matched in both database
Feb-26-2021 12:47:41 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	In the SAE follow-up form on 18FEB2021 the term was updated. In it it says "The term SAE was updated to Worsening ischemic cardiomyopathy (vignette 10 was updated)".
Feb-26-2021 05:35:35	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reissued:Opened	SAE RECON: The term was updated to

090177e196ae2e6b\Final\Final On: 01-Apr-2021 03:12 (GMT)

Header Text: c4591001**Visit:** Logs - Unscheduled**Form Version:** 22-Apr-2020 21:02**Site No:** 4444**Subject No:** 44441385**Generated By:** (b) (4)**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History**Form Status:** Data Complete**Site Name:** (4444) Hospital Militar Central Cirujano Mayor Dr Cosme Argerich**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 17:38

(UTC-03:00) City of Buenos Aires		(b) (4), (b) (6)		'ischemic cardiopathy worsening' in Safety database however recorded as 'Ischemic MYOCARDIOPATHY worsening'in AE CRF. Please confirm correct term. If safety update is required, please submit a follow-up form.
Feb-23-2021 12:08:21 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Answered	This information was previously reported
Feb-23-2021 12:07:23 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	FU sent with SAE update term on 18FEB2021.
Feb-22-2021 15:26:52 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Opened	Clinical Please report surgery: AVR surgery & myocardial revascularization surgery; Lt Int mammary Art (LIMA)-Diag branch (Ant descending Art) bypass & venous bypass to Rt coronary Art. Lt vent systolic function intraop with mild deterioration
Feb-22-2021 15:23:08 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	CLINICAL Event term is 'ischemic cardiopathy worsening'; however, SAE term in 'myocardial ischemia'. Please review SAE event term, harmonize

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				reporting, and update where appropriate
Feb-19-2021 11:36:40 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Ischemic myocardial pathology worsening	New Information
Feb-14-2021 18:42:35 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Ischemic cardiopathy	Initial Entry

4. Start Date Time:

Date	Location	User	Value	Reason
Mar-02-2021 16:25:04 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Feb-23-2021 12:10:05 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Yes, on 05Feb2021 present symptoms.
Feb-22-2021 15:19:56 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reissued:Opened	Clinical Thank you for updated term; does the start date of 05Feb21 remain in view of 16Jan21 SPECT with 5% of LV ischemic.
Feb-19-2021 11:38:53 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	SAE form FU was sent. SAE term is updated.
Feb-17-2021 18:20:08 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	Clinical Event of ischemic cardiomyopathy start date is 05Feb21; however, SAE reports SPECT myocardial scan on 16Jan21 revealed 5% of LV

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Subject No: 44441385

Generated By: (b) (4)

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Form Status: Data Complete

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

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				was ischemic. Please review start date, and update if appropriate
Feb-14-2021 18:42:35 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Feb/5/2021 12:00	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Mar-11-2021 16:46:04 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO End Date Time: Mar/9/2021 19:00	New Information
Feb-14-2021 18:42:35 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

6. Toxicity Grade:

Date	Location	User	Value	Reason
Feb-14-2021 18:42:35 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 3	Initial Entry

7. Is the adverse event serious?

If Yes, NOTIFY PFIZER IMMEDIATELY.

Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).

Date	Location	User	Value	Reason
Mar-02-2021 16:34:22 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Closed	Response satisfies query

090177e196ae2e6b\Final\Final On: 01-Apr-2021 03:12 (GMT)

Header Text: c4591001**Visit:** Logs - Unscheduled**Form Version:** 22-Apr-2020 21:02**Site No:** 4444**Subject No:** 44441385**Generated By:** (b) (4)**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History**Form Status:** Data Complete**Site Name:** (4444) Hospital Militar Central Cirujano Mayor Dr Cosme Argerich**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 17:38

Feb-23-2021 12:11:50 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Answered	Both covid tests were previously reported in the SAE form.
Feb-22-2021 15:28:45 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Opened	Clinical Please report negative COVID test reports on 05 and 07 Feb 2021 to this SAE (#2021161548) as well (from #202161580)
Feb-16-2021 22:22:26 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Feb-14-2021 18:42:35 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	For AE Ischemic cardiopathy: Response to "Is the adverse event serious?" is 'Yes' but "Serious Adverse Event Number" is blank.
Feb-14-2021 18:42:35 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Is this serious event associated with congenital anomaly or birth defect? NO Did this serious event result in death? NO Did this serious event require or prolong hospitalization?	Initial Entry

Header Text: c4591001

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Subject No: 44441385

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete

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

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			<p>YES</p> <p>Did this serious event result in persistent or significant disability/incapacity?</p> <p>NO</p> <p>Is this serious event life threatening?</p> <p>NO</p> <p>Other medically important serious event</p> <p>YES</p>	
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8. Is this adverse event the result of a study Medication Error?

If Yes, record the type of medication error on the Medication Error Log.

Date	Location	User	Value	Reason
Feb-14-2021 18:42:35 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

9. Is this event related to study treatment:

Date	Location	User	Value	Reason
Feb-14-2021 18:42:35 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NOT RELATED If Not Related to study treatment(s), this event is due to: OTHER <i>If Other, specify:</i> unknown	Initial Entry

10. Latest Action Taken with Study Treatment:

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Form Status: Data Complete

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

Subject Initials: ---

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Date	Location	User	Value	Reason
Feb-14-2021 18:42:35 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NOT APPLICABLE	Initial Entry

11. Was a Concomitant Medication given?

Date	Location	User	Value	Reason
Feb-14-2021 18:42:35 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Feb-14-2021 18:42:35 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

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

Date	Location	User	Value	Reason
Mar-11-2021 16:45:46 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: RECOVERED/RESOLVED	New Information
Feb-19-2021 11:36:50 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: RECOVERING/RESOLVING	New Information
Feb-14-2021 18:42:35 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NOT RECOVERED/NOT RESOLVED	Initial Entry

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

Date	Location	User	Value	Reason
Feb-14-2021 18:42:35 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

090177e196ae2e6b\Final\Final On: 01-Apr-2021 03:12 (GMT)

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Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete

Site Name: (4444) Hospital Militar Central Cirujano Mayor Dr
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15. Serious Adverse Event Number: For Pfizer Use Only

Date	Location	User	Value	Reason
Feb-16-2021 22:22:26 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 2021161548	Initial Entry

Header Text: c4591001

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Site No: 4444

Subject No: 44441385

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Answered Queries

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

Subject Initials: ---

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1. Category:

Date	Location	User	Value	Reason
Feb-14-2021 18:45:24 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: ADVERSE EVENT	Initial Entry

2. AE ID:

Date	Location	User	Value	Reason
Feb-14-2021 18:45:24 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 2	Initial Entry

3. Adverse Event:

(If possible specify diagnosis, not individual symptoms)

Date	Location	User	Value	Reason
Mar-02-2021 16:24:27 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Closed	Response satisfies query
Feb-24-2021 12:06:22 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Answered	AE log CRF was updated. Thank you.
Feb-22-2021 14:52:06 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Opened	Clinical On review of the SAE report for Aortic Stenosis, an event of Aortic aneurysm was reported [doppler Echo 08Feb21], yet it does not appear in the CRF. Please review for safety and update AE log CRF

090177e196ae2e6b\Final\Final On: 01-Apr-2021 03:12 (GMT)

Header Text: c4591001**Visit:** Logs - Unscheduled**Form Version:** 22-Apr-2020 21:02**Site No:** 4444**Subject No:** 44441385**Generated By:** (b) (4)**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History**Form Status:** Data Complete, Answered Queries**Site Name:** (4444) Hospital Militar Central Cirujano Mayor Dr Cosme Argerich**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 17:38

				accordingly (in AE reporting period)
Feb-22-2021 14:51:11 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	rewording
Feb-22-2021 14:47:08 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	Clinical On review of the SAE report for Aortic Stenosis, an event of Aortic aneurysm was reported, yet it does not appear in the CRF. Please review for safety and update AE log CRF accordingly (in AE reporting period)
Feb-14-2021 18:45:24 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Severe Aortic Stenosis	Initial Entry

4. Start Date Time:

Date	Location	User	Value	Reason
Feb-17-2021 18:05:47 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	error
Feb-17-2021 18:04:26 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	Clinical SAE of AS has start date of 05Feb2021; however, SAE lab section states ECHO on 27Jan21 reported severe AS. Please review start date of event,

Header Text: c4591001**Visit:** Logs - Unscheduled**Form Version:** 22-Apr-2020 21:02**Site No:** 4444**Subject No:** 44441385**Generated By:** (b) (4)**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History**Form Status:** Data Complete, Answered Queries**Site Name:** (4444) Hospital Militar Central Cirujano Mayor Dr Cosme Argerich**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 17:38

				and update if applicable in both AE/SAE report
Feb-14-2021 18:45:24 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Jan/27/2021 12:00	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Mar-11-2021 17:04:20 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Mar-11-2021 17:04:20 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO End Date Time: Mar/9/2021 19:00	Transcription Error
Mar-11-2021 16:46:50 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	For Severe Aortic Stenosis End Date 19/Mar/2021, is a future date relative to when it was entered on 11/Mar/2021. Please correct.
Mar-11-2021 16:46:50 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO End Date Time: Mar/19/2021 19:00	New Information
Feb-14-2021 18:45:24 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

6. Toxicity Grade:

Date	Location	User	Value	Reason
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Header Text: c4591001**Visit:** Logs - Unscheduled**Form Version:** 22-Apr-2020 21:02**Site No:** 4444**Subject No:** 44441385**Generated By:** (b) (4)**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History**Form Status:** Data Complete, Answered Queries**Site Name:** (4444) Hospital Militar Central Cirujano Mayor Dr Cosme Argerich**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 17:38

Feb-14-2021 18:45:24 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 3	Initial Entry
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7. Is the adverse event serious?**If Yes, NOTIFY PFIZER IMMEDIATELY.**

Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).

Date	Location	User	Value	Reason
Feb-16-2021 22:22:41 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Feb-14-2021 18:45:24 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	For AE Severe Aortic Stenosis: Response to "Is the adverse event serious?" is 'Yes' but "Serious Adverse Event Number" is blank.
Feb-14-2021 18:45:24 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Is this serious event associated with congenital anomaly or birth defect? NO Did this serious event result in death? NO Did this serious event require or prolong hospitalization? YES	Initial Entry

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 4444

Subject No: 44441385

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Answered Queries

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

Subject Initials: ---

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

			<p>Did this serious event result in persistent or significant disability/incapacity?</p> <p>NO</p> <p>Is this serious event life threatening?</p> <p>NO</p> <p>Other medically important serious event</p> <p>YES</p>	
--	--	--	---	--

8. Is this adverse event the result of a study Medication Error?

If Yes, record the type of medication error on the Medication Error Log.

Date	Location	User	Value	Reason
Feb-14-2021 18:45:24 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

9. Is this event related to study treatment:

Date	Location	User	Value	Reason
Feb-14-2021 18:45:24 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NOT RELATED If Not Related to study treatment(s), this event is due to: OTHER If Other, specify: unknown	Initial Entry

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
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090177e196ae2e6b\Final\Final On: 01-Apr-2021 03:12 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 4444

Subject No: 44441385

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Answered Queries

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

Subject Initials: ---

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

Feb-14-2021 18:45:24 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NOT APPLICABLE	Initial Entry
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11. Was a Concomitant Medication given?

Date	Location	User	Value	Reason
Feb-14-2021 18:45:24 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Feb-14-2021 18:45:24 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

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

Date	Location	User	Value	Reason
Mar-13-2021 12:04:32 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Answered	FU was sent on 3/11 where the status was updated to recovered. Thanks.
Mar-12-2021 11:48:37 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Opened	SAE RECON:AER#2021161580 outcome was updated to RECOVERED/RESOLVED on AE CRF while reported as Recovering/resolving in Safety database. Please confirm correct outcome. If safety update is required, please submit a follow-up form.
Mar-11-2021 16:46:31 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: RECOVERED/RESOLVED	New Information

090177e196ae2e6b\Final\Final On: 01-Apr-2021 03:12 (GMT)

Header Text: c4591001**Visit:** Logs - Unscheduled**Form Version:** 22-Apr-2020 21:02**Site No:** 4444**Subject No:** 44441385**Generated By:** (b) (4)**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History**Form Status:** Data Complete, Answered Queries**Site Name:** (4444) Hospital Militar Central Cirujano Mayor Dr Cosme Argerich**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 17:38

Feb-24-2021 16:42:23 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Feb-24-2021 12:07:44 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	New Information
Feb-24-2021 12:07:44 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: RECOVERING/RE SOLVING	New Information
Feb-24-2021 00:01:33 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	SAE RECON:AER#021161580,outcome was reported as Recovering/Resolving to Safety DB however, recorded as NOT RECOVERED/NOT RESOLVED on AE CRF. Please confirm correct outcome. If safety update is required, please submit a follow-up form.
Feb-14-2021 18:45:24 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NOT RECOVERE D/NOT RESOLVE D	Initial Entry

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

Date	Location	User	Value	Reason
Feb-14-2021 18:45:24 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

15. Serious Adverse Event Number: For Pfizer Use Only

Date	Location	User	Value	Reason
Feb-16-2021 22:22:41 (UTC-03:00) City of	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 2021161580	Initial Entry

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 4444

Subject No: 44441385

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Answered Queries

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

Subject Initials: ---

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

Buenos Aires

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

090177e196ae2e6b\Final\Final On: 01-Apr-2021 03:12 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 4444

Subject No: 44441385

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Frozen

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

Subject Initials: ---

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

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1. Category:

Date	Location	User	Value	Reason
Feb-23-2021 16:23:47 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: ADVERSE EVENT	Initial Entry

2. AE ID:

Date	Location	User	Value	Reason
Feb-23-2021 16:23:47 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 3	Initial Entry

3. Adverse Event:

(If possible specify diagnosis, not individual symptoms)

Date	Location	User	Value	Reason
Feb-26-2021 10:23:48 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Feb-24-2021 10:12:37 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	The aneurysm was diagnosed in an Echodoppler performed on 08feb2021. At the moment, no intervention has been performed for this pathology, only monitoring.
Feb-24-2021 08:24:01 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	Clinquery: Was the Abdominal Aortic Aneurysm found on ultrasound/ CT/MRI? No surgery/treatment

090177e196ae2e6b\Final\Final On: 01-Apr-2021 03:12 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 4444

Subject No: 44441385

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Frozen

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

Subject Initials: ---

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

				needed, just monitoring? Thank you.
Feb-23-2021 16:23:47 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Abdominal Aortic Aneurysm	Initial Entry

4. Start Date Time:

Date	Location	User	Value	Reason
Feb-23-2021 16:23:47 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Feb/8/2021 10:50	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Feb-27-2021 10:21:21 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO End Date Time: Feb/26/2021 16:30	New Information
Feb-23-2021 16:23:47 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

6. Toxicity Grade:

Date	Location	User	Value	Reason
Feb-23-2021 16:23:47 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 1	Initial Entry

7. Is the adverse event serious?

If Yes, NOTIFY PFIZER IMMEDIATELY.

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Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 4444

Subject No: 44441385

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Frozen

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

Subject Initials: ---

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

Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).

Date	Location	User	Value	Reason
Feb-23-2021 16:23:47 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NO	Initial Entry

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

Date	Location	User	Value	Reason
Feb-23-2021 16:23:47 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NO	Initial Entry

9. Is this event related to study treatment:

Date	Location	User	Value	Reason
Feb-23-2021 16:23:47 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NOT RELATED If Not Related to study treatment(s), this event is due to: OTHER <i>If Other, specify:</i> unknown	Initial Entry

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Feb-23-2021 16:23:47 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NOT APPLICABLE	Initial Entry

090177e196ae2e6b\Final\Final On: 01-Apr-2021 03:12 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 4444

Subject No: 44441385

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Frozen

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

Subject Initials: ---

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

11. Was a Concomitant Medication given?

Date	Location	User	Value	Reason
Feb-26-2021 20:39:30 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	New Information
Feb-23-2021 16:23:47 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Feb-23-2021 16:23:47 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

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

Date	Location	User	Value	Reason
Feb-27-2021 10:21:39 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Feb-27-2021 10:21:39 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: RECOVERED/RESOLVED	New Information
Feb-27-2021 10:21:21 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	For AE Abdominal Aortic Aneurysm: Response to "What was the outcome of this adverse event?" is 'Not Recovered/Not Resolved' but AE End Date/Time is present.

090177e196ae2e6b\Final\Final On: 01-Apr-2021 03:12 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 4444

Subject No: 44441385

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Frozen

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

Subject Initials: ---

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

Feb-23-2021 16:23:47 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NOT RECOVERED/NOT RE SOLVED	Initial Entry
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14. Did the adverse event cause the subject to be discontinued from the study?

Date	Location	User	Value	Reason
Feb-23-2021 16:23:47 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

Header Text: c4591001

Visit: End of Treatment - Unscheduled

Form: DISPOSITION - TREATMENT - eCRF Audit Trail History

Form Version: 15-Sep-2020 21:55

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 4444

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

Subject No: 44441385

Subject Initials: ---

Generated By: (b) (4)

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

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1. Date of Completion/Discontinuation/Death :

Date	Location	User	Value	Reason
Nov-11-2020 12:21:40 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Nov/11/2020	Initial Entry

2. Phase of Disposition:

Date	Location	User	Value	Reason
Nov-11-2020 12:21:40 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: VACCINATION	Initial Entry

3. Status:

Date	Location	User	Value	Reason
Nov-11-2020 12:21:40 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: COMPLETED	Initial Entry

090177e196ae2e6b\Final\Final On: 01-Apr-2021 03:12 (GMT)

Header Text: c4591001

Visit: Potential ReVax Initial Contact -
Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 4444

Subject No: 44441385

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): 29-Mar-2021 17:38

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I. Date of Visit

Date	Location	User	Value	Reason
Jan-29-2021 14:21:46 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6) [Redacted] [Redacted]	Data Entry: Jan/29/2021	Initial Entry

Header Text: c4591001**Visit:** Potential ReVax Initial Contact -
Unscheduled**Form Version:** 10-Dec-2020 02:25**Site No:** 4444**Subject No:** 44441385**Generated By:** (b) (4)**Form:** FURTHER VACCINATION CONFIRMATION - eCRF Audit
Trail History**Form Status:** Data Complete, Frozen, Verified**Site Name:** (4444) Hospital Militar Central Cirujano Mayor Dr
Cosme Argerich**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 17:38[Back to Form](#)***1. Select appropriate response - Is participant willing to return for Vaccination 3?***

Date	Location	User	Value	Reason
Jan-29-2021 14:22:03 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Jan-29-2021 14:21:54 (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-29-2021 14:21:54 (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

Header Text: c4591001

Visit: Disposition - Unscheduled

Form: TREATMENT UNBLINDED - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 4444

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

Subject No: 44441385

Subject Initials: ---

Generated By: (b) (4)

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

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1. Date Treatment Unblinded :

Date	Location	User	Value	Reason
Jan-29-2021 14:22:03 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Jan/29/2021	Initial Entry

2. Primary Reason for Unblinding:

Date	Location	User	Value	Reason
Jan-29-2021 14:22:03 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: ASSESS ELIGIBILITY FOR ADDITIONAL VACCINATIO N	Initial Entry

090177e196ae2e6b\Final\Final On: 01-Apr-2021 03:12 (GMT)

Header Text: c4591001

Visit: V101_VAX3

Form Version: 22-Apr-2020 21:02

Site No: 4444

Subject No: 44441385

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): 29-Mar-2021 17:38

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1. Date of Visit

Date	Location	User	Value	Reason
Feb-03-2021 16:08:09 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Feb/3/2021	Initial Entry

Header Text: c4591001

Visit: V101_VAX3

Form Version: 10-Dec-2020 02:31

Site No: 4444

Subject No: 44441385

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): 29-Mar-2021 17:38

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I. Consent Was:

Date	Location	User	Value	Reason
Feb-03-2021 16:08:30 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: OBTAINED Date Written Consent Obtained Feb/3/2021	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: 44441385

Subject Initials: ---

Generated By: (b) (4)

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

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1. Date of Completion/Discontinuation/Death :

Date	Location	User	Value	Reason
Feb-03-2021 16:09:38 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Feb/3/2021	Initial Entry

2. Phase of Disposition:

Date	Location	User	Value	Reason
Feb-03-2021 16:09:38 (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
Feb-03-2021 16:09:38 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: COMPLETED	Initial Entry

090177e196ae2e6b\Final\Final On: 01-Apr-2021 03:12 (GMT)

Header Text: c4591001

Visit: V101_VAX3

Form Version: 22-Apr-2020 21:03

Site No: 4444

Subject No: 44441385

Generated By: (b) (4)

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

Form Status: Data Complete, Frozen, Verified

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

Subject Initials: ---

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

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1. Data Origin

Date	Location	User	Value	Reason
Feb-03-2021 16:09:48 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Feb-03-2021 16:09:48 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SERUM	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Feb-04-2021 15:40:59 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Feb-04-2021 06:32:20 (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-03-2021 16:09:48 (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.
Feb-03-2021 16:09:48	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Initial Entry

090177e196ae2e6b\Final\Final On: 01-Apr-2021 03:12 (GMT)

Header Text: c4591001

Visit: V101_VAX3

Form Version: 22-Apr-2020 21:03

Site No: 4444

Subject No: 44441385

Generated By: (b) (4)

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

Form Status: Data Complete, Frozen, Verified

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

Subject Initials: ---

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

(UTC-03:00) City of Buenos Aires		(b) (4), (b) (6)	YES Date of Collection: Feb/3/2021	
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5.a

Date	Location	User	Value	Reason
Feb-04-2021 15:40:59 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BPWC4C	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Feb-04-2021 15:40:59 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BPWC4C	Initial Entry

5.b

Date	Location	User	Value	Reason
Feb-04-2021 17:09:58 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	Agustin Morato Cabral (b) (4)	Data Entry: Sample ID: BS43C5	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Feb-04-2021 17:09:58 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	Agustin Morato Cabral (b) (4)	Data Entry: BS43C5	Initial Entry

5.c

Date	Location	User	Value	Reason
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090177e196ae2e6b\Final\Final On: 01-Apr-2021 03:12 (GMT)

Header Text: c4591001

Visit: V101_VAX3

Form Version: 22-Apr-2020 21:03

Site No: 4444

Subject No: 44441385

Generated By: (b) (4)

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

Form Status: Data Complete, Frozen, Verified

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

Subject Initials: ---

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

Feb-04-2021 18:14:28 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	Agustin Morato Cabral (b) (4)	Data Entry: Sample ID: BS43ML	Initial Entry
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5.c Sample ID

Date	Location	User	Value	Reason
Feb-04-2021 18:14:28 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	Agustin Morato Cabral (b) (4)	Data Entry: BS43ML	Initial Entry

090177e196ae2e6b\Final\Final On: 01-Apr-2021 03:12 (GMT)

Header Text: c4591001

Visit: V101_VAX3

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 4444

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

Subject No: 44441385

Subject Initials: ---

Generated By: (b) (4)

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

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1. Data Origin

Date	Location	User	Value	Reason
Feb-03-2021 16:09:56 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Feb-03-2021 16:09:56 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: NASAL_SWAB	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Feb-04-2021 09:33:09 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Feb-04-2021 06:32:20 (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-03-2021 16:09:56 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Feb-03-2021 16:09:56	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Initial Entry

090177e196ae2e6b\Final\Final On: 01-Apr-2021 03:12 (GMT)

Header Text: c4591001

Visit: V101_VAX3

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 4444

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

Subject No: 44441385

Subject Initials: ---

Generated By: (b) (4)

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

(UTC-03:00) City of Buenos Aires		(b) (4), (b) (6)	YES Date of Collection: Feb/3/2021	
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5.a

Date	Location	User	Value	Reason
Feb-04-2021 09:33:09 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BPWCMV	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Feb-04-2021 09:33:09 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BPWCMV	Initial Entry

090177e196ae2e6b\Final\Final On: 01-Apr-2021 03:12 (GMT)

Header Text: c4591001

Visit: V101_VAX3

Form Version: 10-Dec-2020 02:26

Site No: 4444

Subject No: 44441385

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): 29-Mar-2021 17:38

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1. Was there a temporary delay of vaccination?

Date	Location	User	Value	Reason
Feb-03-2021 16:10:13 (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-03-2021 16:10:13 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: BNT162b2	Initial Entry

3. Formulation:

Date	Location	User	Value	Reason
Feb-03-2021 16:10:13 (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-03-2021 16:10:13 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Feb/3/2021 15:14	Initial Entry

5. Anatomical Location:

Date	Location	User	Value	Reason
Feb-03-2021 16:10:13 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: DELTOID MUSCLE	Initial Entry

6. Body Side:

090177e196ae2e6b\Final\Final On: 01-Apr-2021 03:12 (GMT)

Header Text: c4591001

Visit: V101_VAX3

Form Version: 10-Dec-2020 02:26

Site No: 4444

Subject No: 44441385

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): 29-Mar-2021 17:38

Date	Location	User	Value	Reason
Feb-03-2021 16:10:13 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> LEFT	Initial Entry

7. Route:

Date	Location	User	Value	Reason
Feb-03-2021 16:10:13 (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
Feb-03-2021 16:10:13 (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
Feb-03-2021 16:10:13 (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
Feb-03-2021 16:10:13 (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
Feb-03-2021 16:10:13 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> YES	Initial Entry

090177e196ae2e6b\Final\Final On: 01-Apr-2021 03:12 (GMT)

Header Text: c4591001

Visit: V101_VAX3

Form Version: 10-Dec-2020 02:26

Site No: 4444

Subject No: 44441385

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): 29-Mar-2021 17:38

Buenos Aires

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

090177e196ae2e6b\Final\Final On: 01-Apr-2021 03:12 (GMT)

Header Text: c4591001

Visit: V102_VAX4

Form Version: 22-Apr-2020 21:02

Site No: 4444

Subject No: 44441385

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): 29-Mar-2021 17:38

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I. Date of Visit

Date	Location	User	Value	Reason
Mar-11-2021 03:29:07 (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.
Mar-10-2021 11:54:33 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	The visit took place outside the window for medical reasons of the participant (related to their adverse event)
Mar-10-2021 07:18:10 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000.InFormAdapter.Discrepancy	PFE SDQ PROD (b) (4)	Query 1: Opened	PDQ: Date of visit V102_VAX4 is out of window for 10 days from V101_VAX3 Dose Date. Please verify and update. Else, confirm in query response appropriately. (b) (4)
Mar-08-2021 13:18:33 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry : Mar/8 /2021	Initial Entry

090177e196ae2e6b\Final\Final On: 01-Apr-2021 03:12 (GMT)

Header Text: c4591001

Visit: V102_VAX4

Form Version: 22-Apr-2020 21:02

Site No: 4444

Subject No: 44441385

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): 29-Mar-2021 17:38

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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: 44441385

Subject Initials: ---

Generated By: (b) (4)

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

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1. Data Origin

Date	Location	User	Value	Reason
Mar-08-2021 13:18:46 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Mar-08-2021 13:18:46 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: NASAL_SWAB	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Mar-09-2021 11:53:20 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Mar-09-2021 07:38:17 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Mar-08-2021 13:18:46 (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.

090177e196ae2e6b\Final\Final On: 01-Apr-2021 03:12 (GMT)

Header Text: c4591001

Visit: V102_VAX4

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 4444

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

Subject No: 44441385

Subject Initials: ---

Generated By: (b) (4)

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

Mar-08-2021 13:18:46 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Date of Collection: Mar/8/2021	Initial Entry
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5.a

Date	Location	User	Value	Reason
Mar-09-2021 11:53:20 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BR233Y	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Mar-09-2021 11:53:20 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BR233Y	Initial Entry

090177e196ae2e6b\Final\Final On: 01-Apr-2021 03:12 (GMT)

Header Text: c4591001

Visit: V102_VAX4

Form Version: 10-Dec-2020 02:26

Site No: 4444

Subject No: 44441385

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): 29-Mar-2021 17:38

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1. Was there a temporary delay of vaccination?

Date	Location	User	Value	Reason
Mar-08-2021 13:19:39 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2. Treatment Name

Date	Location	User	Value	Reason
Mar-08-2021 13:19:39 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: BNT162b2	Initial Entry

3. Formulation:

Date	Location	User	Value	Reason
Mar-08-2021 13:19:39 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: INJECTION	Initial Entry

4. Dose Date Time:

Date	Location	User	Value	Reason
Mar-08-2021 13:19:39 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Mar/8/2021 10:30	Initial Entry

5. Anatomical Location:

Date	Location	User	Value	Reason
Mar-08-2021 13:19:39 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: DELTOID MUSCLE	Initial Entry

6. Body Side:

090177e196ae2e6b\Final\Final On: 01-Apr-2021 03:12 (GMT)

Header Text: c4591001

Visit: V102_VAX4

Form Version: 10-Dec-2020 02:26

Site No: 4444

Subject No: 44441385

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): 29-Mar-2021 17:38

Date	Location	User	Value	Reason
Mar-08-2021 13:19:39 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: LEFT	Initial Entry

7. Route:

Date	Location	User	Value	Reason
Mar-08-2021 13:19:39 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: INTRAMUSCULAR	Initial Entry

8. Actual Dose:

Date	Location	User	Value	Reason
Mar-08-2021 13:19:39 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 30.0	Initial Entry

9. Unit:

Date	Location	User	Value	Reason
Mar-08-2021 13:19:39 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: ug	Initial Entry

10. Timeframe Subject Was Observed

Date	Location	User	Value	Reason
Mar-08-2021 13:19:39 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 30 MINUTES	Initial Entry

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

Date	Location	User	Value	Reason
Mar-08-2021 13:19:39 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

090177e196ae2e6b\Final\Final On: 01-Apr-2021 03:12 (GMT)

Header Text: c4591001

Visit: V102_VAX4

Form Version: 10-Dec-2020 02:26

Site No: 4444

Subject No: 44441385

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): 29-Mar-2021 17:38

Buenos Aires

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

090177e196ae2e6b\Final\Final On: 01-Apr-2021 03:12 (GMT)

Header Text: c4591001

Visit: Subject Status - Unscheduled

Form: SUBJECT STATUS - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Verified

Site No: 4444

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

Subject No: 44441385

Subject Initials: ---

Generated By: (b) (4)

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

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I. Subject Status

Date	Location	User	Value	Reason
Mar-10-2021 09:39:19 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	V102 added
Mar-05-2021 05:31:38 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reissued:Candidate	DM Requery 1: As per response, please reschedule V102 and record the visit details in inform. Further, please answer to this query. Thank you.
Mar-04-2021 16:28:42 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	The visit will be scheduled shortly. Thanks
Mar-04-2021 03:53:35 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	DM: V102 overdue based on expected visit window. Please enter data or, if visit will never occur, mark Date of Visit as Not Done with form level comment
Nov-11-2020 12:21:40 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: FOLLOW-UP	Initial Entry
Sep-23-2020 08:19:29 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: ENROLLED/RANDOMIZE D	Initial Entry
Sep-23-2020 08:13:51	ACV0PFEINFP6000	auto calc	Data Entry:	Initial Entry

090177e196ae2e6b\Final\Final On: 01-Apr-2021 03:12 (GMT)

Header Text: c4591001

Visit: Subject Status - Unscheduled

Form: SUBJECT STATUS - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Verified

Site No: 4444

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

Subject No: 44441385

Subject Initials: ---

Generated By: (b) (4)

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

(UTC-03:00) City of Buenos Aires		(autocalc)	SCREENED	
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2. Subject Status Date

Date	Location	User	Value	Reason
Nov-11-2020 12:21:40 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Nov/11/2020	Initial Entry
Sep-23-2020 08:19:29 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sep/22/2020	Initial Entry
Sep-23-2020 08:13:51 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sep/22/2020	Initial Entry

090177e196ae2e6b\Final\Final On: 01-Apr-2021 03:12 (GMT)

Header Text: c4591001

Visit: Investigator Signature - Unscheduled

Form: CASEBOOK SIGNATURE FORM - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Verified

Site No: 4444

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

Subject No: 44441385

Subject Initials: ---

Generated By: (b) (4)

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

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I. Casebook Signature

Date	Location	User	Value	Reason
Nov-10-2020 11:54:17 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Click Here to Enable	Initial Entry