

**Header Text:** c4591001

**Visit:** COHORT\_SELECTION

**Form:** COHORT\_SELECTION

**Form Version:** 30-Jul-2020 21:29

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site No:** 1241

**Site Name:** (1241) Hospital Irma Dulce

**Subject No:** 12411468

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 19:09

[eCRF Audit Trail History](#)

**Cohort Selection**

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

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

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**Header Text:** c4591001

**Visit:** COHORT\_SELECTION

**Form:** MAIN INFORMED CONSENT

**Form Version:** 22-Apr-2020 21:02

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site No:** 1241

**Site Name:** (1241) Hospital Irma Dulce

**Subject No:** 12411468

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 19:09

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**Informed Consent**

1.	Consent Was:	OBTAINED Date Written Consent Obtained Aug/25/2020
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**Header Text:** c4591001

**Visit:** COHORT\_SELECTION

**Form:** DEMOGRAPHY

**Form Version:** 06-Jul-2020 21:55

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site No:** 1241

**Site Name:** (1241) Hospital Irma Dulce

**Subject No:** 12411468

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 19:09

[eCRF Audit Trail History](#)

**Demography**

1.	Subject ID	[12411468]
2.	Birth Date:	(b) (6) 1979
3.	Sex:	FEMALE
4.	Ethnicity:	NOT HISPANIC OR LATINO(A) OR OF SPANISH ORIGIN
5.	Race: (Check X all that apply):	BLACK OR AFRICAN AMERICAN
6.	Racial Designation:	

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**Header Text:** c4591001

**Visit:** V1\_DAY1\_VAX1\_L

**Form Version:** 22-Apr-2020 21:02

**Site No:** 1241

**Subject No:** 12411468

**Generated By:** (b) (4)

**Form:** DATE OF VISIT

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site Name:** (1241) Hospital Irma Dulce

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 19:09

[eCRF Audit Trail History](#)

**Date of Visit**

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

**Header Text:** c4591001**Visit:** V1\_DAY1\_VAX1\_L**Form Version:** 21-Aug-2020 02:50**Site No:** 1241**Subject No:** 12411468**Generated By:** (b) (4)**Form:** INCLUSION/EXCLUSION CRITERIA**Form Status:** Data Complete, Locked, Frozen, Verified**Site Name:** (1241) Hospital Irma Dulce**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 19:09**eCRF Audit Trail History**

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

**Inclusion Criteria**

1.a	Inclusion Number:	1
	Criterion Description:	Male or female participants between the ages of 18 and 55 years, inclusive, 65 and 85 years, inclusive, or 18 and 85 years, inclusive, at randomization (dependent upon study stage)
	Criterion met?	YES
	Criterion ID: (For Pfizer use only)	IN01A00
1.b	Inclusion Number:	2
	Criterion Description:	Participants who are willing and able to comply with all scheduled visits, vaccination plan, laboratory tests, lifestyle considerations, and other study procedures
	Criterion met?	YES
	Criterion ID: (For Pfizer use only)	IN02A00
1.c	Inclusion Number:	3
	Criterion Description:	Healthy participants who are determined by medical history, physical examination, and clinical judgment of the investigator to be eligible for inclusion in the study
	Criterion met?	YES
	Criterion ID: (For Pfizer use only)	IN03A00

**Header Text:** c4591001

**Visit:** V1\_DAY1\_VAX1\_L

**Form:** INCLUSION/EXCLUSION CRITERIA

**Form Version:** 21-Aug-2020 02:50

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site No:** 1241

**Site Name:** (1241) Hospital Irma Dulce

**Subject No:** 12411468

**Subject Initials:** ---

**Generated By:** (b) (4)

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

**Exclusion Criteria**

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

2.b	Exclusion Number:	2
	Criterion Description:	Known infection with human immunodeficiency virus (HIV), hepatitis C virus (HCV), or hepatitis B virus (HBV)
	Criterion met?	NO
	Criterion ID: (For Pfizer use only)	EX02A00

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**Header Text:** c4591001

**Visit:** V1\_DAY1\_VAX1\_L

**Form:** INCLUSION/EXCLUSION CRITERIA

**Form Version:** 21-Aug-2020 02:50

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site No:** 1241

**Site Name:** (1241) Hospital Irma Dulce

**Subject No:** 12411468

**Subject Initials:** ---

**Generated By:** (b) (4)

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2.c	Exclusion Number:	3
	Criterion Description:	History of severe adverse reaction associated with a vaccine and/or severe allergic reaction (eg, anaphylaxis) to any component of the study intervention(s)
	Criterion met?	NO
	Criterion ID: (For Pfizer use only)	EX03A00
2.d	Exclusion Number:	4
	Criterion Description:	Receipt of medications intended to prevent COVID-19
	Criterion met?	NO
	Criterion ID: (For Pfizer use only)	EX04A00
2.e	Exclusion Number:	8
	Criterion Description:	Immunocompromised individuals with known or suspected immunodeficiency, as determined by history and/or laboratory/physical examination
	Criterion met?	NO
	Criterion ID: (For Pfizer use only)	EX08A00

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**Header Text:** c4591001

**Visit:** V1\_DAY1\_VAX1\_L

**Form:** INCLUSION/EXCLUSION CRITERIA

**Form Version:** 21-Aug-2020 02:50

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site No:** 1241

**Site Name:** (1241) Hospital Irma Dulce

**Subject No:** 12411468

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 19:09

2.f	Exclusion Number:	10
	Criterion Description:	Bleeding diathesis or condition associated with prolonged bleeding that would, in the opinion of the investigator, contraindicate intramuscular injection
	Criterion met?	NO
	Criterion ID: (For Pfizer use only)	EX10A00
2.g	Exclusion Number:	11
	Criterion Description:	Women who are pregnant or breastfeeding
	Criterion met?	NO
	Criterion ID: (For Pfizer use only)	EX11A00
2.h	Exclusion Number:	12
	Criterion Description:	Previous vaccination with any coronavirus vaccine
	Criterion met?	NO
	Criterion ID: (For Pfizer use only)	EX12A00
2.i	Exclusion Number:	13
	Criterion Description:	Subjects who receive immunosuppressive therapy, such as cytotoxic agents or systemic corticosteroids
	Criterion met?	NO
	Criterion ID: (For Pfizer use only)	EX13A01

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**Header Text:** c4591001

**Visit:** V1\_DAY1\_VAX1\_L

**Form:** INCLUSION/EXCLUSION CRITERIA

**Form Version:** 21-Aug-2020 02:50

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site No:** 1241

**Site Name:** (1241) Hospital Irma Dulce

**Subject No:** 12411468

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 19:09

2.j	Exclusion Number:	15
	Criterion Description:	Receipt of blood/plasma products or immunoglobulin, from 60 days before study intervention administration or planned receipt throughout the study
	Criterion met?	NO
	Criterion ID: (For Pfizer use only)	EX14A01
2.k	Exclusion Number:	16
	Criterion Description:	Participation in other studies involving study intervention within 28 days prior to study entry and/or during study participation
	Criterion met?	NO
	Criterion ID: (For Pfizer use only)	EX15A01
2.1	Exclusion Number:	17
	Criterion Description:	Previous participation in other studies involving study intervention containing lipid nanoparticles
	Criterion met?	NO
	Criterion ID: (For Pfizer use only)	EX16A01

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**Header Text:** c4591001

**Visit:** V1\_DAY1\_VAX1\_L

**Form:** INCLUSION/EXCLUSION CRITERIA

**Form Version:** 21-Aug-2020 02:50

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site No:** 1241

**Site Name:** (1241) Hospital Irma Dulce

**Subject No:** 12411468

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 19:09

2.m	Exclusion Number:	22
	Criterion Description:	Investigator site staff or Pfizer employees directly involved in the conduct of the study, site staff otherwise supervised by the investigator, and their respective family members
	Criterion met?	NO
	Criterion ID: (For Pfizer use only)	EX21A01

**Header Text:** c4591001

**Visit:** V1\_DAY1\_VAX1\_L

**Form Version:** 22-Apr-2020 21:03

**Site No:** 1241

**Subject No:** 12411468

**Generated By:** (b) (4)

**Form:** DISPOSITION - SCREENING

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site Name:** (1241) Hospital Irma Dulce

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 19:09

[eCRF Audit Trail History](#)

**Disposition - Screening**

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

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**Header Text:** c4591001

**Visit:** V1\_DAY1\_VAX1\_L

**Form Version:** 22-Apr-2020 21:03

**Site No:** 1241

**Subject No:** 12411468

**Generated By:** (b) (4)

**Form:** GENERAL MEDICAL HISTORY

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site Name:** (1241) Hospital Irma Dulce

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 19:09

[eCRF Audit Trail History](#)

**Medical History Details**

1.a	Line/MH Number:	[1]
	Disease/Syndrome /Surgery/Non-Drug Allergies/Drug Allergies:	[Cholecystectomy]
	Start Date:	May/UNK/2019
	Ongoing:	NO End Date: May/UNK/2019

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**Header Text:** c4591001

**Visit:** V1\_DAY1\_VAX1\_L

**Form:** VITAL SIGNS - BASELINE

**Form Version:** 21-Aug-2020 02:51

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site No:** 1241

**Site Name:** (1241) Hospital Irma Dulce

**Subject No:** 12411468

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 19:09

[eCRF Audit Trail History](#)

**Vital Signs**

1.	Date:	Aug/25/2020
2.	Weight:	[69.7]
3.	Unit:	kg
4.	Height:	[165.5]
5.	Unit:	cm
6.	Body Mass Index:	[25.4]

**Vital Signs Details**

7.a	Record Identifier:	1
	Temperature:	[37.1]
	Unit:	C
	Temperature Location:	ORAL CAVITY

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**Header Text:** c4591001

**Visit:** V1\_DAY1\_VAX1\_L

**Form Version:** 21-Aug-2020 02:49

**Site No:** 1241

**Subject No:** 12411468

**Generated By:** (b) (4)

**Form:** LAB URINALYSIS - PREGNANCY TEST

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site Name:** (1241) Hospital Irma Dulce

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 19:09

[eCRF Audit Trail History](#)

**Lab Urinalysis**

1.	Lab Panel:	URINALYSIS
2.	Lab Sub-Panel:	PREGNANCY
3.	Collection Date:	Aug/25/2020
4.	Laboratory Name and Address (Derived)	[STUDY SITE]
5.	Specimen Type:	URINE

**Lab Result**

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

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**Header Text:** c4591001

**Visit:** V1\_DAY1\_VAX1\_L

**Form Version:** 22-Apr-2020 21:03

**Site No:** 1241

**Subject No:** 12411468

**Generated By:** (b) (4)

**Form:** RANDOMIZATION

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site Name:** (1241) Hospital Irma Dulce

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 19:09

[eCRF Audit Trail History](#)

**Disposition**

1.	Randomization Date :	Aug/25/2020
2.	Randomization Number:	[64867]
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:** 1241

**Site Name:** (1241) Hospital Irma Dulce

**Subject No:** 12411468

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 19:09

[eCRF Audit Trail History](#)

**Electronic Sample Tracking**

1.	Data Origin	SITE
2.	Sample Type	SERUM
3.	Sample Collected?	YES Date of Collection: Aug/25/2020
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[ ]

**Aliquot**

Please enter barcode for each aliquot.

5.a	Sample ID	[BPT0VS]
5.b	Sample ID	[BPT0VT]
5.c	Sample ID	[BPT0W8]
5.d	Sample ID	[BLCH4G]
5.e	Sample ID	[BLCH4H]

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**Header Text:** c4591001

**Visit:** V1\_DAY1\_VAX1\_L

**Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB

**Form Version:** 22-Apr-2020 21:03

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site No:** 1241

**Site Name:** (1241) Hospital Irma Dulce

**Subject No:** 12411468

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 19:09

[eCRF Audit Trail History](#)

**Electronic Sample Tracking**

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB
3.	Sample Collected?	YES Date of Collection: Aug/25/2020
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[ ]

**Aliquot**

Please enter barcode for each aliquot.

5.a	Sample ID	[BPT0VZ]
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090177e196ae3f49\Final\Final On: 01-Apr-2021 05:15 (GMT)

**Header Text:** c4591001

**Visit:** V1\_DAY1\_VAX1\_L

**Form Version:** 22-Apr-2020 21:04

**Site No:** 1241

**Subject No:** 12411468

**Generated By:** (b) (4)

**Form:** VACCINATION

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site Name:** (1241) Hospital Irma Dulce

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 19:09

[eCRF Audit Trail History](#)

**Vaccination**

1.	Was there a temporary delay of vaccination?	NO
2.	Treatment Name	[BLINDED THERAPY]
3.	Formulation:	INJECTION
4.	Dose Date Time:	Aug/25/2020 09:07
5.	Anatomical Location:	DELTOID MUSCLE
6.	Body Side:	LEFT
7.	Route:	INTRAMUSCULAR
8.	Actual Dose:	[ ]
9.	Unit:	
10.	Timeframe Subject Was Observed	THE PROTOCOL SPECIFIED OBSERVATION PERIOD
11.	Was the subject observed for at least the protocol specified observation period after investigational product administration?	YES

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**Header Text:** c4591001

**Visit:** V1\_DAY1\_VAX1\_L

**Form Version:** 06-Jul-2020 21:53

**Site No:** 1241

**Subject No:** 12411468

**Generated By:** (b) (4)

**Form:** REACTOGENICITY DIARY

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site Name:** (1241) Hospital Irma Dulce

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 19:09

[eCRF Audit Trail History](#)

**Reactogenicity Diary**

1.	Select appropriate response - Reactogenicity diary collection	NO - REACTOGENICITY E-DIARY NOT COLLECTED FOR THIS SUBJECT
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**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

**Form:** DATE OF VISIT

**Form Version:** 22-Apr-2020 21:02

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site No:** 1241

**Site Name:** (1241) Hospital Irma Dulce

**Subject No:** 12411468

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 19:09

[eCRF Audit Trail History](#)

**Date of Visit**

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

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

**Form:** VITAL SIGNS - TEMP

**Form Version:** 21-Aug-2020 02:51

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site No:** 1241

**Site Name:** (1241) Hospital Irma Dulce

**Subject No:** 12411468

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 19:09

[eCRF Audit Trail History](#)

**Vital Signs**

1.	Date:	Sep/15/2020
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**Vital Signs Details**

2.a	Record Identifier:	1
	Temperature:	[36.7]
	Unit:	C
	Temperature Location:	ORAL CAVITY

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**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

**Form:** LAB URINALYSIS - PREGNANCY TEST

**Form Version:** 21-Aug-2020 02:49

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site No:** 1241

**Site Name:** (1241) Hospital Irma Dulce

**Subject No:** 12411468

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 19:09

[eCRF Audit Trail History](#)

**Lab Urinalysis**

1.	Lab Panel:	URINALYSIS
2.	Lab Sub-Panel:	PREGNANCY
3.	Collection Date:	Sep/15/2020
4.	Laboratory Name and Address (Derived)	[STUDY SITE]
5.	Specimen Type:	URINE

**Lab Result**

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

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**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

**Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB

**Form Version:** 22-Apr-2020 21:03

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site No:** 1241

**Site Name:** (1241) Hospital Irma Dulce

**Subject No:** 12411468

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 19:09

[eCRF Audit Trail History](#)

**Electronic Sample Tracking**

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

**Aliquot**

Please enter barcode for each aliquot.

5.a	Sample ID	[BPWYLM]
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090177e196ae3f49\Final\Final On: 01-Apr-2021 05:15 (GMT)

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

**Form:** VACCINATION

**Form Version:** 22-Apr-2020 21:04

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site No:** 1241

**Site Name:** (1241) Hospital Irma Dulce

**Subject No:** 12411468

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 19:09

**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/15/2020 09:00
5.	Anatomical Location:	DELTOID MUSCLE
6.	Body Side:	LEFT
7.	Route:	INTRAMUSCULAR
8.	Actual Dose:	[ ]
9.	Unit:	
10.	Timeframe Subject Was Observed	THE PROTOCOL SPECIFIED OBSERVATION PERIOD
11.	Was the subject observed for at least the protocol specified observation period after investigational product administration?	YES

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**Header Text:** c4591001

**Visit:** V3\_MONTH1\_POSTVAX2\_L **Form:** DATE OF VISIT

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

**Site No:** 1241 **Site Name:** (1241) Hospital Irma Dulce

**Subject No:** 12411468 **Subject Initials:** ---

**Generated By:** (b) (4) **Generated Time (GMT):** 29-Mar-2021 19:09

[eCRF Audit Trail History](#)

**Date of Visit**

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

**Header Text:** c4591001

**Visit:** V3\_MONTH1\_POSTVAX2\_L **Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

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

**Site No:** 1241 **Site Name:** (1241) Hospital Irma Dulce

**Subject No:** 12411468 **Subject Initials:** ---

**Generated By:** (b) (4) **Generated Time (GMT):** 29-Mar-2021 19:09

[eCRF Audit Trail History](#)

**Electronic Sample Tracking**

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

**Aliquot**

Please enter barcode for each aliquot.

5.a	Sample ID	[BRD3TP]
5.b	Sample ID	[BRXGN7]
5.c	Sample ID	[BRXGN8]

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**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL - New  
Unscheduled Visit

**Form:** DATE OF VISIT - ILLNESS ONSET

**Form Version:** 22-Apr-2020 21:03

**Form Status:** Not Started

**Site No:** 1241

**Site Name:** (1241) Hospital Irma Dulce

**Subject No:** 12411468

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 19:09

**Date of Visit**

1.	Date of Visit	//
2.	Erroneous Visit	

**COVID-19 Illness Visit**

3.	COVID-19 Illness Visit:	
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**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL - New  
Unscheduled Visit

**Form Version:** 20-Feb-2021 02:17

**Site No:** 1241

**Subject No:** 12411468

**Generated By:** (b) (4)

**Form:** SIGNS AND SYMPTOMS OF POTENTIAL  
COVID-19

**Form Status:** Not Started

**Site Name:** (1241) Hospital Irma Dulce

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 19:09

**Signs and Symptoms**

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

**Symptoms**

4.	Symptoms:	
	Was symptom present?	

**Symptoms - Other**

5.	Symptoms - Other Text:	[ ]
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**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL - New  
Unscheduled Visit

**Form Version:** 22-Apr-2020 21:03

**Site No:** 1241

**Subject No:** 12411468

**Generated By:** (b) (4)

**Form:** ELECTRONIC SAMPLE TRACKING - NASAL  
SWAB SELF

**Form Status:** Not Started

**Site Name:** (1241) Hospital Irma Dulce

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 19:09

**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	[ ]
----	-----------	-----

090177e196ae3f49\Final\Final On: 01-Apr-2021 05:15 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL - New  
Unscheduled Visit

**Form:** ELECTRONIC SAMPLE TRACKING - NASAL  
SWAB

**Form Version:** 22-Apr-2020 21:03

**Form Status:** Not Started

**Site No:** 1241

**Site Name:** (1241) Hospital Irma Dulce

**Subject No:** 12411468

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 19:09

**Electronic Sample Tracking**

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

**Aliquot**

Please enter barcode for each aliquot.

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

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL - New  
Unscheduled Visit

**Form:** HEALTH CARE UTILIZATION

**Form Version:** 20-Feb-2021 02:19

**Form Status:** Not Started

**Site No:** 1241

**Site Name:** (1241) Hospital Irma Dulce

**Subject No:** 12411468

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 19:09

**Health Care Utilization**

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

**Health Care Utilization Other**

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

**Health Care Utilization**

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

090177e196ae3f49\Final\Final On: 01-Apr-2021 05:15 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL - New  
Unscheduled Visit

**Form:** ILLNESS DETAILS

**Form Version:** 06-Jul-2020 21:52

**Form Status:** Not Started

**Site No:** 1241

**Site Name:** (1241) Hospital Irma Dulce

**Subject No:** 12411468

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 19:09

**Illness Details**

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



**Header Text:** c4591001

**Visit:** POT\_COVID\_CONVA - New  
Unscheduled Visit

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

**Form Version:** 22-Apr-2020 21:04

**Form Status:** Not Started

**Site No:** 1241

**Site Name:** (1241) Hospital Irma Dulce

**Subject No:** 12411468

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 19:09

**Date of Visit**

1.	Date of Visit	//
2.	Erroneous Visit	

**COVID-19 Illness Visit**

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

**Header Text:** c4591001**Visit:** POT\_COVID\_CONVA - New  
Unscheduled Visit**Form:** ELECTRONIC SAMPLE TRACKING -  
IMMUNOGENICITY**Form Version:** 22-Apr-2020 21:03**Form Status:** Not Started**Site No:** 1241**Site Name:** (1241) Hospital Irma Dulce**Subject No:** 12411468**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 19:09**Electronic Sample Tracking**

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

**Aliquot**

Please enter barcode for each aliquot.

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

**Header Text:** c4591001

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

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

**Site No:** 1241 **Site Name:** (1241) Hospital Irma Dulce

**Subject No:** 12411468 **Subject Initials:** ---

**Generated By:** (b) (4) **Generated Time (GMT):** 29-Mar-2021 19:09

**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:** 1241    **Site Name:** (1241) Hospital Irma Dulce

**Subject No:** 12411468    **Subject Initials:** ---

**Generated By:** (b) (4)    **Generated Time (GMT):** 29-Mar-2021 19:09

**Unplanned Assessments**

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

**Header Text:** c4591001

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

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

**Site No:** 1241

**Site Name:** (1241) Hospital Irma Dulce

**Subject No:** 12411468

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 19:09

[eCRF Audit Trail History](#)

**Disposition - Treatment**

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

090177e196ae3f49\Final\Final On: 01-Apr-2021 05:15 (GMT)

**Header Text:** c4591001

**Visit:** Follow-Up - Unscheduled

**Form:** DISPOSITION - FOLLOW-UP

**Form Version:** 15-Sep-2020 21:53

**Form Status:** Not Started

**Site No:** 1241

**Site Name:** (1241) Hospital Irma Dulce

**Subject No:** 12411468

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 19:09

**Disposition - Follow-Up**

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

**Header Text:** c4591001

**Visit:** POT\_COVID\_REPEAT\_SWAB **Form:** DATE OF VISIT - REPEAT SWAB  
- New Unscheduled Visit

**Form Version:** 10-Oct-2020 15:57 **Form Status:** Not Started

**Site No:** 1241

**Site Name:** (1241) Hospital Irma Dulce

**Subject No:** 12411468

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 19:09

**Date of Visit**

1.	Date of Visit	//
2.	Erroneous Visit	

**COVID-19 Repeat Swab**

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

**Header Text:** c4591001**Visit:** POT\_COVID\_REPEAT\_SWAB - New Unscheduled Visit **Form:** ELECTRONIC SAMPLE TRACKING - REPEAT SWAB**Form Version:** 10-Oct-2020 15:57 **Form Status:** Not Started**Site No:** 1241**Site Name:** (1241) Hospital Irma Dulce**Subject No:** 12411468**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 19:09**Electronic Sample Tracking**

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

**Aliquot**

Please enter barcode for each aliquot.

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



**Header Text:** c4591001

**Visit:** Logs

**Form:** ADVERSE EVENT REPORT

**Form Version:** 22-Apr-2020 21:02

**Site No:** 1241

**Site Name:** (1241) Hospital Irma Dulce

**Subject No:** 12411468

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 19:09

#	Category	AE Identifier	Adverse Event	Start Date	Is the Adverse Event Still Ongoing	Form Instance
1.	ADVERSE EVENT	1	Injection site pain	Jan/25/2021 20:00	NO End Date Time:  Jan/26/2021 UNK:UNK	<a href="#">Repeating Pages</a>
2.	ADVERSE EVENT	2	Chills	Jan/25/2021 20:00	NO End Date Time:  Jan/26/2021 UNK:UNK	<a href="#">Repeating Pages</a>

090177e196ae3f49\Final\Final On: 01-Apr-2021 05:15 (GMT)

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

**Form:** ADVERSE EVENT REPORT

**Form Version:** 22-Apr-2020 21:02

**Form Status:** Data Complete, Frozen

**Site No:** 1241

**Site Name:** (1241) Hospital Irma Dulce

**Subject No:** 12411468

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 19:09

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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)	[Injection site pain]
4.	Start Date Time:	Jan/25/2021 20:00
5.	Is the adverse event still ongoing?	NO End Date Time: Jan/26/2021 UNK:UNK
6.	Toxicity Grade:	1

090177e196ae3f49\Final\Final On: 01-Apr-2021 05:15 (GMT)

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

**Form:** ADVERSE EVENT REPORT

**Form Version:** 22-Apr-2020 21:02

**Form Status:** Data Complete, Frozen

**Site No:** 1241

**Site Name:** (1241) Hospital Irma Dulce

**Subject No:** 12411468

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 19:09

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

090177e196ae3f49\Final\Final On: 01-Apr-2021 05:15 (GMT)

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

**Form:** ADVERSE EVENT REPORT

**Form Version:** 22-Apr-2020 21:02

**Form Status:** Data Complete, Frozen

**Site No:** 1241

**Site Name:** (1241) Hospital Irma Dulce

**Subject No:** 12411468

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 19:09

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	[ ]

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

**Form Version:** 22-Apr-2020 21:02

**Site No:** 1241

**Subject No:** 12411468

**Generated By:** (b) (4)

**Form:** ADVERSE EVENT REPORT

**Form Status:** Data Complete, Frozen

**Site Name:** (1241) Hospital Irma Dulce

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 19:09

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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)	[Chills]
4.	Start Date Time:	Jan/25/2021 20:00
5.	Is the adverse event still ongoing?	NO End Date Time: Jan/26/2021 UNK:UNK
6.	Toxicity Grade:	1

090177e196ae3f49\Final\Final On: 01-Apr-2021 05:15 (GMT)

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

**Form:** ADVERSE EVENT REPORT

**Form Version:** 22-Apr-2020 21:02

**Form Status:** Data Complete, Frozen

**Site No:** 1241

**Site Name:** (1241) Hospital Irma Dulce

**Subject No:** 12411468

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 19:09

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

090177e196ae3f49\Final\Final On: 01-Apr-2021 05:15 (GMT)

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

**Form:** ADVERSE EVENT REPORT

**Form Version:** 22-Apr-2020 21:02

**Form Status:** Data Complete, Frozen

**Site No:** 1241

**Site Name:** (1241) Hospital Irma Dulce

**Subject No:** 12411468

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 19:09

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	[ ]

**Header Text:** c4591001

**Visit:** Logs

**Form:** MEDICATION ERROR

**Form Version:** 17-Jul-2020 21:54

**Site No:** 1241

**Site Name:** (1241) Hospital Irma Dulce

**Subject No:** 12411468

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 19:09

#	Category	Medication Error	Start Date	Is the medication error Still Ongoing	Study Medication Errors Action	Form Instance
1.						<a href="#">Repeating Pages</a>



**Header Text:** c4591001

**Visit:** Logs - Unscheduled

**Form:** MEDICATION ERROR

**Form Version:** 17-Jul-2020 21:54

**Form Status:** Not Started

**Site No:** 1241

**Site Name:** (1241) Hospital Irma Dulce

**Subject No:** 12411468

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 19:09

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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	[ ]

090177e196ae3f49\Final\Final On: 01-Apr-2021 05:15 (GMT)

**Header Text:** c4591001

**Visit:** Logs

**Form:** CONCOMITANT MEDICATIONS - NON STUDY VACCINATIONS

**Form Version:** 22-Apr-2020 21:03

**Site No:** 1241

**Site Name:** (1241) Hospital Irma Dulce

**Subject No:** 12411468

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 19:09

#	Sponsor-Defined Identifier	Category for Medication	Concomitant Medications Pre-specified	Name of Medication	Start Date	Form Instance
1.						<a href="#">Repeating Pages</a>

**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:** 1241

**Site Name:** (1241) Hospital Irma Dulce

**Subject No:** 12411468

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 19:09

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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:	//

090177e196ae3f49\Final\Final On: 01-Apr-2021 05:15 (GMT)

**Header Text:** c4591001

**Visit:** Logs

**Form:** CONCOMITANT MEDICATIONS - PROHIBITED

**Form Version:** 22-Apr-2020 21:03

**Site No:** 1241

**Site Name:** (1241) Hospital Irma Dulce

**Subject No:** 12411468

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 19:09

#	Sponsor-Defined Identifier	Category for Medication	Concomitant Medications Pre-specified	Name of Medication	Dose Description	Form Instance
1.						<a href="#">Repeating Pages</a>

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

**Form:** CONCOMITANT MEDICATIONS - PROHIBITED

**Form Version:** 22-Apr-2020 21:03

**Form Status:** Not Started

**Site No:** 1241

**Site Name:** (1241) Hospital Irma Dulce

**Subject No:** 12411468

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 19:09

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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?	

090177e196ae3f49\Final\Final On: 01-Apr-2021 05:15 (GMT)

**Header Text:** c4591001

**Visit:** Logs

**Form:** RADIATION TREATMENT

**Form Version:** 22-Apr-2020 21:02

**Site No:** 1241

**Site Name:** (1241) Hospital Irma Dulce

**Subject No:** 12411468

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 19:09

#	Category	Treatment Identifier	Con Non-Drug Treatments Pre-specified	Treatment	Start Date	Form Instance
1.						<a href="#">Repeating Pages</a>

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

**Form:** RADIATION TREATMENT

**Form Version:** 22-Apr-2020 21:02

**Form Status:** Not Started

**Site No:** 1241

**Site Name:** (1241) Hospital Irma Dulce

**Subject No:** 12411468

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 19:09

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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?	

090177e196ae3f49\Final\Final On: 01-Apr-2021 05:15 (GMT)

**Header Text:** c4591001

**Visit:** Logs

**Form:** TRANSFUSIONS

**Form Version:** 22-Apr-2020 21:03

**Site No:** 1241

**Site Name:** (1241) Hospital Irma Dulce

**Subject No:** 12411468

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 19:09

#	Transfusion Type	Date of Transfusion	Form Instance
1.			<a href="#">Repeating Pages</a>



**Header Text:** c4591001

**Visit:** Logs - Unscheduled

**Form:** TRANSFUSIONS

**Form Version:** 22-Apr-2020 21:03

**Form Status:** Not Started

**Site No:** 1241

**Site Name:** (1241) Hospital Irma Dulce

**Subject No:** 12411468

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 19:09

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

**Header Text:** c4591001

**Visit:** Unplanned Vaccination -  
Unscheduled

**Form:** DATE OF VISIT

**Form Version:** 22-Apr-2020 21:02

**Form Status:** Not Started

**Site No:** 1241

**Site Name:** (1241) Hospital Irma Dulce

**Subject No:** 12411468

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 19:09

**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:** 1241

**Site Name:** (1241) Hospital Irma Dulce

**Subject No:** 12411468

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 19:09

**Vital Signs**

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

**Vital Signs Details**

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

090177e196ae3f49\Final\Final On: 01-Apr-2021 05:15 (GMT)

**Header Text:** c4591001

**Visit:** Unplanned Vaccination -  
Unscheduled

**Form:** LAB URINALYSIS - PREGNANCY TEST

**Form Version:** 20-Feb-2021 02:14

**Form Status:** Not Started

**Site No:** 1241

**Site Name:** (1241) Hospital Irma Dulce

**Subject No:** 12411468

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 19:09

**Lab Urinalysis**

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

**Lab Result**

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

090177e196ae3f49\Final\Final On: 01-Apr-2021 05:15 (GMT)

**Header Text:** c4591001

**Visit:** Unplanned Vaccination -  
Unscheduled

**Form:** VACCINATION

**Form Version:** 10-Dec-2020 02:26

**Form Status:** Not Started

**Site No:** 1241

**Site Name:** (1241) Hospital Irma Dulce

**Subject No:** 12411468

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 19:09

**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?	

090177e196ae3f49\Final\Final On: 01-Apr-2021 05:15 (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:** 1241

**Site Name:** (1241) Hospital Irma Dulce

**Subject No:** 12411468

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 19:09

**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:** 1241

**Site Name:** (1241) Hospital Irma Dulce

**Subject No:** 12411468

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 19:09

**Contact Outcome**

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

**Header Text:** c4591001

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

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

**Site No:** 1241      **Site Name:** (1241) Hospital Irma Dulce

**Subject No:** 12411468      **Subject Initials:** ---

**Generated By:** (b) (4)      **Generated Time (GMT):** 29-Mar-2021 19:09

[eCRF Audit Trail History](#)

**Date of Visit**

1.	Date of Visit	Jan/21/2021
2.	Erroneous Visit	



**Header Text:** c4591001

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

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

**Site No:** 1241      **Site Name:** (1241) Hospital Irma Dulce

**Subject No:** 12411468      **Subject Initials:** ---

**Generated By:** (b) (4)      **Generated Time (GMT):** 29-Mar-2021 19:09

[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:** TREATMENT UNBLINDED

**Form Version:** 22-Apr-2020 21:03

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1241

**Site Name:** (1241) Hospital Irma Dulce

**Subject No:** 12411468

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 19:09

[eCRF Audit Trail History](#)

**Treatment Unblinded**

1.	Date Treatment Unblinded :	Jan/21/2021
2.	Primary Reason for Unblinding:	ASSESS ELIGIBILITY FOR ADDITIONAL VACCINATION

**Header Text:** c4591001

**Visit:** Disposition - Unscheduled

**Form:** WITHDRAWAL OF CONSENT

**Form Version:** 22-Apr-2020 21:03

**Form Status:** Not Started

**Site No:** 1241

**Site Name:** (1241) Hospital Irma Dulce

**Subject No:** 12411468

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 19:09

**Withdrawal Of Consent**

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

**Header Text:** c4591001

**Visit:** Disposition - Unscheduled

**Form:** DEATH DETAILS CODED

**Form Version:** 22-Apr-2020 21:03

**Form Status:** Not Started

**Site No:** 1241

**Site Name:** (1241) Hospital Irma Dulce

**Subject No:** 12411468

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 19:09

**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:** DATE OF VISIT

**Form Version:** 22-Apr-2020 21:02

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1241

**Site Name:** (1241) Hospital Irma Dulce

**Subject No:** 12411468

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 19:09

[eCRF Audit Trail History](#)

**Date of Visit**

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

**Header Text:** c4591001

**Visit:** V101\_VAX3

**Form:** INFORMED CONSENT - FURTHER VACCINATION

**Form Version:** 10-Dec-2020 02:31

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1241

**Site Name:** (1241) Hospital Irma Dulce

**Subject No:** 12411468

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 19:09

[eCRF Audit Trail History](#)

**Informed Consent - Further Vaccination**

1.	Consent Was:	OBTAINED Date Written Consent Obtained Jan/25/2021
----	--------------	--

**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:** 1241

**Site Name:** (1241) Hospital Irma Dulce

**Subject No:** 12411468

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 19:09

**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 _____
----	--	-------------------------

090177e196ae3f49\Final\Final On: 01-Apr-2021 05:15 (GMT)

**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:** 1241

**Site Name:** (1241) Hospital Irma Dulce

**Subject No:** 12411468

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 19:09

[eCRF Audit Trail History](#)

**Disposition - Screening for Further Vaccination**

1.	Date of Completion/Discontinuation/Death :	Jan/25/2021
2.	Phase of Disposition:	REPEAT SCREENING 1
3.	Status:	COMPLETED
4.	Specify Status:	[ ]

090177e196ae3f49\Final\Final On: 01-Apr-2021 05:15 (GMT)



**Header Text:** c4591001

**Visit:** V101\_VAX3

**Form Version:** 14-Jan-2021 02:21

**Site No:** 1241

**Subject No:** 12411468

**Generated By:** (b) (4)

**Form:** LAB URINALYSIS - PREGNANCY TEST

**Form Status:** Data Complete, Frozen, Verified

**Site Name:** (1241) Hospital Irma Dulce

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 19:09

[eCRF Audit Trail History](#)

**Lab Urinalysis**

1.	Lab Panel:	URINALYSIS
2.	Lab Sub-Panel:	PREGNANCY
3.	Collection Date:	Jan/25/2021
4.	Laboratory Name and Address (Derived)	[STUDY SITE]
5.	Specimen Type:	URINE

**Lab Result**

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

090177e196ae3f49\Final\Final On: 01-Apr-2021 05:15 (GMT)

**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:** 1241

**Site Name:** (1241) Hospital Irma Dulce

**Subject No:** 12411468

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 19:09

[eCRF Audit Trail History](#)

**Electronic Sample Tracking**

1.	Data Origin	SITE
2.	Sample Type	SERUM
3.	Sample Collected?	YES Date of Collection: Jan/25/2021
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[ ]

**Aliquot**

Please enter barcode for each aliquot.

5.a	Sample ID	[BPTKXV]
5.b	Sample ID	[BSCYYL]
5.c	Sample ID	[BSCYYM]

090177e196ae3f49\Final\Final On: 01-Apr-2021 05:15 (GMT)

**Header Text:** c4591001

**Visit:** V101\_VAX3

**Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB

**Form Version:** 22-Apr-2020 21:03

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1241

**Site Name:** (1241) Hospital Irma Dulce

**Subject No:** 12411468

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 19:09

[eCRF Audit Trail History](#)

**Electronic Sample Tracking**

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB
3.	Sample Collected?	YES Date of Collection: Jan/25/2021
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[ ]

**Aliquot**

Please enter barcode for each aliquot.

5.a	Sample ID	[BPTKXJ]
-----	-----------	----------

090177e196ae3f49\Final\Final On: 01-Apr-2021 05:15 (GMT)

**Header Text:** c4591001

**Visit:** V101\_VAX3

**Form:** VACCINATION

**Form Version:** 10-Dec-2020 02:26

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1241

**Site Name:** (1241) Hospital Irma Dulce

**Subject No:** 12411468

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 19:09

[eCRF Audit Trail History](#)

**Vaccination**

1.	Was there a temporary delay of vaccination?	NO
2.	Treatment Name	[BNT162b2]
3.	Formulation:	INJECTION
4.	Dose Date Time:	Jan/25/2021 11:10
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

090177e196ae3f49\Final\Final On: 01-Apr-2021 05:15 (GMT)

**Header Text:** c4591001

**Visit:** V102\_VAX4

**Form:** DATE OF VISIT

**Form Version:** 22-Apr-2020 21:02

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1241

**Site Name:** (1241) Hospital Irma Dulce

**Subject No:** 12411468

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 19:09

[eCRF Audit Trail History](#)

**Date of Visit**

1.	Date of Visit	Feb/15/2021
2.	Erroneous Visit	

**Header Text:** c4591001

**Visit:** V102\_VAX4

**Form:** LAB URINALYSIS - PREGNANCY TEST

**Form Version:** 14-Jan-2021 02:21

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1241

**Site Name:** (1241) Hospital Irma Dulce

**Subject No:** 12411468

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 19:09

[eCRF Audit Trail History](#)

**Lab Urinalysis**

1.	Lab Panel:	URINALYSIS
2.	Lab Sub-Panel:	PREGNANCY
3.	Collection Date:	Feb/15/2021
4.	Laboratory Name and Address (Derived)	[STUDY SITE]
5.	Specimen Type:	URINE

**Lab Result**

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

090177e196ae3f49\Final\Final On: 01-Apr-2021 05:15 (GMT)

**Header Text:** c4591001

**Visit:** V102\_VAX4

**Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB

**Form Version:** 22-Apr-2020 21:03

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1241

**Site Name:** (1241) Hospital Irma Dulce

**Subject No:** 12411468

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 19:09

[eCRF Audit Trail History](#)

**Electronic Sample Tracking**

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB
3.	Sample Collected?	YES Date of Collection: Feb/15/2021
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	[BRKF3Y]
-----	-----------	----------

090177e196ae3f49\Final\Final On: 01-Apr-2021 05:15 (GMT)

**Header Text:** c4591001

**Visit:** V102\_VAX4

**Form:** VACCINATION

**Form Version:** 10-Dec-2020 02:26

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1241

**Site Name:** (1241) Hospital Irma Dulce

**Subject No:** 12411468

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 19:09

[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/15/2021 09:07
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

090177e196ae3f49\Final\Final On: 01-Apr-2021 05:15 (GMT)



**Header Text:** c4591001

**Visit:** V103\_MONTH1

**Form Version:** 22-Apr-2020 21:02

**Site No:** 1241

**Subject No:** 12411468

**Generated By:** (b) (4)

**Form:** DATE OF VISIT

**Form Status:** Not Started

**Site Name:** (1241) Hospital Irma Dulce

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 19:09

**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:** 1241

**Subject No:** 12411468

**Generated By:** (b) (4)

**Form:** CONTACT OUTCOME

**Form Status:** Not Started

**Site Name:** (1241) Hospital Irma Dulce

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 19:09

**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:** 1241

**Subject No:** 12411468

**Generated By:** (b) (4)

**Form:** DATE OF VISIT

**Form Status:** Not Started

**Site Name:** (1241) Hospital Irma Dulce

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 19:09

**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:** 1241

**Subject No:** 12411468

**Generated By:** (b) (4)

**Form:** CONTACT OUTCOME

**Form Status:** Not Started

**Site Name:** (1241) Hospital Irma Dulce

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 19:09

**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:** 1241

**Subject No:** 12411468

**Generated By:** (b) (4)

**Form:** DATE OF VISIT

**Form Status:** Not Started

**Site Name:** (1241) Hospital Irma Dulce

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 19:09

**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:** 1241

**Subject No:** 12411468

**Generated By:** (b) (4)

**Form:** CONTACT OUTCOME

**Form Status:** Not Started

**Site Name:** (1241) Hospital Irma Dulce

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 19:09

**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:** 1241

**Site Name:** (1241) Hospital Irma Dulce

**Subject No:** 12411468

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 19:09

**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:** SUBJECT STATUS

**Form Version:** 22-Apr-2020 21:03

**Form Status:** Data Complete, Verified

**Site No:** 1241

**Site Name:** (1241) Hospital Irma Dulce

**Subject No:** 12411468

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 19:09

[eCRF Audit Trail History](#)

**Subject Status**

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



**Header Text:** c4591001

**Visit:** Investigator Signature -  
Unscheduled

**Form:** CASEBOOK SIGNATURE FORM

**Form Version:** 22-Apr-2020 21:04

**Form Status:** Data Complete, Signed, Verified

**Site No:** 1241

**Site Name:** (1241) Hospital Irma Dulce

**Subject No:** 12411468

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 19:09

[eCRF Audit Trail History](#)

**Casebook Signature Form**

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

**Visit:** Investigator Signature -  
Unscheduled

**Form:** CASEBOOK SIGNATURE FORM

**Form Version:** 22-Apr-2020 21:04

**Form Status:** Data Complete, Signed, Verified

**Site No:** 1241

**Site Name:** (1241) Hospital Irma Dulce

**Subject No:** 12411468

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 19:09

[Audit Trail](#)

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

- CRF\_Sign

Name	Signature Meaning	Date	Type	Action
(b) (6)	Approved	Feb-24-2021 15:32:46 (UTC-03:00) City of Buenos Aires	BOOK	Signed

**Affidavit:**

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

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

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

**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:** 1241

**Site Name:** (1241) Hospital Irma Dulce

**Subject No:** 12411468

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 19:09

[Back to Form](#)

Item	Date	User	Comment
Form	Jan-25-2021 11:51:48 (UTC-03:00) City of Buenos Aires	(b) (4), (b) (6)	Not Applicable

090177e196ae3f49\Final\Final On: 01-Apr-2021 05:15 (GMT)

**Header Text:** c4591001

**Visit:** Investigator Signature -  
Unscheduled

**Form:** CASEBOOK SIGNATURE FORM - Signature  
History

**Form Version:** 22-Apr-2020 21:04

**Form Status:** Data Complete, Signed, Verified

**Site No:** 1241

**Site Name:** (1241) Hospite Irma Dulce

**Subject No:** 12411468

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 19:09

[Back to Form](#)

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

- CRF\_Sign

Name	Signature Meaning	Date	Type	Action
(b) (6) [Redacted]	Approved	Feb-24-2021 15:32:46 (UTC-03:00) City of Buenos Aires	BOOK	Signed

**Affidavit:**

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

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

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

(b) (6) [Redacted]	N/A	Feb-15-2021 09:51:48 (UTC-03:00) City of Buenos Aires		Edit - All signatures invalidated
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**Affidavit:**

N/A

(b) (6) [Redacted]	Approved	Feb-05-2021 14:31:58 (UTC-03:00) City of Buenos Aires	BOOK	Signed
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090177e196ae3f49\Final\Final On: 01-Apr-2021 05:15 (GMT)

**Header Text:** c4591001

**Visit:** Investigator Signature -  
Unscheduled

**Form:** CASEBOOK SIGNATURE FORM - Signature  
History

**Form Version:** 22-Apr-2020 21:04

**Form Status:** Data Complete, Signed, Verified

**Site No:** 1241

**Site Name:** (1241) Hospital Irma Dulce

**Subject No:** 12411468

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 19:09

**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-02-2021 08:37:15 (UTC-03:00) City of Buenos Aires		Edit - All signatures invalidated
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**Affidavit:**

N/A

Edson Moreira	Approved	Jan-27-2021 14:13:13 (UTC-03:00) City of Buenos Aires	BOOK	Signed
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**Affidavit:**

By my dated signature below, I, EdsonMoreira, 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.

090177e196ae3f49\Final\Final On: 01-Apr-2021 05:15 (GMT)

**Header Text:** c4591001

**Visit:** Investigator Signature -  
Unscheduled

**Form:** CASEBOOK SIGNATURE FORM - Signature  
History

**Form Version:** 22-Apr-2020 21:04

**Form Status:** Data Complete, Signed, Verified

**Site No:** 1241

**Site Name:** (1241) Hospital Irma Dulce

**Subject No:** 12411468

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 19:09

(b) (6)	N/A	Jan-25-2021 11:51:00 (UTC-03:00) City of Buenos Aires		Edit - All signatures invalidated
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**Affidavit:**

N/A

(b) (6)	Approved	Oct-22-2020 17:57:39 (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.

090177e196ae3f49\Final\Final On: 01-Apr-2021 05:15 (GMT)

**Header Text:** c4591001

**Visit:** COHORT\_SELECTION

**Form:** COHORT SELECTION - eCRF Audit Trail History

**Form Version:** 30-Jul-2020 21:29

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site No:** 1241

**Site Name:** (1241) Hospital Irma Dulce

**Subject No:** 12411468

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 19:09

[Back to Form](#)

*1. Select appropriate response - Protocol version*

Date	Location	User	Value	Reason
Aug-25-2020 10:14:28 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 30 JUN 2020	Initial Entry

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

Date	Location	User	Value	Reason
Aug-25-2020 10:14:28 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> STAGE 3 COHORTS	Initial Entry

**Header Text:** c4591001

**Visit:** COHORT\_SELECTION

**Form:** MAIN INFORMED CONSENT - eCRF Audit Trail History

**Form Version:** 22-Apr-2020 21:02

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site No:** 1241

**Site Name:** (1241) Hospital Irma Dulce

**Subject No:** 12411468

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 19:09

[Back to Form](#)

**1. Consent Was:**

Date	Location	User	Value	Reason
Aug-25-2020 10:14:36 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> OBTAINED Date Written Consent Obtained  Aug/25/2020	Initial Entry

090177e196ae3f49\Final\Final On: 01-Apr-2021 05:15 (GMT)



**Header Text:** c4591001

**Visit:** COHORT\_SELECTION

**Form Version:** 06-Jul-2020 21:55

**Site No:** 1241

**Subject No:** 12411468

**Generated By:** (b) (4)

**Form:** DEMOGRAPHY - eCRF Audit Trail History

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site Name:** (1241) Hospital Irma Dulce

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 19:09

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**1. Subject ID**

Date	Location	User	Value	Reason
Aug-25-2020 10:14:19 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 12411468	Item copied from previous form

**2. Birth Date:**

Date	Location	User	Value	Reason
Aug-25-2020 10:14:16 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> (b) (6) 1979	Enrollment Entry

**3. Sex:**

Date	Location	User	Value	Reason
Aug-25-2020 10:14:48 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> FEMALE	Initial Entry

**4. Ethnicity:**

Date	Location	User	Value	Reason
Aug-25-2020 10:14:48 (UTC-03:00) City	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NOT HISPANIC OR LATINO(A) OR OF	Initial Entry

090177e196ae3f49\Final\Final On: 01-Apr-2021 05:15 (GMT)

**Header Text:** c4591001

**Visit:** COHORT\_SELECTION

**Form:** DEMOGRAPHY - eCRF Audit Trail History

**Form Version:** 06-Jul-2020 21:55

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site No:** 1241

**Site Name:** (1241) Hospital Irma Dulce

**Subject No:** 12411468

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 19:09

of Buenos Aires

SPANISH ORIGIN

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

Date	Location	User	Value	Reason
Aug-25-2020 10:14:48 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BLACK OR AFRIC AN AMERICAN	Initial Entry

**Header Text:** c4591001

**Visit:** V1\_DAY1\_VAX1\_L

**Form Version:** 22-Apr-2020 21:02

**Site No:** 1241

**Subject No:** 12411468

**Generated By:** (b) (4)

**Form:** DATE OF VISIT - eCRF Audit Trail History

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site Name:** (1241) Hospital Irma Dulce

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 19:09

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*1. Date of Visit*

Date	Location	User	Value	Reason
Aug-25-2020 10:15:00 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Aug/25/2020	Initial Entry

090177e196ae3f49\Final\Final On: 01-Apr-2021 05:15 (GMT)

**Header Text:** c4591001

**Visit:** V1\_DAY1\_VAX1\_L

**Form:** INCLUSION/EXCLUSION CRITERIA - eCRF  
Audit Trail History

**Form Version:** 21-Aug-2020 02:50

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site No:** 1241

**Site Name:** (1241) Hospital Irma Dulce

**Subject No:** 12411468

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 19:09

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*I.a*

Date	Location	User	Value	Reason
Aug-25-2020 10:15:32 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Incl 1</b> <b>usio</b> <b>n N</b> <b>um</b> <b>ber:</b> <b>Crit Male or female</b> <b>erio participants bet</b> <b>n D</b> <b>ween the ages</b> <b>escr</b> <b>of 18 and 55 ye</b> <b>ipti</b> <b>ars, inclusive, 6</b> <b>on:</b> <b>5 and 85 years,</b> <b>inclusive, or 18</b> <b>and 85 years, i</b> <b>nclusive, at ran</b> <b>domization (de</b> <b>pendent upon s</b> <b>tudy stage)</b> <b>Crit YES</b> <b>erio</b> <b>n m</b> <b>et?:</b>	Initial Entry

090177e196ae3f49\Final\Final On: 01-Apr-2021 05:15 (GMT)

**Header Text:** c4591001

**Visit:** V1\_DAY1\_VAX1\_L

**Form:** INCLUSION/EXCLUSION CRITERIA - eCRF  
Audit Trail History

**Form Version:** 21-Aug-2020 02:50

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site No:** 1241

**Site Name:** (1241) Hospital Irma Dulce

**Subject No:** 12411468

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 19:09

			<b>Crit IN01A00 erion I D: (For Pfizer er use only)</b> :	
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***1.a Inclusion Number:***

Date	Location	User	Value	Reason
Aug-25-2020 10:15:32 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 1	Initial Entry

***1.a Criterion Description:***

Date	Location	User	Value	Reason
Aug-25-2020 10:15:32 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Male or female participants between the ages of 18 and 55 years, inclusive, 65 and 85 years, inclusive, or 18 and 85 years, inclusive, at randomization (dependent upon study stage)	Initial Entry

090177e196ae3f49\Final\Final On: 01-Apr-2021 05:15 (GMT)

**Header Text:** c4591001

**Visit:** V1\_DAY1\_VAX1\_L

**Form:** INCLUSION/EXCLUSION CRITERIA - eCRF  
Audit Trail History

**Form Version:** 21-Aug-2020 02:50

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site No:** 1241

**Site Name:** (1241) Hospital Irma Dulce

**Subject No:** 12411468

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 19:09

***1.a Criterion met?***

Date	Location	User	Value	Reason
Aug-25-2020 10:15:32 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

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

Date	Location	User	Value	Reason
Aug-25-2020 10:15:32 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> IN01A00	Initial Entry

***1.b***

Date	Location	User	Value	Reason
Aug-25-2020 10:15:32 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Incl 2 usio n N umb er:	Initial Entry

090177e196ae3f49\Final\Final On: 01-Apr-2021 05:15 (GMT)

**Header Text:** c4591001

**Visit:** V1\_DAY1\_VAX1\_L

**Form:** INCLUSION/EXCLUSION CRITERIA - eCRF  
Audit Trail History

**Form Version:** 21-Aug-2020 02:50

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site No:** 1241

**Site Name:** (1241) Hospital Irma Dulce

**Subject No:** 12411468

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 19:09

			<p><b>Crit</b> Participants w <b>erio</b> ho are willing <b>n De</b> and able to co <b>scri</b> mply with all s <b>ptio</b> cheduled visits <b>n:</b> , vaccination pl an, laboratory t ests, lifestyle c onsiderations, and other study procedures</p> <p><b>Crit</b> YES <b>erio</b> <b>n m</b> <b>et?:</b></p> <p><b>Crit</b> IN02A00 <b>erio</b> <b>n ID</b> <b>: (Fo</b> <b>r Pfi</b> <b>zer</b> <b>use</b> <b>only</b> <b>):</b></p>	
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090177e196ae3f49\Final\Final On: 01-Apr-2021 05:15 (GMT)

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form: INCLUSION/EXCLUSION CRITERIA - eCRF  
Audit Trail History

Form Version: 21-Aug-2020 02:50

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1241

Site Name: (1241) Hospital Irma Dulce

Subject No: 12411468

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 19:09

**1.b Inclusion Number:**

Date	Location	User	Value	Reason
Aug-25-2020 10:15:32 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 2	Initial Entry

**1.b Criterion Description:**

Date	Location	User	Value	Reason
Aug-25-2020 10:15:32 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Participants who are willing and able to co mply with all schedul ed visits, vaccination plan, laboratory tests, lifestyle consideratio ns, and other study pr ocedures	Initial Entry

**1.b Criterion met?**

Date	Location	User	Value	Reason
Aug-25-2020 10:15:32 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

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

Date	Location	User	Value	Reason
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090177e196ae3f49\Final\Final On: 01-Apr-2021 05:15 (GMT)



Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form: INCLUSION/EXCLUSION CRITERIA - eCRF  
Audit Trail History

Form Version: 21-Aug-2020 02:50

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1241

Site Name: (1241) Hospital Irma Dulce

Subject No: 12411468

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 19:09

Aug-25-2020 10:15:32 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> IN02A00	Initial Entry
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*I.c*

Date	Location	User	Value	Reason
Aug-25-2020 10:15:32 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Incl 3</b> <b>usio</b> <b>n N</b> <b>umb</b> <b>er:</b> <b>Crit</b> Healthy partici <b>erio</b> pants who are <b>n De</b> determined by <b>scri</b> medical history <b>ptio</b> , physical exa <b>n:</b> mination, and c linical judge nt of the invest igator to be eli gible for inclus ion in the study  <b>Crit</b> YES <b>erio</b> <b>n m</b> <b>et?:</b>	Initial Entry

090177e196ae3f49\Final\Final On: 01-Apr-2021 05:15 (GMT)

**Header Text:** c4591001

**Visit:** V1\_DAY1\_VAX1\_L

**Form:** INCLUSION/EXCLUSION CRITERIA - eCRF  
Audit Trail History

**Form Version:** 21-Aug-2020 02:50

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site No:** 1241

**Site Name:** (1241) Hospital Irma Dulce

**Subject No:** 12411468

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 19:09

			<b>Crit IN03A00 erion ID : (F or P fizer use only ):</b>	
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**Header Text:** c4591001

**Visit:** V1\_DAY1\_VAX1\_L

**Form:** INCLUSION/EXCLUSION CRITERIA - eCRF  
Audit Trail History

**Form Version:** 21-Aug-2020 02:50

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site No:** 1241

**Site Name:** (1241) Hospital Irma Dulce

**Subject No:** 12411468

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 19:09

***1.c Inclusion Number:***

Date	Location	User	Value	Reason
Aug-25-2020 10:15:32 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 3	Initial Entry

***1.c Criterion Description:***

Date	Location	User	Value	Reason
Aug-25-2020 10:15:32 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Healthy participants who are determined b y medical history, ph ysical examination, a nd clinical judgment of the investigator to be eligible for inclusi on in the study	Initial Entry

***1.c Criterion met?***

Date	Location	User	Value	Reason
Aug-25-2020 10:15:32 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

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

Date	Location	User	Value	Reason
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090177e196ae3f49\Final\Final On: 01-Apr-2021 05:15 (GMT)

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form: INCLUSION/EXCLUSION CRITERIA - eCRF  
Audit Trail History

Form Version: 21-Aug-2020 02:50

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1241

Site Name: (1241) Hospital Irma Dulce

Subject No: 12411468

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 19:09

Aug-25-2020 10:15:32 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> IN03A00	Initial Entry
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*1.d*

Date	Location	User	Value	Reason
Aug-25-2020 10:15:32 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Incl 4</b> <b>usio</b> <b>n N</b> <b>umb</b> <b>er:</b> <b>Crit</b> Capable of giv <b>erio</b> ing personal si <b>n De</b> gned informed <b>scri</b> consent, which <b>ptio</b> includes compl <b>n:</b> iance with the requirements a nd restrictions listed in the IC D and in this p rotocol  <b>Crit</b> YES <b>erio</b> <b>n m</b> <b>et?:</b>	Initial Entry

090177e196ae3f49\Final\Final On: 01-Apr-2021 05:15 (GMT)

**Header Text:** c4591001

**Visit:** V1\_DAY1\_VAX1\_L

**Form:** INCLUSION/EXCLUSION CRITERIA - eCRF  
Audit Trail History

**Form Version:** 21-Aug-2020 02:50

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site No:** 1241

**Site Name:** (1241) Hospital Irma Dulce

**Subject No:** 12411468

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 19:09

			<b>Crit IN04A00 erio n ID : (Fo r Pfi zer use only ):</b>	
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Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form: INCLUSION/EXCLUSION CRITERIA - eCRF  
Audit Trail History

Form Version: 21-Aug-2020 02:50

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1241

Site Name: (1241) Hospital Irma Dulce

Subject No: 12411468

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 19:09

***1.d Inclusion Number:***

Date	Location	User	Value	Reason
Aug-25-2020 10:15:32 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 4	Initial Entry

***1.d Criterion Description:***

Date	Location	User	Value	Reason
Aug-25-2020 10:15:32 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Capable of giving per sonal signed informe d consent, which incl udes compliance with the requirements and restrictions listed in t he ICD and in this pr otocol	Initial Entry

***1.d Criterion met?***

Date	Location	User	Value	Reason
Aug-25-2020 10:15:32 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

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

Date	Location	User	Value	Reason
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090177e196ae3f49\Final\Final On: 01-Apr-2021 05:15 (GMT)

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form: INCLUSION/EXCLUSION CRITERIA - eCRF  
Audit Trail History

Form Version: 21-Aug-2020 02:50

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1241

Site Name: (1241) Hospital Irma Dulce

Subject No: 12411468

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 19:09

Aug-25-2020 10:15:32 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> IN04A00	Initial Entry
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2.a

Date	Location	User	Value	Reason
Aug-25-2020 10:15:32 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Excl 1 usio n N umb er: Crit Other medical erio or psychiatric c n De ondition incl. r scri ecent (within p ptio ast year) or acti n: ve suicidal idea tion/behavior/l ab abnormality that may increa se the risk of st udy participati on Crit NO erio n m et?:	Initial Entry

090177e196ae3f49\Final\Final On: 01-Apr-2021 05:15 (GMT)

**Header Text:** c4591001

**Visit:** V1\_DAY1\_VAX1\_L

**Form:** INCLUSION/EXCLUSION CRITERIA - eCRF  
Audit Trail History

**Form Version:** 21-Aug-2020 02:50

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site No:** 1241

**Site Name:** (1241) Hospital Irma Dulce

**Subject No:** 12411468

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 19:09

			<b>Crit EX01A00 erion ID : (F or P fizer use only ):</b>	
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**2.a Exclusion Number:**

Date	Location	User	Value	Reason
Aug-25-2020 10:15:32 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 1	Initial Entry

**2.a Criterion Description:**

Date	Location	User	Value	Reason
Aug-25-2020 10:15:32 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Other medical or psy chiatric condition incl . recent (within past y ear) or active suicidal ideation/behavior/lab abnormality that may increase the risk of st udy participation	Initial Entry

**2.a Criterion met?**

090177e196ae3f49\Final\Final On: 01-Apr-2021 05:15 (GMT)



Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form: INCLUSION/EXCLUSION CRITERIA - eCRF  
Audit Trail History

Form Version: 21-Aug-2020 02:50

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1241

Site Name: (1241) Hospital Irma Dulce

Subject No: 12411468

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 19:09

Date	Location	User	Value	Reason
Aug-25-2020 10:15:32 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

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

Date	Location	User	Value	Reason
Aug-25-2020 10:15:32 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> EX01A00	Initial Entry

*2.b*

Date	Location	User	Value	Reason
Aug-25-2020 10:15:32 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Excl 2</b> <b>usion</b> <b>Num</b> <b>ber:</b> <b>Crite</b> Known infecti <b>riou</b> on with huma <b>Desc</b> n immunodefi <b>riptio</b> ciency virus ( <b>n:</b> HIV), hepatiti s C virus (HC V), or hepatiti s B virus (HB V)	Initial Entry

090177e196ae3f49\Final\Final On: 01-Apr-2021 05:15 (GMT)



Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form: INCLUSION/EXCLUSION CRITERIA - eCRF  
Audit Trail History

Form Version: 21-Aug-2020 02:50

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1241

Site Name: (1241) Hospital Irma Dulce

Subject No: 12411468

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 19:09

**2.b Exclusion Number:**

Date	Location	User	Value	Reason
Aug-25-2020 10:15:32 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 2	Initial Entry

**2.b Criterion Description:**

Date	Location	User	Value	Reason
Aug-25-2020 10:15:32 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Known infection with human immunodefici ency virus (HIV), hep atitis C virus (HCV), or hepatitis B virus ( HBV)	Initial Entry

**2.b Criterion met?**

Date	Location	User	Value	Reason
Aug-25-2020 10:15:32 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

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

Date	Location	User	Value	Reason
Aug-25-2020 10:15:32	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> EX02A00	Initial Entry

090177e196ae3f49\Final\Final On: 01-Apr-2021 05:15 (GMT)

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

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

Site No: 1241

Site Name: (1241) Hospital Irma Dulce

Subject No: 12411468

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 19:09

(UTC-03:00) City  
of Buenos Aires

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

2.c

Date	Location	User	Value	Reason
Aug-25-2020 10:15:32 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Excl 3</b> <b>usio</b> <b>n N</b> <b>umb</b> <b>er:</b> <b>Crit</b> History of severe <b>erio</b> re adverse reac <b>n De</b> tion associated <b>scri</b> with a vaccine <b>ptio</b> and/or severe a <b>n:</b> llergic reaction (eg, anaphylax is) to any com ponent of the s tudy interventi on(s)  <b>Crit</b> NO <b>erio</b> <b>n m</b> <b>et?:</b>	Initial Entry

090177e196ae3f49\Final\Final On: 01-Apr-2021 05:15 (GMT)

**Header Text:** c4591001

**Visit:** V1\_DAY1\_VAX1\_L

**Form:** INCLUSION/EXCLUSION CRITERIA - eCRF  
Audit Trail History

**Form Version:** 21-Aug-2020 02:50

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site No:** 1241

**Site Name:** (1241) Hospital Irma Dulce

**Subject No:** 12411468

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 19:09

			<b>Crit EX03A00 erio n ID : (Fo r Pfi zer use only ):</b>	
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Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form: INCLUSION/EXCLUSION CRITERIA - eCRF  
Audit Trail History

Form Version: 21-Aug-2020 02:50

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1241

Site Name: (1241) Hospital Irma Dulce

Subject No: 12411468

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 19:09

**2.c Exclusion Number:**

Date	Location	User	Value	Reason
Aug-25-2020 10:15:32 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 3	Initial Entry

**2.c Criterion Description:**

Date	Location	User	Value	Reason
Aug-25-2020 10:15:32 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> History of severe adverse reaction associated with a vaccine and /or severe allergic reaction (eg, anaphylaxis ) to any component of the study intervention (s)	Initial Entry

**2.c Criterion met?**

Date	Location	User	Value	Reason
Aug-25-2020 10:15:32 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

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

Date	Location	User	Value	Reason
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**Header Text:** c4591001

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**Form Status:** Data Complete, Locked, Frozen, Verified

**Site No:** 1241

**Site Name:** (1241) Hospital Irma Dulce

**Subject No:** 12411468

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 19:09

Aug-25-2020 10:15:32 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> EX03A00	Initial Entry
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**2.d**

Date	Location	User	Value	Reason
Aug-25-2020 10:15:32 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Exclusion Number:</b> 4 <b>Criterion Description:</b> Receipt of medication is intended to prevent COVID-19 <b>Criterion met?:</b> NO <b>Criterion ID: (Formerly):</b> EX04A00	Initial Entry

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Site No: 1241

Site Name: (1241) Hospital Irma Dulce

Subject No: 12411468

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 19:09

**2.d Exclusion Number:**

Date	Location	User	Value	Reason
Aug-25-2020 10:15:32 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 4	Initial Entry

**2.d Criterion Description:**

Date	Location	User	Value	Reason
Aug-25-2020 10:15:32 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Receipt of medication s intended to prevent COVID-19	Initial Entry

**2.d Criterion met?**

Date	Location	User	Value	Reason
Aug-25-2020 10:15:32 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

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

Date	Location	User	Value	Reason
Aug-25-2020 10:15:32 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> EX04A00	Initial Entry

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Form Status: Data Complete, Locked, Frozen, Verified

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Subject No: 12411468

Subject Initials: ---

Generated By: (b) (4)

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2.e

Date	Location	User	Value	Reason
Aug-25-2020 10:15:32 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Excl 8</b> <b>usio</b> <b>n Nu</b> <b>mbe</b> <b>r:</b> <b>Crit Immunocompr</b> <b>erio omised individ</b> <b>n De uals with kno</b> <b>scrip wn or suspecte</b> <b>tion: d immunodef</b> <b>ciency, as dete</b> <b>rmined by hist</b> <b>ory and/or lab</b> <b>oratory/physic</b> <b>al examination</b>  <b>Crit NO</b> <b>erio</b> <b>n me</b> <b>t?:</b> <b>Crit EX08A00</b> <b>erio</b> <b>n ID</b> <b>: (Fo</b> <b>r Pfi</b> <b>zer u</b> <b>se on</b> <b>ly):</b>	Initial Entry

090177e196ae3f49\Final\Final On: 01-Apr-2021 05:15 (GMT)

**Header Text:** c4591001

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**Site Name:** (1241) Hospital Irma Dulce

**Subject No:** 12411468

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 19:09

**2.e Exclusion Number:**

Date	Location	User	Value	Reason
Aug-25-2020 10:15:32 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 8	Initial Entry

**2.e Criterion Description:**

Date	Location	User	Value	Reason
Aug-25-2020 10:15:32 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Immunocompromised individuals with kno wn or suspected imm unodeficiency, as dete rmined by history and /or laboratory/physica l examination	Initial Entry

**2.e Criterion met?**

Date	Location	User	Value	Reason
Aug-25-2020 10:15:32 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

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

Date	Location	User	Value	Reason
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Site Name: (1241) Hospital Irma Dulce

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Subject Initials: ---

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Aug-25-2020 10:15:32 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> EX08A00	Initial Entry
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2.f

Date	Location	User	Value	Reason
Aug-25-2020 10:15:32 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Excl 10 usio n Nu mbe r: Crit Bleeding diath erio esis or conditio n De n associated wi scri th prolonged bl ptio eeding that wo n: uld, in the opin ion of the inve stigator, contra indicate intram uscular injecti on Crit NO erio n me t?:	Initial Entry

090177e196ae3f49\Final\Final On: 01-Apr-2021 05:15 (GMT)

**Header Text:** c4591001

**Visit:** V1\_DAY1\_VAX1\_L

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**Site No:** 1241

**Site Name:** (1241) Hospital Irma Dulce

**Subject No:** 12411468

**Subject Initials:** ---

**Generated By:** (b) (4)

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			<b>Crit EX10A00 erio n ID : (Fo r Pfi zer use only ):</b>	
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Header Text: c4591001

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Site Name: (1241) Hospital Irma Dulce

Subject No: 12411468

Subject Initials: ---

Generated By: (b) (4)

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**2.f Exclusion Number:**

Date	Location	User	Value	Reason
Aug-25-2020 10:15:32 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 10	Initial Entry

**2.f Criterion Description:**

Date	Location	User	Value	Reason
Aug-25-2020 10:15:32 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Bleeding diathesis or condition associated with prolonged bleedi ng that would, in the opinion of the investi gator, contraindicate i ntramuscular injectio n	Initial Entry

**2.f Criterion met?**

Date	Location	User	Value	Reason
Aug-25-2020 10:15:32 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

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

Date	Location	User	Value	Reason
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**Site Name:** (1241) Hospital Irma Dulce

**Subject No:** 12411468

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 19:09

Aug-25-2020 10:15:32 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> EX10A00	Initial Entry
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2.g

Date	Location	User	Value	Reason
Aug-25-2020 10:15:32 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Exclusion Number:</b> 11 <b>Criterion Description:</b> Women who are pregnant or breastfeeding <b>Criterion met?:</b> NO <b>Criterion ID: (For Pfizer use only):</b> EX11A00	Initial Entry

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**Header Text:** c4591001

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**Site No:** 1241

**Site Name:** (1241) Hospital Irma Dulce

**Subject No:** 12411468

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 19:09

**2.g Exclusion Number:**

Date	Location	User	Value	Reason
Aug-25-2020 10:15:32 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 11	Initial Entry

**2.g Criterion Description:**

Date	Location	User	Value	Reason
Aug-25-2020 10:15:32 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Women who are preg nant or breastfeeding	Initial Entry

**2.g Criterion met?**

Date	Location	User	Value	Reason
Aug-25-2020 10:15:32 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

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

Date	Location	User	Value	Reason
Aug-25-2020 10:15:32 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> EX11A00	Initial Entry

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**Subject No:** 12411468

**Subject Initials:** ---

**Generated By:** (b) (4)

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**2.h**

Date	Location	User	Value	Reason
Aug-25-2020 10:15:32 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Exclusion Number:</b> <b>Criterion Description:</b> Previous vaccination with any coronavirus vaccine <b>Criterion met?:</b> NO <b>Criterion ID: (For Pfizer use only):</b> EX12A00	Initial Entry

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**Header Text:** c4591001

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**Form Status:** Data Complete, Locked, Frozen, Verified

**Site No:** 1241

**Site Name:** (1241) Hospital Irma Dulce

**Subject No:** 12411468

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 19:09

**2.h Exclusion Number:**

Date	Location	User	Value	Reason
Aug-25-2020 10:15:32 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 12	Initial Entry

**2.h Criterion Description:**

Date	Location	User	Value	Reason
Aug-25-2020 10:15:32 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Previous vaccination with any coronavirus vaccine	Initial Entry

**2.h Criterion met?**

Date	Location	User	Value	Reason
Aug-25-2020 10:15:32 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

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

Date	Location	User	Value	Reason
Aug-25-2020 10:15:32 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> EX12A00	Initial Entry

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**Site Name:** (1241) Hospital Irma Dulce

**Subject No:** 12411468

**Subject Initials:** ---

**Generated By:** (b) (4)

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2.i

Date	Location	User	Value	Reason
Aug-25-2020 10:15:32 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Exclusion Number:</b> <b>Criterion Description:</b> Subjects who receive immunosuppressive therapy, such as cytotoxic agents or systemic corticosteroids <b>Criterion met?:</b> <b>Criterion ID:</b> EX13A01 <b>D: (For Pfizer use only):</b>	Initial Entry

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Site Name: (1241) Hospital Irma Dulce

Subject No: 12411468

Subject Initials: ---

Generated By: (b) (4)

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**2.i Exclusion Number:**

Date	Location	User	Value	Reason
Aug-25-2020 10:15:32 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 13	Initial Entry

**2.i Criterion Description:**

Date	Location	User	Value	Reason
Aug-25-2020 10:15:32 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Subjects who receive immunosuppressive t herapy, such as cyto toxic agents or systemi c corticosteroids	Initial Entry

**2.i Criterion met?**

Date	Location	User	Value	Reason
Aug-25-2020 10:15:32 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

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

Date	Location	User	Value	Reason
Aug-25-2020 10:15:32 (UTC-03:00) City	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> EX13A01	Initial Entry

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of Buenos Aires

2.j

Date	Location	User	Value	Reason
Aug-25-2020 10:15:32 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Excl 15</b> <b>usio</b> <b>n Nu</b> <b>mbe</b> <b>r:</b> <b>Crit</b> Receipt of blo <b>erio</b> od/plasma pro <b>n De</b> ducts or immu <b>scrip</b> noglobulin, fro <b>tion:</b> m 60 days bef ore study inter vention admini stration or plan ned receipt thr oughout the st udy <b>Crit</b> NO <b>erio</b> <b>n me</b> <b>t?:</b>	Initial Entry

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			<b>Crit EX14A01 erio n ID : (Fo r Pfi zer use only ):</b>	
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**2.j Exclusion Number:**

Date	Location	User	Value	Reason
Aug-25-2020 10:15:32 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 15	Initial Entry

**2.j Criterion Description:**

Date	Location	User	Value	Reason
Aug-25-2020 10:15:32 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Receipt of blood/plasma products or immunoglobulin, from 60 days before study intervention administration or planned receipt throughout the study	Initial Entry

**2.j Criterion met?**

Date	Location	User	Value	Reason
Aug-25-2020 10:15:32 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

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

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**Subject Initials:** ---

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Aug-25-2020 10:15:32 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> EX14A01	Initial Entry
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2.k

Date	Location	User	Value	Reason
Aug-25-2020 10:15:32 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<p><b>Data Entry:</b></p> <p><b>Excl 16</b></p> <p><b>usio</b></p> <p><b>n Nu</b></p> <p><b>mbe</b></p> <p><b>r:</b></p> <p><b>Crite</b> Participation i</p> <p><b>tion</b> n other studie</p> <p><b>Desc</b> s involving st</p> <p><b>ripti</b> udy interventi</p> <p><b>on:</b> on within 28</p> <p>days prior to s</p> <p>tudy entry and</p> <p>/or during stu</p> <p>dy participati</p> <p>on</p> <p><b>Crite</b> NO</p> <p><b>tion</b></p> <p><b>met?</b></p> <p>:</p> <p><b>Crite</b> EX15A01</p> <p><b>tion</b></p> <p><b>ID:</b> (</p> <p><b>For</b></p> <p><b>Pfize</b></p> <p><b>r use</b></p> <p><b>only)</b></p> <p>:</p>	Initial Entry

090177e196ae3f49\Final\Final On: 01-Apr-2021 05:15 (GMT)



Header Text: c4591001

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Aug-25-2020 10:15:32 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 16	Initial Entry

**2.k Criterion Description:**

Date	Location	User	Value	Reason
Aug-25-2020 10:15:32 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Participation in other studies involving stu dy intervention withi n 28 days prior to stu dy entry and/or durin g study participation	Initial Entry

**2.k Criterion met?**

Date	Location	User	Value	Reason
Aug-25-2020 10:15:32 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

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

Date	Location	User	Value	Reason
Aug-25-2020 10:15:32	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> EX15A01	Initial Entry

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Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1241

Site Name: (1241) Hospital Irma Dulce

Subject No: 12411468

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 19:09

(UTC-03:00) City of Buenos Aires	(b) (4), (b) (6)
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2.1

Date	Location	User	Value	Reason
Aug-25-2020 10:15:32 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<p><b>Data Entry:</b></p> <p><b>Exclusion Number:</b></p> <p><b>Criterion Description:</b> Previous participation in other studies involving study intervention containing lipid nanoparticles</p> <p><b>Criterion met?:</b> NO</p> <p><b>Criterion ID: (For Pfizer use only):</b> EX16A01</p>	Initial Entry

090177e196ae3f49\Final\Final On: 01-Apr-2021 05:15 (GMT)

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form: INCLUSION/EXCLUSION CRITERIA - eCRF  
Audit Trail History

Form Version: 21-Aug-2020 02:50

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1241

Site Name: (1241) Hospital Irma Dulce

Subject No: 12411468

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 19:09

**2.1 Exclusion Number:**

Date	Location	User	Value	Reason
Aug-25-2020 10:15:32 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 17	Initial Entry

**2.1 Criterion Description:**

Date	Location	User	Value	Reason
Aug-25-2020 10:15:32 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Previous participatio n in other studies inv olving study interven tion containing lipid nanoparticles	Initial Entry

**2.1 Criterion met?**

Date	Location	User	Value	Reason
Aug-25-2020 10:15:32 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**2.1 Criterion ID: (For Pfizer use only)**

Date	Location	User	Value	Reason
Aug-25-2020 10:15:32 (UTC-03:00) City	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> EX16A01	Initial Entry

090177e196ae3f49\Final\Final On: 01-Apr-2021 05:15 (GMT)

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form: INCLUSION/EXCLUSION CRITERIA - eCRF  
Audit Trail History

Form Version: 21-Aug-2020 02:50

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1241

Site Name: (1241) Hospital Irma Dulce

Subject No: 12411468

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 19:09

of Buenos Aires				
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**2.m**

Date	Location	User	Value	Reason
Aug-25-2020 10:15:32 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Excl 22</b> <b>usio</b> <b>n N</b> <b>um</b> <b>ber:</b> <b>Crit</b> Investigator sit <b>erio</b> e staff or Pfize <b>n D</b> r employees di <b>escr</b> rectly involved <b>ipti</b> in the conduct <b>on:</b> of the study, sit e staff otherwi se supervised b y the investigat or, and their re spective famil y members  <b>Crit</b> NO <b>erio</b> <b>n m</b> <b>et?:</b>	Initial Entry

090177e196ae3f49\Final\Final On: 01-Apr-2021 05:15 (GMT)

**Header Text:** c4591001

**Visit:** V1\_DAY1\_VAX1\_L

**Form Version:** 21-Aug-2020 02:50

**Site No:** 1241

**Subject No:** 12411468

**Generated By:** (b) (4)

**Form:** INCLUSION/EXCLUSION CRITERIA - eCRF  
Audit Trail History

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site Name:** (1241) Hospital Irma Dulce

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 19:09

			<b>Crit EX21A01 erion ID : (F or P fize r us e on ly):</b>	
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Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form: INCLUSION/EXCLUSION CRITERIA - eCRF  
Audit Trail History

Form Version: 21-Aug-2020 02:50

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1241

Site Name: (1241) Hospital Irma Dulce

Subject No: 12411468

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 19:09

**2.m Exclusion Number:**

Date	Location	User	Value	Reason
Aug-25-2020 10:15:32 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 22	Initial Entry

**2.m Criterion Description:**

Date	Location	User	Value	Reason
Aug-25-2020 10:15:32 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Investigator site staff or Pfizer employees directly involved in t he conduct of the stu dy, site staff otherwis e supervised by the i nvestigator, and their respective family me mbers	Initial Entry

**2.m Criterion met?**

Date	Location	User	Value	Reason
Aug-25-2020 10:15:32 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**2.m Criterion ID: (For Pfizer use only)**

090177e196ae3f49\Final\Final On: 01-Apr-2021 05:15 (GMT)

**Header Text:** c4591001

**Visit:** V1\_DAY1\_VAX1\_L

**Form:** INCLUSION/EXCLUSION CRITERIA - eCRF  
Audit Trail History

**Form Version:** 21-Aug-2020 02:50

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site No:** 1241

**Site Name:** (1241) Hospital Irma Dulce

**Subject No:** 12411468

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 19:09

Date	Location	User	Value	Reason
Aug-25-2020 10:15:32 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> EX21A01	Initial Entry

**Header Text:** c4591001

**Visit:** V1\_DAY1\_VAX1\_L

**Form:** DISPOSITION - SCREENING - eCRF Audit Trail History

**Form Version:** 22-Apr-2020 21:03

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site No:** 1241

**Site Name:** (1241) Hospital Irma Dulce

**Subject No:** 12411468

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 19:09

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**1. Date of Completion/Discontinuation/Death**

Date	Location	User	Value	Reason
Aug-25-2020 10:15:41 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Aug/25/2020	Initial Entry

**2. Phase of Disposition:**

Date	Location	User	Value	Reason
Aug-25-2020 10:15:41 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SCREENING	Initial Entry

**3. Status:**

Date	Location	User	Value	Reason
Aug-25-2020 10:15:41 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> COMPLETED	Initial Entry

090177e196ae3f49\Final\Final On: 01-Apr-2021 05:15 (GMT)



**Header Text:** c4591001

**Visit:** V1\_DAY1\_VAX1\_L

**Form:** GENERAL MEDICAL HISTORY - eCRF Audit Trail History

**Form Version:** 22-Apr-2020 21:03

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site No:** 1241

**Site Name:** (1241) Hospital Irma Dulce

**Subject No:** 12411468

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 19:09

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*1.a*

Date	Location	User	Value	Reason
Aug-25-2020 10:16:57 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Line/MH Number:</b> 1 <b>Medical History Term:</b> Cholecystectomy <b>Start Date:</b> May/UNK /2019 <b>Ongoing:</b> NO End Date: May/UNK/2019	Initial Entry

*1.a Line/MH Number:*

Date	Location	User	Value	Reason
Aug-25-2020 10:16:57 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 1	Initial Entry

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

Date	Location	User	Value	Reason
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090177e196ae3f49\Final\Final On: 01-Apr-2021 05:15 (GMT)

**Header Text:** c4591001

**Visit:** V1\_DAY1\_VAX1\_L

**Form:** GENERAL MEDICAL HISTORY - eCRF Audit Trail History

**Form Version:** 22-Apr-2020 21:03

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site No:** 1241

**Site Name:** (1241) Hospital Irma Dulce

**Subject No:** 12411468

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 19:09

Aug-25-2020 10:16:57 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Cholecystectomy	Initial Entry
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**1.a Start Date:**

Date	Location	User	Value	Reason
Aug-25-2020 10:16:57 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> May/UNK/2019	Initial Entry

**1.a Ongoing:**

Date	Location	User	Value	Reason
Aug-25-2020 10:16:57 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO End Date: May/UNK/2019	Initial Entry

090177e196ae3f49\Final\Final On: 01-Apr-2021 05:15 (GMT)

**Header Text:** c4591001

**Visit:** V1\_DAY1\_VAX1\_L

**Form:** VITAL SIGNS - BASELINE - eCRF Audit Trail History

**Form Version:** 21-Aug-2020 02:51

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site No:** 1241

**Site Name:** (1241) Hospital Irma Dulce

**Subject No:** 12411468

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 19:09

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**1. Date:**

Date	Location	User	Value	Reason
Aug-25-2020 10:17:28 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Aug/25/2020	Initial Entry

**2. Weight:**

Date	Location	User	Value	Reason
Aug-25-2020 10:17:28 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 69.7	Initial Entry

**3. Unit:**

Date	Location	User	Value	Reason
Aug-25-2020 10:17:28 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> kg	Initial Entry

**4. Height:**

Date	Location	User	Value	Reason
Aug-25-2020 10:17:28	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 165.5	Initial Entry

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Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form: VITAL SIGNS - BASELINE - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:51

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1241

Site Name: (1241) Hospital Irma Dulce

Subject No: 12411468

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 19:09

(UTC-03:00) City of Buenos Aires	(b) (4), (b) (6)
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5. Unit:

Date	Location	User	Value	Reason
Aug-25-2020 10:17:28 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> cm	Initial Entry

6. Body Mass Index:

Date	Location	User	Value	Reason
Aug-25-2020 10:17:28 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 25.4	Initial Entry

7.a

Date	Location	User	Value	Reason
Aug-25-2020 10:17:28 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Record Identifier::</b> <b>Temperature:</b> 37.1 <b>Temperature Unit:</b> <b>Temperature Location:</b> ORAL CAVIT <b>::</b> Y	Initial Entry

090177e196ae3f49\Final\Final On: 01-Apr-2021 05:15 (GMT)

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form: VITAL SIGNS - BASELINE - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:51

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1241

Site Name: (1241) Hospital Irma Dulce

Subject No: 12411468

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 19:09

7.a Record Identifier:

Date	Location	User	Value	Reason
Aug-25-2020 10:17:28 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 1	Initial Entry

7.a Temperature:

Date	Location	User	Value	Reason
Aug-25-2020 10:17:28 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 37.1	Initial Entry

7.a Unit:

Date	Location	User	Value	Reason
Aug-25-2020 10:17:28 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> C	Initial Entry

7.a Temperature Location:

Date	Location	User	Value	Reason
Aug-25-2020 10:17:28 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> ORAL CAVITY	Initial Entry

090177e196ae3f49\Final\Final On: 01-Apr-2021 05:15 (GMT)

**Header Text:** c4591001

**Visit:** V1\_DAY1\_VAX1\_L

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

**Form Version:** 21-Aug-2020 02:49

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site No:** 1241

**Site Name:** (1241) Hospital Irma Dulce

**Subject No:** 12411468

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 19:09

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**1. Lab Panel:**

Date	Location	User	Value	Reason
Aug-25-2020 10:17:39 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> URINALYSIS	Initial Entry

**2. Lab Sub-Panel:**

Date	Location	User	Value	Reason
Aug-25-2020 10:17:39 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> PREGNANCY	Initial Entry

**3. Collection Date:**

Date	Location	User	Value	Reason
Aug-25-2020 10:17:39 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Aug/25/2020	Initial Entry

**4. Laboratory Name and Address (Derived)**

Date	Location	User	Value	Reason
Aug-25-2020 10:17:39	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> STUDY SITE	Initial Entry

090177e196ae3f49\Final\Final On: 01-Apr-2021 05:15 (GMT)

**Header Text:** c4591001

**Visit:** V1\_DAY1\_VAX1\_L

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

**Form Version:** 21-Aug-2020 02:49

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site No:** 1241

**Site Name:** (1241) Hospital Irma Dulce

**Subject No:** 12411468

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 19:09

(UTC-03:00) City of Buenos Aires

**5. Specimen Type:**

Date	Location	User	Value	Reason
Aug-25-2020 10:17:39 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> URINE	Initial Entry

**6.a**

Date	Location	User	Value	Reason
Aug-25-2020 10:17:39 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Sponsor-</b> 113 <b>Defined Identifier:</b> <b>Test::</b> Choriogon adotropin Beta_PX11 3 <b>Result::</b> NEGATIV E <b>Not Done</b> ::	Initial Entry

**6.a Sponsor ID:**

Date	Location	User	Value	Reason
Aug-25-2020 10:17:39	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 113	Initial Entry

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**Header Text:** c4591001

**Visit:** V1\_DAY1\_VAX1\_L

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

**Form Version:** 21-Aug-2020 02:49

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site No:** 1241

**Site Name:** (1241) Hospital Irma Dulce

**Subject No:** 12411468

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 19:09

(UTC-03:00) City of Buenos Aires				
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**6.a Test:**

Date	Location	User	Value	Reason
Aug-25-2020 10:17:39 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Choriogonadotropin Beta_PX113	Initial Entry

**6.a Result:**

Date	Location	User	Value	Reason
Aug-25-2020 10:17:39 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NEGATIVE	Initial Entry

090177e196ae3f49\Final\Final On: 01-Apr-2021 05:15 (GMT)



**Header Text:** c4591001

**Visit:** V1\_DAY1\_VAX1\_L

**Form Version:** 22-Apr-2020 21:03

**Site No:** 1241

**Subject No:** 12411468

**Generated By:** (b) (4)

**Form:** RANDOMIZATION - eCRF Audit Trail History

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site Name:** (1241) Hospital Irma Dulce

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 19:09

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**1. Randomization Date :**

Date	Location	User	Value	Reason
Aug-25-2020 10:17:51 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Aug/25/2020	Initial Entry

**2. Randomization Number:**

Date	Location	User	Value	Reason
Aug-25-2020 10:17:51 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 64867	Initial Entry

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**Header Text:** c4591001

**Visit:** V1\_DAY1\_VAX1\_L

**Form Version:** 22-Apr-2020 21:03

**Site No:** 1241

**Subject No:** 12411468

**Generated By:** (b) (4)

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

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site Name:** (1241) Hospital Irma Dulce

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 19:09

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**1. Data Origin**

Date	Location	User	Value	Reason
Aug-25-2020 13:27:55 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SITE	Initial Entry

**2. Sample Type**

Date	Location	User	Value	Reason
Aug-25-2020 13:27:55 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SERUM	Initial Entry

**3. Sample Collected?**

Date	Location	User	Value	Reason
Aug-25-2020 13:28:04 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Aug-25-2020 13:27:55 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review

090177e196ae3f49\Final\Final On: 01-Apr-2021 05:15 (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: 1241

Site Name: (1241) Hospital Irma Dulce

Subject No: 12411468

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 19:09

				and correct as appropriate.
Aug-25-2020 13:27:55 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES Date of Collection:  Aug/25/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Aug-25-2020 13:28:04 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sample ID BPT0V : S	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Aug-25-2020 13:28:04 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BPT0VS	Initial Entry

5.b

Date	Location	User	Value	Reason
Aug-25-2020 13:28:13 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sample ID BPT0V : T	Initial Entry

090177e196ae3f49\Final\Final On: 01-Apr-2021 05:15 (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:** 1241

**Site Name:** (1241) Hospital Irma Dulce

**Subject No:** 12411468

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 19:09

**5.b Sample ID**

Date	Location	User	Value	Reason
Aug-25-2020 13:28:13 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BPT0VT	Initial Entry

**5.c**

Date	Location	User	Value	Reason
Aug-25-2020 13:28:21 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sample ID BPT0W : 8	Initial Entry

**5.c Sample ID**

Date	Location	User	Value	Reason
Aug-25-2020 13:28:21 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BPT0W8	Initial Entry

**5.d**

Date	Location	User	Value	Reason
Aug-25-2020 13:28:45 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sample ID BLCH4 : G	Initial Entry

090177e196ae3f49\Final\Final On: 01-Apr-2021 05:15 (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:** 1241

**Site Name:** (1241) Hospital Irma Dulce

**Subject No:** 12411468

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 19:09

**5.d Sample ID**

Date	Location	User	Value	Reason
Aug-25-2020 13:28:45 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BLCH4G	Initial Entry

**5.e**

Date	Location	User	Value	Reason
Aug-25-2020 13:28:52 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sample ID BLCH4 : H	Initial Entry

**5.e Sample ID**

Date	Location	User	Value	Reason
Aug-25-2020 13:28:52 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BLCH4H	Initial Entry

090177e196ae3f49\Final\Final On: 01-Apr-2021 05:15 (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:** 1241

**Site Name:** (1241) Hospital Irma Dulce

**Subject No:** 12411468

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 19:09

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**1. Data Origin**

Date	Location	User	Value	Reason
Aug-25-2020 13:29:04 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SITE	Initial Entry

**2. Sample Type**

Date	Location	User	Value	Reason
Aug-25-2020 13:29:04 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> NASAL_SWAB	Initial Entry

**3. Sample Collected?**

Date	Location	User	Value	Reason
Aug-25-2020 13:29:21 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Aug-25-2020 13:29:04 (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

090177e196ae3f49\Final\Final On: 01-Apr-2021 05:15 (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: 1241

Site Name: (1241) Hospital Irma Dulce

Subject No: 12411468

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 19:09

				and correct as appropriate.
Aug-25-2020 13:29:04 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES Date of Collection:  Aug/25/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Aug-25-2020 13:29:21 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample ID</b> BPT0V : Z	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Aug-25-2020 13:29:21 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BPT0VZ	Initial Entry

090177e196ae3f49\Final\Final On: 01-Apr-2021 05:15 (GMT)

**Header Text:** c4591001

**Visit:** V1\_DAY1\_VAX1\_L

**Form Version:** 22-Apr-2020 21:04

**Site No:** 1241

**Subject No:** 12411468

**Generated By:** (b) (4)

**Form:** VACCINATION - eCRF Audit Trail History

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site Name:** (1241) Hospital Irma Dulce

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 19:09

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**1. Was there a temporary delay of vaccination?**

Date	Location	User	Value	Reason
Aug-25-2020 10:18:28 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**2. Treatment Name**

Date	Location	User	Value	Reason
Aug-25-2020 10:18:28 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> BLINDED THERAPY	Initial Entry

**3. Formulation:**

Date	Location	User	Value	Reason
Aug-25-2020 10:18:28 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> INJECTION	Initial Entry

**4. Dose Date Time:**

Date	Location	User	Value	Reason
Aug-25-2020 10:18:28 (UTC-03:00) City	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Aug/25/2020 09:07	Initial Entry

090177e196ae3f49\Final\Final On: 01-Apr-2021 05:15 (GMT)



Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form: VACCINATION - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1241

Site Name: (1241) Hospital Irma Dulce

Subject No: 12411468

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 19:09

of Buenos Aires

**5. Anatomical Location:**

Date	Location	User	Value	Reason
Aug-25-2020 10:18:28 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> DELTOID MUSCLE	Initial Entry

**6. Body Side:**

Date	Location	User	Value	Reason
Aug-25-2020 10:18:28 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> LEFT	Initial Entry

**7. Route:**

Date	Location	User	Value	Reason
Aug-25-2020 10:18:28 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> INTRAMUSCULAR	Initial Entry

**10. Timeframe Subject Was Observed**

Date	Location	User	Value	Reason
Aug-25-2020 10:18:28 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> THE PROTOCOL SPE CIFIED OBSERVATIO N PERIOD	Initial Entry

090177e196ae3f49\Final\Final On: 01-Apr-2021 05:15 (GMT)

**Header Text:** c4591001

**Visit:** V1\_DAY1\_VAX1\_L

**Form:** VACCINATION - eCRF Audit Trail History

**Form Version:** 22-Apr-2020 21:04

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site No:** 1241

**Site Name:** (1241) Hospital Irma Dulce

**Subject No:** 12411468

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 19:09

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

Date	Location	User	Value	Reason
Aug-25-2020 10:18:28 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

**Header Text:** c4591001

**Visit:** V1\_DAY1\_VAX1\_L

**Form Version:** 06-Jul-2020 21:53

**Site No:** 1241

**Subject No:** 12411468

**Generated By:** (b) (4)

**Form:** REACTOGENICITY DIARY - eCRF Audit Trail History

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site Name:** (1241) Hospital Irma Dulce

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 19:09

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*1. Select appropriate response - Reactogenicity diary collection*

Date	Location	User	Value	Reason
Aug-25-2020 10:18:34 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO - REACTOGENI CITY E-DIARY NO T COLLECTED FO R THIS SUBJECT	Initial Entry

090177e196ae3f49\Final\Final On: 01-Apr-2021 05:15 (GMT)

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

**Form Version:** 22-Apr-2020 21:02

**Site No:** 1241

**Subject No:** 12411468

**Generated By:** (b) (4)

**Form:** DATE OF VISIT - eCRF Audit Trail History

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site Name:** (1241) Hospital Irma Dulce

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 19:09

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*1. Date of Visit*

Date	Location	User	Value	Reason
Sep-15-2020 10:48:30 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sep/15/2020	Initial Entry

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

**Form Version:** 21-Aug-2020 02:51

**Site No:** 1241

**Subject No:** 12411468

**Generated By:** (b) (4)

**Form:** VITAL SIGNS - TEMP - eCRF Audit Trail History

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site Name:** (1241) Hospital Irma Dulce

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 19:09

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**1. Date:**

Date	Location	User	Value	Reason
Sep-15-2020 10:48:45 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sep/15/2020	Initial Entry

**2.a**

Date	Location	User	Value	Reason
Sep-15-2020 10:48:45 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Record Identifier::</b> <b>Temperature:</b> 36.7 <b>Temperature Unit:</b> <b>Temperature Location:</b> ORAL CAVIT <b>:</b> Y	Initial Entry

**2.a Record Identifier:**

Date	Location	User	Value	Reason
Sep-15-2020 10:48:45 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 1	Initial Entry

090177e196ae3f49\Final\Final On: 01-Apr-2021 05:15 (GMT)

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

**Form:** VITAL SIGNS - TEMP - eCRF Audit Trail History

**Form Version:** 21-Aug-2020 02:51

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site No:** 1241

**Site Name:** (1241) Hospital Irma Dulce

**Subject No:** 12411468

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 19:09

**2.a Temperature:**

Date	Location	User	Value	Reason
Sep-15-2020 10:48:45 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 36.7	Initial Entry

**2.a Unit:**

Date	Location	User	Value	Reason
Sep-15-2020 10:48:45 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> C	Initial Entry

**2.a Temperature Location:**

Date	Location	User	Value	Reason
Sep-15-2020 10:48:45 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> ORAL CAVITY	Initial Entry

090177e196ae3f49\Final\Final On: 01-Apr-2021 05:15 (GMT)

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

**Form Version:** 21-Aug-2020 02:49

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site No:** 1241

**Site Name:** (1241) Hospital Irma Dulce

**Subject No:** 12411468

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 19:09

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**1. Lab Panel:**

Date	Location	User	Value	Reason
Sep-15-2020 10:48:55 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> URINALYSIS	Initial Entry

**2. Lab Sub-Panel:**

Date	Location	User	Value	Reason
Sep-15-2020 10:48:55 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> PREGNANCY	Initial Entry

**3. Collection Date:**

Date	Location	User	Value	Reason
Sep-15-2020 10:48:55 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sep/15/2020	Initial Entry

**4. Laboratory Name and Address (Derived)**

Date	Location	User	Value	Reason
Sep-15-2020 10:48:55	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> STUDY SITE	Initial Entry

090177e196ae3f49\Final\Final On: 01-Apr-2021 05:15 (GMT)

Header Text: c4591001

Visit: V2\_VAX2\_L

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

Form Version: 21-Aug-2020 02:49

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1241

Site Name: (1241) Hospital Irma Dulce

Subject No: 12411468

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 19:09

(UTC-03:00) City of Buenos Aires

5. Specimen Type:

Date	Location	User	Value	Reason
Sep-15-2020 10:48:55 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> URINE	Initial Entry

6.a

Date	Location	User	Value	Reason
Sep-15-2020 10:48:55 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> Sponsor- 113 Defined Identifier: Test:: Choriogon adotropin Beta_PX113 Result:: NEGATIVE Not Done ::	Initial Entry

6.a Sponsor ID:

Date	Location	User	Value	Reason
Sep-15-2020 10:48:55	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 113	Initial Entry

090177e196ae3f49\Final\Final On: 01-Apr-2021 05:15 (GMT)



**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

**Form Version:** 21-Aug-2020 02:49

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site No:** 1241

**Site Name:** (1241) Hospital Irma Dulce

**Subject No:** 12411468

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 19:09

(UTC-03:00) City of Buenos Aires				
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**6.a Test:**

Date	Location	User	Value	Reason
Sep-15-2020 10:48:55 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Choriogonadotropin Beta_PX113	Initial Entry

**6.a Result:**

Date	Location	User	Value	Reason
Sep-15-2020 10:48:55 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NEGATIVE	Initial Entry

090177e196ae3f49\Final\Final On: 01-Apr-2021 05:15 (GMT)

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

**Form Version:** 22-Apr-2020 21:03

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site No:** 1241

**Site Name:** (1241) Hospital Irma Dulce

**Subject No:** 12411468

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 19:09

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**1. Data Origin**

Date	Location	User	Value	Reason
Sep-15-2020 13:32:56 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SITE	Initial Entry

**2. Sample Type**

Date	Location	User	Value	Reason
Sep-15-2020 13:32:56 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> NASAL_SWAB	Initial Entry

**3. Sample Collected?**

Date	Location	User	Value	Reason
Sep-15-2020 13:33:03 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Sep-15-2020 13:32:56 (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

090177e196ae3f49\Final\Final On: 01-Apr-2021 05:15 (GMT)

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

**Form Version:** 22-Apr-2020 21:03

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site No:** 1241

**Site Name:** (1241) Hospital Irma Dulce

**Subject No:** 12411468

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 19:09

				and correct as appropriate.
Sep-15-2020 13:32:56 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES Date of Collection:  Sep/15/2020	Initial Entry

**5.a**

Date	Location	User	Value	Reason
Sep-15-2020 13:33:03 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample I</b> BPWYL <b>D:</b> M	Initial Entry

**5.a Sample ID**

Date	Location	User	Value	Reason
Sep-15-2020 13:33:03 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BPWYLM	Initial Entry

090177e196ae3f49\Final\Final On: 01-Apr-2021 05:15 (GMT)

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

**Form Version:** 22-Apr-2020 21:04

**Site No:** 1241

**Subject No:** 12411468

**Generated By:** (b) (4)

**Form:** VACCINATION - eCRF Audit Trail History

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site Name:** (1241) Hospital Irma Dulce

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 19:09

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**1. Was there a temporary delay of vaccination?**

Date	Location	User	Value	Reason
Sep-15-2020 10:49:46 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**2. Treatment Name**

Date	Location	User	Value	Reason
Sep-15-2020 10:49:46 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> BLINDED THERAPY	Initial Entry

**3. Formulation:**

Date	Location	User	Value	Reason
Sep-15-2020 10:49:46 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> INJECTION	Initial Entry

**4. Dose Date Time:**

Date	Location	User	Value	Reason
Sep-15-2020 10:49:46 (UTC-03:00) City	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sep/15/2020 09:00	Initial Entry

090177e196ae3f49\Final\Final On: 01-Apr-2021 05:15 (GMT)

Header Text: c4591001

Visit: V2\_VAX2\_L

Form: VACCINATION - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1241

Site Name: (1241) Hospital Irma Dulce

Subject No: 12411468

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 19:09

of Buenos Aires

5. Anatomical Location:

Date	Location	User	Value	Reason
Sep-15-2020 10:49:46 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> DELTOID MUSCLE	Initial Entry

6. Body Side:

Date	Location	User	Value	Reason
Sep-15-2020 10:49:46 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> LEFT	Initial Entry

7. Route:

Date	Location	User	Value	Reason
Sep-15-2020 10:49:46 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> INTRAMUSCULAR	Initial Entry

10. Timeframe Subject Was Observed

Date	Location	User	Value	Reason
Sep-15-2020 10:49:46 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> THE PROTOCOL SPE CIFIED OBSERVATIO N PERIOD	Initial Entry

090177e196ae3f49\Final\Final On: 01-Apr-2021 05:15 (GMT)

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

**Form:** VACCINATION - eCRF Audit Trail History

**Form Version:** 22-Apr-2020 21:04

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site No:** 1241

**Site Name:** (1241) Hospital Irma Dulce

**Subject No:** 12411468

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 19:09

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

Date	Location	User	Value	Reason
Sep-15-2020 10:49:46 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

**Header Text:** c4591001

**Visit:** V3\_MONTH1\_POSTVAX2\_L **Form:** DATE OF VISIT - eCRF Audit Trail History

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

**Site No:** 1241 **Site Name:** (1241) Hospital Irma Dulce

**Subject No:** 12411468 **Subject Initials:** ---

**Generated By:** (b) (4) **Generated Time (GMT):** 29-Mar-2021 19:09

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*1. Date of Visit*

Date	Location	User	Value	Reason
Oct-13-2020 09:31:55 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Oct/13/2020	Initial Entry

090177e196ae3f49\Final\Final On: 01-Apr-2021 05:15 (GMT)

**Header Text:** c4591001

**Visit:** V3\_MONTH1\_POSTVAX2\_L **Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - eCRF Audit Trail History

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

**Site No:** 1241 **Site Name:** (1241) Hospital Irma Dulce

**Subject No:** 12411468 **Subject Initials:** ---

**Generated By:** (b) (4) **Generated Time (GMT):** 29-Mar-2021 19:09

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**1. Data Origin**

Date	Location	User	Value	Reason
Oct-14-2020 08:45:22 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SITE	Initial Entry

**2. Sample Type**

Date	Location	User	Value	Reason
Oct-14-2020 08:45:22 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SERUM	Initial Entry

**3. Sample Collected?**

Date	Location	User	Value	Reason
Oct-14-2020 08:45:31 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Oct-14-2020 08:45:22 (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

090177e196ae3f49\Final\Final On: 01-Apr-2021 05:15 (GMT)



Header Text: c4591001

Visit: V3\_MONTH1\_POSTVAX2\_L Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - eCRF Audit Trail History

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

Site No: 1241 Site Name: (1241) Hospital Irma Dulce

Subject No: 12411468 Subject Initials: ---

Generated By: (b) (4) Generated Time (GMT): 29-Mar-2021 19:09

				and correct as appropriate.
Oct-14-2020 08:45:22 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES Date of Collection:  Oct/13/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Oct-14-2020 08:45:31 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sample ID BRD3T : P	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Oct-14-2020 08:45:31 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BRD3TP	Initial Entry

5.b

Date	Location	User	Value	Reason
Oct-14-2020 08:45:42 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sample I BRXGN D: 7	Initial Entry

090177e196ae3f49\Final\Final On: 01-Apr-2021 05:15 (GMT)

**Header Text:** c4591001

**Visit:** V3\_MONTH1\_POSTVAX2\_L **Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - eCRF Audit Trail History

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

**Site No:** 1241 **Site Name:** (1241) Hospital Irma Dulce

**Subject No:** 12411468 **Subject Initials:** ---

**Generated By:** (b) (4) **Generated Time (GMT):** 29-Mar-2021 19:09

**5.b Sample ID**

Date	Location	User	Value	Reason
Oct-14-2020 08:45:42 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BRXGN7	Initial Entry

**5.c**

Date	Location	User	Value	Reason
Oct-14-2020 08:45:56 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample I</b> BRXGN <b>D:</b> 8	Initial Entry

**5.c Sample ID**

Date	Location	User	Value	Reason
Oct-14-2020 08:45:56 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BRXGN8	Initial Entry

090177e196ae3f49\Final\Final On: 01-Apr-2021 05:15 (GMT)

**Header Text:** c4591001

**Visit:** End of Treatment - Unscheduled **Form:** DISPOSITION - TREATMENT - eCRF Audit Trail History

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

**Site No:** 1241

**Site Name:** (1241) Hospital Irma Dulce

**Subject No:** 12411468

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 19:09

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**1. Date of Completion/Discontinuation/Death :**

Date	Location	User	Value	Reason
Oct-13-2020 09:32:16 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Oct/13/2020	Initial Entry

**2. Phase of Disposition:**

Date	Location	User	Value	Reason
Oct-13-2020 09:32:16 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> VACCINATION	Initial Entry

**3. Status:**

Date	Location	User	Value	Reason
Oct-13-2020 09:32:16 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> COMPLETED	Initial Entry

090177e196ae3f49\Final\Final On: 01-Apr-2021 05:15 (GMT)

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

**Form:** ADVERSE EVENT REPORT - Audit Trail

**Form Version:** 22-Apr-2020 21:02

**Form Status:**

**Site No:** 1241

**Site Name:** (1241) Hospital Irma Dulce

**Subject No:** 12411468

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 19:09

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Date	Location	User	Value	Reason
Feb-15-2021 09:53:47 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Created	

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

**Form:** ADVERSE EVENT REPORT - Audit Trail

**Form Version:** 22-Apr-2020 21:02

**Form Status:**

**Site No:** 1241

**Site Name:** (1241) Hospital Irma Dulce

**Subject No:** 12411468

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 19:09

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Date	Location	User	Value	Reason
Feb-15-2021 09:54:33 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Created	

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History

**Form Version:** 22-Apr-2020 21:02

**Form Status:** Data Complete, Frozen

**Site No:** 1241

**Site Name:** (1241) Hospital Irma Dulce

**Subject No:** 12411468

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 19:09

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**1. Category:**

Date	Location	User	Value	Reason
Feb-15-2021 09:53:47 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> ADVERSE EVENT	Initial Entry

**2. AE ID:**

Date	Location	User	Value	Reason
Feb-15-2021 09:53:47 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 1	Initial Entry

**3. Adverse Event:**

*(If possible specify diagnosis, not individual symptoms)*

Date	Location	User	Value	Reason
Feb-15-2021 09:53:47 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Injection site pain	Initial Entry

**4. Start Date Time:**

Date	Location	User	Value	Reason
Feb-15-2021 09:53:47	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Jan/25/2021 20:00	Initial Entry

090177e196ae3f49\Final\Final On: 01-Apr-2021 05:15 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen

Site No: 1241

Site Name: (1241) Hospital Irma Dulce

Subject No: 12411468

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 19:09

(UTC-03:00) City of Buenos Aires		(b) (4), (b) (6)		
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5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Feb-15-2021 09:53:47 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO End Date Time: Jan/26/2021 UNK: UNK	Initial Entry

6. Toxicity Grade:

Date	Location	User	Value	Reason
Feb-15-2021 09:53:47 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 1	Initial Entry

7. Is the adverse event serious?

If Yes, NOTIFY PFIZER IMMEDIATELY.

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

Date	Location	User	Value	Reason
Feb-15-2021	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>	Initial Entry

090177e196ae3f49\Final\Final On: 01-Apr-2021 05:15 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen

Site No: 1241

Site Name: (1241) Hospital Irma Dulce

Subject No: 12411468

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 19:09

09:53:47 (UTC-03:00) City of Buenos Aires		(b) (4), (b) (6)	NO	
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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-15-2021 09:53:47 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**9. Is this event related to study treatment:**

Date	Location	User	Value	Reason
Feb-15-2021 09:53:47 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> RELATED	Initial Entry

**10. Latest Action Taken with Study Treatment:**

Date	Location	User	Value	Reason
Feb-15-2021 09:53:47 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NOT APPLICABLE	Initial Entry

**11. Was a Concomitant Medication given?**

Date	Location	User	Value	Reason
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090177e196ae3f49\Final\Final On: 01-Apr-2021 05:15 (GMT)



**Header Text:** c4591001

**Visit:** Logs - Unscheduled

**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History

**Form Version:** 22-Apr-2020 21:02

**Form Status:** Data Complete, Frozen

**Site No:** 1241

**Site Name:** (1241) Hospital Irma Dulce

**Subject No:** 12411468

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 19:09

Feb-15-2021 09:53:47 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry
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**12. Was a Non-Drug Treatment given?**

Date	Location	User	Value	Reason
Feb-15-2021 09:53:47 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

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

Date	Location	User	Value	Reason
Feb-15-2021 09:53:47 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> RECOVERED/RESO LVED	Initial Entry

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

Date	Location	User	Value	Reason
Feb-15-2021 09:53:47 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

090177e196ae3f49\Final\Final On: 01-Apr-2021 05:15 (GMT)

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History

**Form Version:** 22-Apr-2020 21:02

**Form Status:** Data Complete, Frozen

**Site No:** 1241

**Site Name:** (1241) Hospital Irma Dulce

**Subject No:** 12411468

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 19:09

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**1. Category:**

Date	Location	User	Value	Reason
Feb-15-2021 09:54:33 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> ADVERSE EVENT	Initial Entry

**2. AE ID:**

Date	Location	User	Value	Reason
Feb-15-2021 09:54:33 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 2	Initial Entry

**3. Adverse Event:**

*(If possible specify diagnosis, not individual symptoms)*

Date	Location	User	Value	Reason
Feb-15-2021 09:54:33 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Chills	Initial Entry

**4. Start Date Time:**

Date	Location	User	Value	Reason
Feb-15-2021	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>	Initial Entry

090177e196ae3f49\Final\Final On: 01-Apr-2021 05:15 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen

Site No: 1241

Site Name: (1241) Hospital Irma Dulce

Subject No: 12411468

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 19:09

09:54:33 (UTC-03:00) City of Buenos Aires		(b) (4), (b) (6)	Jan/25/2021 20:00	
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**5. Is the adverse event still ongoing?**

Date	Location	User	Value	Reason
Feb-15-2021 09:54:33 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO End Date Time:  Jan/26/2021 UNK: UNK	Initial Entry

**6. Toxicity Grade:**

Date	Location	User	Value	Reason
Feb-15-2021 09:54:33 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 1	Initial Entry

**7. Is the adverse event serious?**

**If Yes, NOTIFY PFIZER IMMEDIATELY.**

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

Date	Location	User	Value	Reason
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090177e196ae3f49\Final\Final On: 01-Apr-2021 05:15 (GMT)

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History

**Form Version:** 22-Apr-2020 21:02

**Form Status:** Data Complete, Frozen

**Site No:** 1241

**Site Name:** (1241) Hospital Irma Dulce

**Subject No:** 12411468

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 19:09

Feb-15-2021 09:54:33 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry
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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-15-2021 09:54:33 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**9. Is this event related to study treatment:**

Date	Location	User	Value	Reason
Feb-15-2021 09:54:33 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> RELATED	Initial Entry

**10. Latest Action Taken with Study Treatment:**

Date	Location	User	Value	Reason
Feb-15-2021 09:54:33 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NOT APPLICABLE	Initial Entry

**11. Was a Concomitant Medication given?**

090177e196ae3f49\Final\Final On: 01-Apr-2021 05:15 (GMT)

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History

**Form Version:** 22-Apr-2020 21:02

**Form Status:** Data Complete, Frozen

**Site No:** 1241

**Site Name:** (1241) Hospital Irma Dulce

**Subject No:** 12411468

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 19:09

Date	Location	User	Value	Reason
Feb-15-2021 09:54:33 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**12. Was a Non-Drug Treatment given?**

Date	Location	User	Value	Reason
Feb-15-2021 09:54:33 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

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

Date	Location	User	Value	Reason
Feb-15-2021 09:54:33 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> RECOVERED/RESO LVED	Initial Entry

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

Date	Location	User	Value	Reason
Feb-15-2021 09:54:33 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

090177e196ae3f49\Final\Final On: 01-Apr-2021 05:15 (GMT)

**Header Text:** c4591001

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

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

**Site No:** 1241

**Site Name:** (1241) Hospital Irma Dulce

**Subject No:** 12411468

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 19:09

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*1. Date of Visit*

Date	Location	User	Value	Reason
Feb-04-2021 08:16:01 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Feb-02-2021 08:37:15 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Transcription Error
Feb-02-2021 08:37:15 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Jan/21/2021	Transcription Error
Feb-01-2021 23:10:34 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	According to the patient chart, potential revax contact was performed on 21Jan21. Please review and correct, if applicable. In case it is necessary, please send a DCF to IMPALA.

090177e196ae3f49\Final\Final On: 01-Apr-2021 05:15 (GMT)

**Header Text:** c4591001

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

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

**Site No:** 1241      **Site Name:** (1241) Hospital Irma Dulce

**Subject No:** 12411468      **Subject Initials:** ---

**Generated By:** (b) (4)      **Generated Time (GMT):** 29-Mar-2021 19:09

Jan-25-2021 11:51:10 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Jan/25/2021	Initial Entry
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090177e196ae3f49\Final\Final On: 01-Apr-2021 05:15 (GMT)

**Header Text:** c4591001

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

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

**Site No:** 1241 **Site Name:** (1241) Hospital Irma Dulce

**Subject No:** 12411468 **Subject Initials:** ---

**Generated By:** (b) (4) **Generated Time (GMT):** 29-Mar-2021 19:09

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

Date	Location	User	Value	Reason
Jan-25-2021 11:51:19 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Participant is willing to return for Vaccination 3 Participant is:  eligible per local/n ational recommen dations and confir med to have receiv ed only placebo at Vaccination 1/2	Initial Entry

090177e196ae3f49\Final\Final On: 01-Apr-2021 05:15 (GMT)



**Header Text:** c4591001

**Visit:** Disposition - Unscheduled

**Form:** TREATMENT UNBLINDED - eCRF Audit Trail History

**Form Version:** 22-Apr-2020 21:03

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1241

**Site Name:** (1241) Hospital Irma Dulce

**Subject No:** 12411468

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 19:09

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**1. Date Treatment Unblinded :**

Date	Location	User	Value	Reason
Jan-25-2021 11:51:00 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Jan/21/2021	Initial Entry

**2. Primary Reason for Unblinding:**

Date	Location	User	Value	Reason
Jan-25-2021 11:51:00 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> ASSESS ELIGIBILI TY FOR ADDITION AL VACCINATION	Initial Entry

090177e196ae3f49\Final\Final On: 01-Apr-2021 05:15 (GMT)

**Header Text:** c4591001

**Visit:** V101\_VAX3

**Form Version:** 22-Apr-2020 21:02

**Site No:** 1241

**Subject No:** 12411468

**Generated By:** (b) (4)

**Form:** DATE OF VISIT - eCRF Audit Trail History

**Form Status:** Data Complete, Frozen, Verified

**Site Name:** (1241) Hospital Irma Dulce

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 19:09

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*1. Date of Visit*

Date	Location	User	Value	Reason
Jan-25-2021 11:51:28 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Jan/25/2021	Initial Entry

**Header Text:** c4591001

**Visit:** V101\_VAX3

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

**Form Version:** 10-Dec-2020 02:31

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1241

**Site Name:** (1241) Hospital Irma Dulce

**Subject No:** 12411468

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 19:09

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**1. Consent Was:**

Date	Location	User	Value	Reason
Jan-25-2021 11:51:34 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> OBTAINED Date Written Consent Obtained  Jan/25/2021	Initial Entry

090177e196ae3f49\Final\Final On: 01-Apr-2021 05:15 (GMT)

**Header Text:** c4591001

**Visit:** V101\_VAX3

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

**Form Version:** 10-Dec-2020 02:31

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1241

**Site Name:** (1241) Hospital Irma Dulce

**Subject No:** 12411468

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 19:09

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**1. Date of Completion/Discontinuation/Death :**

Date	Location	User	Value	Reason
Jan-25-2021 11:52:01 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Jan/25/2021	Initial Entry

**2. Phase of Disposition:**

Date	Location	User	Value	Reason
Jan-25-2021 11:52:01 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> REPEAT SCREENING 1	Initial Entry

**3. Status:**

Date	Location	User	Value	Reason
Jan-25-2021 11:52:01 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> COMPLETED	Initial Entry

090177e196ae3f49\Final\Final On: 01-Apr-2021 05:15 (GMT)

**Header Text:** c4591001

**Visit:** V101\_VAX3

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

**Form Version:** 14-Jan-2021 02:21

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1241

**Site Name:** (1241) Hospital Irma Dulce

**Subject No:** 12411468

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 19:09

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**1. Lab Panel:**

Date	Location	User	Value	Reason
Jan-25-2021 11:52:14 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> URINALYSIS	Initial Entry

**2. Lab Sub-Panel:**

Date	Location	User	Value	Reason
Jan-25-2021 11:52:14 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> PREGNANCY	Initial Entry

**3. Collection Date:**

Date	Location	User	Value	Reason
Jan-25-2021 11:52:14 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Jan/25/2021	Initial Entry

**4. Laboratory Name and Address (Derived)**

Date	Location	User	Value	Reason
Jan-25-2021 11:52:14	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> STUDY SITE	Initial Entry

090177e196ae3f49\Final\Final On: 01-Apr-2021 05:15 (GMT)

Header Text: c4591001

Visit: V101\_VAX3

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

Form Version: 14-Jan-2021 02:21

Form Status: Data Complete, Frozen, Verified

Site No: 1241

Site Name: (1241) Hospital Irma Dulce

Subject No: 12411468

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 19:09

(UTC-03:00) City of Buenos Aires

5. Specimen Type:

Date	Location	User	Value	Reason
Jan-25-2021 11:52:14 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> URINE	Initial Entry

6.a

Date	Location	User	Value	Reason
Jan-25-2021 11:52:14 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> Sponsor- 113 Defined Identifier: Test:: Choriogon adotropin Beta_PX11 3 Result:: NEGATIV E Not Done ::	Initial Entry

6.a Sponsor ID:

Date	Location	User	Value	Reason
Jan-25-2021 11:52:14	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 113	Initial Entry

090177e196ae3f49\Final\Final On: 01-Apr-2021 05:15 (GMT)

**Header Text:** c4591001

**Visit:** V101\_VAX3

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

**Form Version:** 14-Jan-2021 02:21

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1241

**Site Name:** (1241) Hospital Irma Dulce

**Subject No:** 12411468

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 19:09

(UTC-03:00) City of Buenos Aires				
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**6.a Test:**

Date	Location	User	Value	Reason
Jan-25-2021 11:52:14 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Choriogonadotropin Beta_PX113	Initial Entry

**6.a Result:**

Date	Location	User	Value	Reason
Jan-25-2021 11:52:14 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NEGATIVE	Initial Entry

090177e196ae3f49\Final\Final On: 01-Apr-2021 05:15 (GMT)

**Header Text:** c4591001

**Visit:** V101\_VAX3

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

**Form Version:** 22-Apr-2020 21:03

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1241

**Site Name:** (1241) Hospital Irma Dulce

**Subject No:** 12411468

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 19:09

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**1. Data Origin**

Date	Location	User	Value	Reason
Jan-25-2021 14:54:29 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SITE	Initial Entry

**2. Sample Type**

Date	Location	User	Value	Reason
Jan-25-2021 14:54:29 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SERUM	Initial Entry

**3. Sample Collected?**

Date	Location	User	Value	Reason
Jan-25-2021 14:54:40 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Jan-25-2021 14:54:29 (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

090177e196ae3f49\Final\Final On: 01-Apr-2021 05:15 (GMT)



Header Text: c4591001

Visit: V101\_VAX3

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1241

Site Name: (1241) Hospital Irma Dulce

Subject No: 12411468

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 19:09

				and correct as appropriate.
Jan-25-2021 14:54:29 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES Date of Collection:  Jan/25/2021	Initial Entry

5.a

Date	Location	User	Value	Reason
Jan-25-2021 14:54:40 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample I</b> BPTKX <b>D:</b> V	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Jan-25-2021 14:54:40 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BPTKXV	Initial Entry

5.b

Date	Location	User	Value	Reason
Jan-25-2021 14:54:51 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample ID</b> BSCYY : L	Initial Entry

090177e196ae3f49\Final\Final On: 01-Apr-2021 05:15 (GMT)

**Header Text:** c4591001

**Visit:** V101\_VAX3

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

**Form Version:** 22-Apr-2020 21:03

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1241

**Site Name:** (1241) Hospital Irma Dulce

**Subject No:** 12411468

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 19:09

**5.b Sample ID**

Date	Location	User	Value	Reason
Jan-25-2021 14:54:51 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BSCYYL	Initial Entry

**5.c**

Date	Location	User	Value	Reason
Jan-25-2021 14:54:57 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample I</b> BSCYY <b>D:</b> M	Initial Entry

**5.c Sample ID**

Date	Location	User	Value	Reason
Jan-25-2021 14:54:57 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BSCYYM	Initial Entry

090177e196ae3f49\Final\Final On: 01-Apr-2021 05:15 (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:** 1241

**Site Name:** (1241) Hospital Irma Dulce

**Subject No:** 12411468

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 19:09

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**1. Data Origin**

Date	Location	User	Value	Reason
Jan-25-2021 14:21:22 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SITE	Initial Entry

**2. Sample Type**

Date	Location	User	Value	Reason
Jan-25-2021 14:21:22 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> NASAL_SWAB	Initial Entry

**3. Sample Collected?**

Date	Location	User	Value	Reason
Jan-25-2021 14:21:30 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Jan-25-2021 14:21:22 (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

090177e196ae3f49\Final\Final On: 01-Apr-2021 05:15 (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: 1241

Site Name: (1241) Hospital Irma Dulce

Subject No: 12411468

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 19:09

				and correct as appropriate.
Jan-25-2021 14:21:22 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES Date of Collection:  Jan/25/2021	Initial Entry

5.a

Date	Location	User	Value	Reason
Jan-25-2021 14:21:30 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample ID</b> BPTKX : J	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Jan-25-2021 14:21:30 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BPTKXJ	Initial Entry

090177e196ae3f49\Final\Final On: 01-Apr-2021 05:15 (GMT)

**Header Text:** c4591001

**Visit:** V101\_VAX3

**Form Version:** 10-Dec-2020 02:26

**Site No:** 1241

**Subject No:** 12411468

**Generated By:** (b) (4)

**Form:** VACCINATION - eCRF Audit Trail History

**Form Status:** Data Complete, Frozen, Verified

**Site Name:** (1241) Hospital Irma Dulce

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 19:09

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**1. Was there a temporary delay of vaccination?**

Date	Location	User	Value	Reason
Jan-25-2021 11:52:46 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**2. Treatment Name**

Date	Location	User	Value	Reason
Jan-25-2021 11:52:46 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> BNT162b2	Initial Entry

**3. Formulation:**

Date	Location	User	Value	Reason
Jan-25-2021 11:52:46 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> INJECTION	Initial Entry

**4. Dose Date Time:**

Date	Location	User	Value	Reason
Jan-25-2021 11:52:46 (UTC-03:00) City	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Jan/25/2021 11:10	Initial Entry

090177e196ae3f49\Final\Final On: 01-Apr-2021 05:15 (GMT)

Header Text: c4591001

Visit: V101\_VAX3

Form: VACCINATION - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:26

Form Status: Data Complete, Frozen, Verified

Site No: 1241

Site Name: (1241) Hospital Irma Dulce

Subject No: 12411468

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 19:09

of Buenos Aires

5. Anatomical Location:

Date	Location	User	Value	Reason
Jan-25-2021 11:52:46 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> DELTOID MUSCLE	Initial Entry

6. Body Side:

Date	Location	User	Value	Reason
Jan-25-2021 11:52:46 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> LEFT	Initial Entry

7. Route:

Date	Location	User	Value	Reason
Jan-25-2021 11:52:46 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> INTRAMUSCULAR	Initial Entry

8. Actual Dose:

Date	Location	User	Value	Reason
Jan-25-2021 11:52:46 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 30.0	Initial Entry

090177e196ae3f49\Final\Final On: 01-Apr-2021 05:15 (GMT)

**Header Text:** c4591001

**Visit:** V101\_VAX3

**Form:** VACCINATION - eCRF Audit Trail History

**Form Version:** 10-Dec-2020 02:26

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1241

**Site Name:** (1241) Hospital Irma Dulce

**Subject No:** 12411468

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 19:09

**9. Unit:**

Date	Location	User	Value	Reason
Jan-25-2021 11:52:46 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> ug	Initial Entry

**10. Timeframe Subject Was Observed**

Date	Location	User	Value	Reason
Jan-25-2021 11:52:46 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 30 MINUTES	Initial Entry

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

Date	Location	User	Value	Reason
Jan-25-2021 11:52:46 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

090177e196ae3f49\Final\Final On: 01-Apr-2021 05:15 (GMT)

**Header Text:** c4591001

**Visit:** V102\_VAX4

**Form Version:** 22-Apr-2020 21:02

**Site No:** 1241

**Subject No:** 12411468

**Generated By:** (b) (4)

**Form:** DATE OF VISIT - eCRF Audit Trail History

**Form Status:** Data Complete, Frozen, Verified

**Site Name:** (1241) Hospital Irma Dulce

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 19:09

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*1. Date of Visit*

Date	Location	User	Value	Reason
Feb-15-2021 09:51:48 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Feb/15/2021	Initial Entry



**Header Text:** c4591001

**Visit:** V102\_VAX4

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

**Form Version:** 14-Jan-2021 02:21

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1241

**Site Name:** (1241) Hospital Irma Dulce

**Subject No:** 12411468

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 19:09

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**1. Lab Panel:**

Date	Location	User	Value	Reason
Feb-15-2021 09:52:02 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> URINALYSIS	Initial Entry

**2. Lab Sub-Panel:**

Date	Location	User	Value	Reason
Feb-15-2021 09:52:02 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> PREGNANCY	Initial Entry

**3. Collection Date:**

Date	Location	User	Value	Reason
Feb-15-2021 09:52:02 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Feb/15/2021	Initial Entry

**4. Laboratory Name and Address (Derived)**

Date	Location	User	Value	Reason
Feb-15-2021 09:52:02	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> STUDY SITE	Initial Entry

090177e196ae3f49\Final\Final On: 01-Apr-2021 05:15 (GMT)

Header Text: c4591001

Visit: V102\_VAX4

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

Form Version: 14-Jan-2021 02:21

Form Status: Data Complete, Frozen, Verified

Site No: 1241

Site Name: (1241) Hospital Irma Dulce

Subject No: 12411468

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 19:09

(UTC-03:00) City  
of Buenos Aires

**5. Specimen Type:**

Date	Location	User	Value	Reason
Feb-15-2021 09:52:02 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> URINE	Initial Entry

**6.a**

Date	Location	User	Value	Reason
Feb-15-2021 09:52:02 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Sponsor-</b> 113 <b>Defined I</b> <b>dentifier:</b> <b>Test::</b> Choriogon adotropin Beta_PX11 3 <b>Result::</b> NEGATIV E <b>Not Done</b> ::	Initial Entry

**6.a Sponsor ID:**

Date	Location	User	Value	Reason
Feb-15-2021 09:52:02	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 113	Initial Entry

090177e196ae3f49\Final\Final On: 01-Apr-2021 05:15 (GMT)

**Header Text:** c4591001

**Visit:** V102\_VAX4

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

**Form Version:** 14-Jan-2021 02:21

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1241

**Site Name:** (1241) Hospital Irma Dulce

**Subject No:** 12411468

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 19:09

(UTC-03:00) City of Buenos Aires				
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**6.a Test:**

Date	Location	User	Value	Reason
Feb-15-2021 09:52:02 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Choriogonadotropin Beta_PX113	Initial Entry

**6.a Result:**

Date	Location	User	Value	Reason
Feb-15-2021 09:52:02 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NEGATIVE	Initial Entry

090177e196ae3f49\Final\Final On: 01-Apr-2021 05:15 (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:** 1241

**Site Name:** (1241) Hospital Irma Dulce

**Subject No:** 12411468

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 19:09

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**1. Data Origin**

Date	Location	User	Value	Reason
Feb-15-2021 10:03:45 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SITE	Initial Entry

**2. Sample Type**

Date	Location	User	Value	Reason
Feb-15-2021 10:03:45 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> NASAL_SWAB	Initial Entry

**3. Sample Collected?**

Date	Location	User	Value	Reason
Feb-15-2021 10:03:56 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Feb-15-2021 10:03:45 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review

090177e196ae3f49\Final\Final On: 01-Apr-2021 05:15 (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:** 1241

**Site Name:** (1241) Hospital Irma Dulce

**Subject No:** 12411468

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 19:09

				and correct as appropriate.
Feb-15-2021 10:03:45 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES Date of Collection:  Feb/15/2021	Initial Entry

**5.a**

Date	Location	User	Value	Reason
Feb-15-2021 10:03:56 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample ID</b> BRKF3 : Y	Initial Entry

**5.a Sample ID**

Date	Location	User	Value	Reason
Feb-15-2021 10:03:56 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BRKF3Y	Initial Entry

090177e196ae3f49\Final\Final On: 01-Apr-2021 05:15 (GMT)

**Header Text:** c4591001

**Visit:** V102\_VAX4

**Form Version:** 10-Dec-2020 02:26

**Site No:** 1241

**Subject No:** 12411468

**Generated By:** (b) (4)

**Form:** VACCINATION - eCRF Audit Trail History

**Form Status:** Data Complete, Frozen, Verified

**Site Name:** (1241) Hospital Irma Dulce

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 19:09

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**1. Was there a temporary delay of vaccination?**

Date	Location	User	Value	Reason
Feb-15-2021 09:52:30 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**2. Treatment Name**

Date	Location	User	Value	Reason
Feb-15-2021 09:52:30 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> BNT162b2	Initial Entry

**3. Formulation:**

Date	Location	User	Value	Reason
Feb-15-2021 09:52:30 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> INJECTION	Initial Entry

**4. Dose Date Time:**

Date	Location	User	Value	Reason
Feb-15-2021 09:52:30 (UTC-03:00) City	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Feb/15/2021 09:07	Initial Entry

090177e196ae3f49\Final\Final On: 01-Apr-2021 05:15 (GMT)

Header Text: c4591001

Visit: V102\_VAX4

Form: VACCINATION - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:26

Form Status: Data Complete, Frozen, Verified

Site No: 1241

Site Name: (1241) Hospital Irma Dulce

Subject No: 12411468

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 19:09

of Buenos Aires

5. Anatomical Location:

Date	Location	User	Value	Reason
Feb-15-2021 09:52:30 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> DELTOID MUSCLE	Initial Entry

6. Body Side:

Date	Location	User	Value	Reason
Feb-15-2021 09:52:30 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> LEFT	Initial Entry

7. Route:

Date	Location	User	Value	Reason
Feb-15-2021 09:52:30 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> INTRAMUSCULAR	Initial Entry

8. Actual Dose:

Date	Location	User	Value	Reason
Feb-15-2021 09:52:30 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 30.0	Initial Entry

090177e196ae3f49\Final\Final On: 01-Apr-2021 05:15 (GMT)

**Header Text:** c4591001

**Visit:** V102\_VAX4

**Form:** VACCINATION - eCRF Audit Trail History

**Form Version:** 10-Dec-2020 02:26

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1241

**Site Name:** (1241) Hospital Irma Dulce

**Subject No:** 12411468

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 19:09

**9. Unit:**

Date	Location	User	Value	Reason
Feb-15-2021 09:52:30 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> ug	Initial Entry

**10. Timeframe Subject Was Observed**

Date	Location	User	Value	Reason
Feb-15-2021 09:52:30 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 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-15-2021 09:52:30 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

090177e196ae3f49\Final\Final On: 01-Apr-2021 05:15 (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:** 1241

**Site Name:** (1241) Hospital Irma Dulce

**Subject No:** 12411468

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 19:09

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**1. Subject Status**

Date	Location	User	Value	Reason
Oct-13-2020 09:32:16 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> FOLLOW-UP	Initial Entry
Aug-25-2020 10:17:51 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> ENROLLED/RANDO MIZED	Initial Entry
Aug-25-2020 10:15:41 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SCREENED	Initial Entry

**2. Subject Status Date**

Date	Location	User	Value	Reason
Oct-13-2020 09:32:16 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> Oct/13/2020	Initial Entry
Aug-25-2020 10:17:51 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> Aug/25/2020	Initial Entry
Aug-25-2020	ACV0PFEINFP6000	auto calc	<b>Data Entry:</b>	Initial Entry

090177e196ae3f49\Final\Final On: 01-Apr-2021 05:15 (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:** 1241

**Site Name:** (1241) Hospital Irma Dulce

**Subject No:** 12411468

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 19:09

10:15:41 (UTC-03:00) City of Buenos Aires		(autocalc)	Aug/25/2020	
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**Header Text:** c4591001

**Visit:** Investigator Signature -  
Unscheduled

**Form Version:** 22-Apr-2020 21:04

**Site No:** 1241

**Subject No:** 12411468

**Generated By:** (b) (4)

**Form:** CASEBOOK SIGNATURE FORM - eCRF Audit  
Trail History

**Form Status:** Data Complete, Signed, Verified

**Site Name:** (1241) Hospital Irma Dulce

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 19:09

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*1. Casebook Signature*

Date	Location	User	Value	Reason
Oct-22-2020 17:57:27 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Click Here to Enable	Initial Entry

090177e196ae3f49\Final\Final On: 01-Apr-2021 05:15 (GMT)