

**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:** 12411471

**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

**Header Text:** c4591001

**Visit:** COHORT\_SELECTION

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

**Site No:** 1241

**Subject No:** 12411471

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

**Form:** MAIN INFORMED CONSENT

**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](#)

**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:** 12411471

**Subject Initials:** ---

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

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

[eCRF Audit Trail History](#)

**Demography**

1.	Subject ID	[12411471]
2.	Birth Date:	(b) (6) 1986
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 WHITE
6.	Racial Designation:	

**Header Text:** c4591001

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

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

**Site No:** 1241

**Subject No:** 12411471

**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: 12411471

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
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

090177e196ae3f32\Final\Final On: 01-Apr-2021 05:12 (GMT)

**Header Text:** c4591001

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

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

**Site No:** 1241

**Subject No:** 12411471

**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

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
2.c	Exclusion Number:	3
	Criterion Description:	History of severe adverse reaction associated with a vaccine and/or severe allergic reaction (eg, anaphylaxis) to any component of the study intervention(s)
	Criterion met?	NO
	Criterion ID: (For Pfizer use only)	EX03A00
2.d	Exclusion Number:	4
	Criterion Description:	Receipt of medications intended to prevent COVID-19
	Criterion met?	NO
	Criterion ID: (For Pfizer use only)	EX04A00

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**Header Text:** c4591001

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

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

**Site No:** 1241

**Subject No:** 12411471

**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

2.e	Exclusion Number:	8
	Criterion Description:	Immunocompromised individuals with known or suspected immunodeficiency, as determined by history and/or laboratory/physical examination
	Criterion met?	NO
	Criterion ID: (For Pfizer use only)	EX08A00
2.f	Exclusion Number:	10
	Criterion Description:	Bleeding diathesis or condition associated with prolonged bleeding that would, in the opinion of the investigator, contraindicate intramuscular injection
	Criterion met?	NO
	Criterion ID: (For Pfizer use only)	EX10A00
2.g	Exclusion Number:	11
	Criterion Description:	Women who are pregnant or breastfeeding
	Criterion met?	NO
	Criterion ID: (For Pfizer use only)	EX11A00
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 Version:** 21-Aug-2020 02:50

**Site No:** 1241

**Subject No:** 12411471

**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

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.l	Exclusion Number:	17
	Criterion Description:	Previous participation in other studies involving study intervention containing lipid nanoparticles
	Criterion met?	NO
	Criterion ID: (For Pfizer use only)	EX16A01
2.m	Exclusion Number:	22
	Criterion Description:	Investigator site staff or Pfizer employees directly involved in the conduct of the study, site staff otherwise supervised by the investigator, and their respective family members
	Criterion met?	NO
	Criterion ID: (For Pfizer use only)	EX21A01

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**Header Text:** c4591001

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

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

**Site No:** 1241

**Subject No:** 12411471

**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:	[ ]

**Header Text:** c4591001

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

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

**Site No:** 1241

**Subject No:** 12411471

**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

[Form Comments](#)

[eCRF Audit Trail History](#)

**Medical History Details**

1.a	Line/MH Number:	[1]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Headache]
	Start Date:	Aug/20/2020
	Ongoing:	NO End Date: Aug/20/2020

**Header Text:** c4591001

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

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

**Site No:** 1241

**Subject No:** 12411471

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

**Form:** VITAL SIGNS - BASELINE

**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](#)

**Vital Signs**

1.	Date:	Aug/25/2020
2.	Weight:	[63.9]
3.	Unit:	kg
4.	Height:	[164.5]
5.	Unit:	cm
6.	Body Mass Index:	[23.6]

**Vital Signs Details**

7.a	Record Identifier:	1
	Temperature:	[36.9]
	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:** 12411471

**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:** 12411471

**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:	[65073]
3.	Randomization Group:	[ ]

**Header Text:** c4591001

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

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

**Site No:** 1241

**Subject No:** 12411471

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

**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

**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](#)

**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	[BPT0WH]
5.b	Sample ID	[BPT0WJ]
5.c	Sample ID	[BPT0WK]
5.d	Sample ID	[BLCH4N]
5.e	Sample ID	[BLCH4P]

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**Header Text:** c4591001

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

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

**Site No:** 1241

**Subject No:** 12411471

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

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

**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](#)

**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	[BPT0W2]
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090177e196ae3f32\Final\Final On: 01-Apr-2021 05:12 (GMT)

**Header Text:** c4591001

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

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

**Site No:** 1241

**Subject No:** 12411471

**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 09:57
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

090177e196ae3f32\Final\Final On: 01-Apr-2021 05:12 (GMT)

**Header Text:** c4591001

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

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

**Site No:** 1241

**Subject No:** 12411471

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

**Site No:** 1241

**Subject No:** 12411471

**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	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:** 12411471

**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:	[36.5]
	Unit:	C
	Temperature Location:	ORAL CAVITY

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

**Site No:** 1241

**Subject No:** 12411471

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

**Site No:** 1241

**Subject No:** 12411471

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

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

**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](#)

**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	[BPWYLZ]
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090177e196ae3f32\Final\Final On: 01-Apr-2021 05:12 (GMT)

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

**Site No:** 1241

**Subject No:** 12411471

**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:	Sep/15/2020 09:50
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

090177e196ae3f32\Final\Final On: 01-Apr-2021 05:12 (GMT)

**Header Text:** c4591001

**Visit:** V3\_MONTH1\_POSTVAX2\_L

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

**Site No:** 1241

**Subject No:** 12411471

**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	Oct/13/2020
2.	Erroneous Visit	

090177e196ae3f32\Final\Final On: 01-Apr-2021 05:12 (GMT)

**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:** 12411471

**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	[BRD3X2]
5.b	Sample ID	[BRXGNM]
5.c	Sample ID	[BRXGNN]

090177e196ae3f32\Final\Final On: 01-Apr-2021 05:12 (GMT)

**Header Text:** c4591001

**Visit:** V4\_MONTH6\_L

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

**Site No:** 1241

**Subject No:** 12411471

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

**Form:** DATE OF VISIT

**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](#)

**Date of Visit**

1.	Date of Visit	Mar/9/2021
2.	Erroneous Visit	

**Header Text:** c4591001

**Visit:** V4\_MONTH6\_L

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

**Site No:** 1241

**Subject No:** 12411471

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

**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

**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](#)

**Electronic Sample Tracking**

1.	Data Origin	SITE
2.	Sample Type	SERUM
3.	Sample Collected?	YES Date of Collection: Mar/9/2021
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	[BRCFLW]
5.b	Sample ID	[BSCYM6]
5.c	Sample ID	[BSCYM7]

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**Header Text:** c4591001

**Visit:** V5\_MONTH12\_L

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

**Site No:** 1241

**Subject No:** 12411471

**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:** V5\_MONTH12\_L

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

**Site No:** 1241

**Subject No:** 12411471

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

**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

**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	[ ]
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**Header Text:** c4591001

**Visit:** V6\_MONTH24\_L

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

**Site No:** 1241

**Subject No:** 12411471

**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:** V6\_MONTH24\_L

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

**Site No:** 1241

**Subject No:** 12411471

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

**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

**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	[ ]
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090177e196ae3f32\Final\Final On: 01-Apr-2021 05:12 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL - New Unscheduled Visit      **Form:** DATE OF VISIT - ILLNESS ONSET

**Form Version:** 22-Apr-2020 21:03      **Form Status:** Not Started

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

**Subject No:** 12411471      **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:** SIGNS AND SYMPTOMS OF POTENTIAL COVID-19

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

**Form Status:** Not Started

**Site No:** 1241

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

**Subject No:** 12411471

**Subject Initials:** ---

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

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

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

**Form Status:** Not Started

**Site No:** 1241

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

**Subject No:** 12411471

**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	[ ]
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090177e196ae3f32\Final\Final On: 01-Apr-2021 05:12 (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:** 12411471

**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	[ ]
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**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL - New Unscheduled Visit      **Form:** HEALTH CARE UTILIZATION

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

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

**Subject No:** 12411471      **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:	[ ]
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**Health Care Utilization**

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

090177e196ae3f32\Final\Final On: 01-Apr-2021 05:12 (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:** 12411471

**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:** 12411471

**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\_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:** 12411471

**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	[ ]
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**Header Text:** c4591001

**Visit:** Unplanned - New Unscheduled Visit

**Form:** DATE OF VISIT

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

**Form Status:** Not Started

**Site No:** 1241

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

**Subject No:** 12411471

**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:** 12411471

**Subject Initials:** ---

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

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

**Unplanned Assessments**

1.	Assessments	
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**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:** 12411471

**Subject Initials:** ---

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

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

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**Disposition - Treatment**

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

**Header Text:** c4591001

**Visit:** Follow-Up - Unscheduled

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

**Site No:** 1241

**Subject No:** 12411471

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

**Form:** DISPOSITION - FOLLOW-UP

**Form Status:** Not Started

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

**Subject Initials:** ---

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

**Form Version:** 10-Oct-2020 15:57

**Form Status:** Not Started

**Site No:** 1241

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

**Subject No:** 12411471

**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:	
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**Header Text:** c4591001

**Visit:** POT\_COVID\_REPEAT\_SWAB - New **Form:** ELECTRONIC SAMPLE TRACKING - REPEAT SWAB  
Unscheduled Visit

**Form Version:** 10-Oct-2020 15:57

**Form Status:** Not Started

**Site No:** 1241

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

**Subject No:** 12411471

**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	[ ]
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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: 12411471

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	Aug/25/2020 09:58	NO End Date Time:  Aug/26/2020 UNK: UNK	<a href="#">Repeating Pages</a>
2.	ADVERSE EVENT	2	Injection site pain	Sep/15/2020 12:00	NO End Date Time:  Sep/21/2020 UNK: UNK	<a href="#">Repeating Pages</a>
3.	ADVERSE EVENT	3	Injection site swelling	Sep/15/2020 12:00	NO End Date Time:  Sep/21/2020 UNK: UNK	<a href="#">Repeating Pages</a>
4.	ADVERSE EVENT	4	Fever	Sep/15/2020 18:00	NO End Date Time:  Sep/18/2020 UNK: UNK	<a href="#">Repeating Pages</a>
5.	ADVERSE EVENT	5	Chills	Sep/15/2020 18:00	NO End Date Time:  Sep/18/2020 UNK: UNK	<a href="#">Repeating Pages</a>
6.	ADVERSE EVENT	6	Headache	Sep/15/2020 18:00	NO End Date Time:  Sep/18/2020 UNK: UNK	<a href="#">Repeating Pages</a>
7.	ADVERSE EVENT	7	Fatigue	Sep/15/2020 18:00	NO End Date Time:	<a href="#">Repeating Pages</a>

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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: 12411471

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
					Sep/18/2020 UNK: UNK	
8.	ADVERSE EVENT	8	Myalgia	Sep/15/2020 18:00	NO End Date Time:  Sep/18/2020 UNK: UNK	<a href="#">Repeating Pages</a>
9.	ADVERSE EVENT	9	Nausea	Sep/15/2020 18:00	NO End Date Time:  Sep/18/2020 UNK: UNK	<a href="#">Repeating Pages</a>
10.	ADVERSE EVENT	10	Reactive axillary lymph node in the left arm	Sep/16/2020 UNK:UNK	NO End Date Time:  Sep/26/2020 UNK: UNK	<a href="#">Repeating Pages</a>
11.	ADVERSE EVENT	11	Left mumps	Feb/UNK/2021 UNK:UNK	YES	<a href="#">Repeating Pages</a>

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**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1241

**Subject No:** 12411471

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

**Form:** ADVERSE EVENT REPORT

**Form Status:** Data Complete, Locked, 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:	[1]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[Injection site pain]
4.	Start Date Time:	Aug/25/2020 09:58
5.	Is the adverse event still ongoing?	NO End Date Time: Aug/26/2020 UNK:UNK
6.	Toxicity Grade:	1
7.	Is the adverse event serious?  If Yes, NOTIFY PFIZER IMMEDIATELY.  Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).	NO
8.	Is this adverse event the result of a study Medication Error? If Yes, record the type of medication error on the Medication Error Log.	NO
9.	Is this event related to study treatment:	RELATED
10.	Latest Action Taken with Study Treatment:	NOT APPLICABLE

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**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1241

**Subject No:** 12411471

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

**Form:** ADVERSE EVENT REPORT

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

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

**Subject Initials:** ---

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

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

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1241

**Subject No:** 12411471

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

**Form:** ADVERSE EVENT REPORT

**Form Status:** Data Complete, Locked, 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)	[Injection site pain]
4.	Start Date Time:	Sep/15/2020 12:00
5.	Is the adverse event still ongoing?	NO End Date Time: Sep/21/2020 UNK:UNK
6.	Toxicity Grade:	2
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

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**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1241

**Subject No:** 12411471

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

**Form:** ADVERSE EVENT REPORT

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

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

**Subject Initials:** ---

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

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

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1241

**Subject No:** 12411471

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

**Form:** ADVERSE EVENT REPORT

**Form Status:** Data Complete, Locked, 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:	[3]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[Injection site swelling]
4.	Start Date Time:	Sep/15/2020 12:00
5.	Is the adverse event still ongoing?	NO End Date Time: Sep/21/2020 UNK:UNK
6.	Toxicity Grade:	2
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

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**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1241

**Subject No:** 12411471

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

**Form:** ADVERSE EVENT REPORT

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

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

**Subject Initials:** ---

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

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

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1241

**Subject No:** 12411471

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

**Form:** ADVERSE EVENT REPORT

**Form Status:** Data Complete, Locked, 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:	[4]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[Fever]
4.	Start Date Time:	Sep/15/2020 18:00
5.	Is the adverse event still ongoing?	NO End Date Time: Sep/18/2020 UNK:UNK
6.	Toxicity Grade:	2
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

090177e196ae3f32\Final\Final On: 01-Apr-2021 05:12 (GMT)

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1241

**Subject No:** 12411471

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

**Form:** ADVERSE EVENT REPORT

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

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

**Subject Initials:** ---

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

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

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1241

**Subject No:** 12411471

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

**Form:** ADVERSE EVENT REPORT

**Form Status:** Data Complete, Locked, 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:	[5]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[Chills]
4.	Start Date Time:	Sep/15/2020 18:00
5.	Is the adverse event still ongoing?	NO End Date Time: Sep/18/2020 UNK:UNK
6.	Toxicity Grade:	2
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

090177e196ae3f32\Final\Final On: 01-Apr-2021 05:12 (GMT)

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1241

**Subject No:** 12411471

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

**Form:** ADVERSE EVENT REPORT

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

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

**Subject Initials:** ---

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

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

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1241

**Subject No:** 12411471

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

**Form:** ADVERSE EVENT REPORT

**Form Status:** Data Complete, Locked, 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:	[6]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[Headache]
4.	Start Date Time:	Sep/15/2020 18:00
5.	Is the adverse event still ongoing?	NO End Date Time: Sep/18/2020 UNK:UNK
6.	Toxicity Grade:	2
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

090177e196ae3f32\Final\Final On: 01-Apr-2021 05:12 (GMT)

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1241

**Subject No:** 12411471

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

**Form:** ADVERSE EVENT REPORT

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

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

**Subject Initials:** ---

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

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

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1241

**Subject No:** 12411471

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

**Form:** ADVERSE EVENT REPORT

**Form Status:** Data Complete, Locked, 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:	[7]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[Fatigue]
4.	Start Date Time:	Sep/15/2020 18:00
5.	Is the adverse event still ongoing?	NO End Date Time: Sep/18/2020 UNK:UNK
6.	Toxicity Grade:	2
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

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**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1241

**Subject No:** 12411471

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

**Form:** ADVERSE EVENT REPORT

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

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

**Subject Initials:** ---

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

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

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1241

**Subject No:** 12411471

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

**Form:** ADVERSE EVENT REPORT

**Form Status:** Data Complete, Locked, 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:	[8]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[Myalgia]
4.	Start Date Time:	Sep/15/2020 18:00
5.	Is the adverse event still ongoing?	NO End Date Time: Sep/18/2020 UNK:UNK
6.	Toxicity Grade:	2
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

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**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1241

**Subject No:** 12411471

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

**Form:** ADVERSE EVENT REPORT

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

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

**Subject Initials:** ---

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

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

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1241

**Subject No:** 12411471

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

**Form:** ADVERSE EVENT REPORT

**Form Status:** Data Complete, Locked, 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:	[9]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[Nausea]
4.	Start Date Time:	Sep/15/2020 18:00
5.	Is the adverse event still ongoing?	NO End Date Time: Sep/18/2020 UNK:UNK
6.	Toxicity Grade:	2
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

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**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1241

**Subject No:** 12411471

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

**Form:** ADVERSE EVENT REPORT

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

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

**Subject Initials:** ---

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

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

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1241

**Subject No:** 12411471

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

**Form:** ADVERSE EVENT REPORT

**Form Status:** Data Complete, Locked, 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:	[10]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[Reactive axillary lymph node in the left arm]
4.	Start Date Time:	Sep/16/2020 UNK:UNK
5.	Is the adverse event still ongoing?	NO End Date Time: Sep/26/2020 UNK:UNK
6.	Toxicity Grade:	2
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

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**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1241

**Subject No:** 12411471

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

**Form:** ADVERSE EVENT REPORT

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

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

**Subject Initials:** ---

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

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

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1241

**Subject No:** 12411471

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

**Form:** ADVERSE EVENT REPORT

**Form Status:** Data Complete

**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:	[11]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[Left mumps]
4.	Start Date Time:	Feb/UNK/2021 UNK:UNK
5.	Is the adverse event still ongoing?	YES
6.	Toxicity Grade:	1
7.	Is the adverse event serious?  If Yes, NOTIFY PFIZER IMMEDIATELY.  Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).	NO
8.	Is this adverse event the result of a study Medication Error? If Yes, record the type of medication error on the Medication Error Log.	NO
9.	Is this event related to study treatment:	NOT RELATED If Not Related to study treatment(s), this event is due to: OTHER If Other, specify: [Sjogren syndrome]

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**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1241

**Subject No:** 12411471

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

**Form:** ADVERSE EVENT REPORT

**Form Status:** Data Complete

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

**Subject Initials:** ---

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

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

**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:** 12411471

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

**Site No:** 1241

**Subject No:** 12411471

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

**Form:** MEDICATION ERROR

**Form Status:** Not Started

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

**Subject Initials:** ---

**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	[ ]

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**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:** 12411471

**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>

090177e196ae3f32\Final\Final On: 01-Apr-2021 05:12 (GMT)

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

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

**Form Status:** Not Started

**Site No:** 1241

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

**Subject No:** 12411471

**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:	//

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**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:** 12411471

**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>

090177e196ae3f32\Final\Final On: 01-Apr-2021 05:12 (GMT)

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1241

**Subject No:** 12411471

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

**Form:** CONCOMITANT MEDICATIONS - PROHIBITED

**Form Status:** Not Started

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

**Subject Initials:** ---

**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?	

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**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:** 12411471

**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>

090177e196ae3f32\Final\Final On: 01-Apr-2021 05:12 (GMT)

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1241

**Subject No:** 12411471

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

**Form:** RADIATION TREATMENT

**Form Status:** Not Started

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

**Subject Initials:** ---

**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?	

**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:** 12411471

**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>

090177e196ae3f32\Final\Final On: 01-Apr-2021 05:12 (GMT)

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1241

**Subject No:** 12411471

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

**Form:** TRANSFUSIONS

**Form Status:** Not Started

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

**Subject Initials:** ---

**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:** 12411471

**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:** 12411471

**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:	

**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:** 12411471

**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:	

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**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:** 12411471

**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?	

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**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:** 12411471

**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:** 12411471

**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:** V201\_SURVEIL\_CONSENT -  
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:** 12411471

**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:** V201\_SURVEIL\_CONSENT -  
Unscheduled

**Form:** INFORMED CONSENT - ASYMPTOMATIC  
SURVEILLANCE

**Form Version:** 14-Jan-2021 02:29

**Form Status:** Not Started

**Site No:** 1241

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

**Subject No:** 12411471

**Subject Initials:** ---

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

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

**Informed Consent - Asymptomatic Surveillance**

1.	Consent Was:	
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**Header Text:** c4591001

**Visit:** V201\_SURVEIL\_CONSENT -  
Unscheduled

**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:** 12411471

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

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**Header Text:** c4591001

**Visit:** V201\_SURVEIL\_CONSENT -  
Unscheduled

**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:** 12411471

**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:** Potential ReVax Initial Contact -  
Unscheduled

**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:** 12411471

**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 -  
Unscheduled

**Form:** FURTHER VACCINATION CONFIRMATION

**Form Version:** 10-Dec-2020 02:25

**Form Status:** Data Complete, Frozen

**Site No:** 1241

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

**Subject No:** 12411471

**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 and NOT confirmed to have received only placebo at Vaccination 1/2
----	---	--

**Header Text:** c4591001

**Visit:** Disposition - Unscheduled

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

**Site No:** 1241

**Subject No:** 12411471

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

**Form:** TREATMENT UNBLINDED

**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](#)

**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:** 12411471

**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:** 12411471

**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:** Subject Status - Unscheduled

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

**Site No:** 1241

**Subject No:** 12411471

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

**Form:** SUBJECT STATUS

**Form Status:** Data Complete, Verified

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

**Subject Initials:** ---

**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:** 12411471

**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:** 12411471

**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	Mar-10-2021 17:42:33 (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:** V1\_DAY1\_VAX1\_L

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

**Site No:** 1241

**Subject No:** 12411471

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

**Form:** GENERAL MEDICAL HISTORY - Comments

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

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

**Subject Initials:** ---

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

[Back to Form](#)

Item	Date	User	Comment
Form	Oct-29-2020 11:07:05 (UTC-03:00) City of Buenos Aires	(b) (4), (b) (6) [REDACTED]	
Form	Aug-25-2020 11:48:01 (UTC-03:00) City of Buenos Aires	(b) (4), (b) (6) [REDACTED]	Not Applicable

**Header Text:** c4591001

**Visit:** Investigator Signature - Unscheduled

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

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

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

**Site No:** 1241

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

**Subject No:** 12411471

**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)	Approved	Mar-10-2021 17:42:33 (UTC-03:00) City of Buenos Aires	BOOK	Signed

**Affidavit:**

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

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

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

(b) (6)	N/A	Mar-09-2021 09:52:01 (UTC-03:00) City of Buenos Aires		Edit - All signatures invalidated
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**Affidavit:**

N/A

(b) (6)	Approved	Feb-05-2021 14:36:15 (UTC-03:00) City of Buenos Aires	BOOK	Signed
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**Affidavit:**

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

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

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

(b) (6)	N/A	Jan-29-2021 08:58:21 (UTC-03:00) City of Buenos Aires		Edit - All signatures invalidated
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**Affidavit:**

N/A

090177e196ae3f32\Final\Final On: 01-Apr-2021 05:12 (GMT)

**Header Text:** c4591001

**Visit:** Investigator Signature - Unscheduled

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

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

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

**Site No:** 1241

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

**Subject No:** 12411471

**Subject Initials:** ---

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

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

Edson Moreira	Approved	Oct-29-2020 16:47:33 (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.

(b) (6)	N/A	Oct-29-2020 11:07:05 (UTC-03:00) City of Buenos Aires		Edit - All signatures invalidated
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**Affidavit:**

N/A

(b) (6)	Approved	Oct-22-2020 19:40:26 (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.

090177e196ae3f32\Final\Final On: 01-Apr-2021 05:12 (GMT)

**Header Text:** c4591001

**Visit:** COHORT\_SELECTION

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

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

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

**Site No:** 1241

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

**Subject No:** 12411471

**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 11:46:56 (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 11:46:56 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> STAGE 3 COHORTS	Initial Entry

090177e196ae3f32\Final\Final On: 01-Apr-2021 05:12 (GMT)

**Header Text:** c4591001

**Visit:** COHORT\_SELECTION

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

**Site No:** 1241

**Subject No:** 12411471

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

**Form:** MAIN INFORMED CONSENT - 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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*I. Consent Was:*

Date	Location	User	Value	Reason
Aug-25-2020 11:47:01 (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

090177e196ae3f32\Final\Final On: 01-Apr-2021 05:12 (GMT)

Header Text: c4591001

Visit: COHORT\_SELECTION

Form Version: 06-Jul-2020 21:55

Site No: 1241

Subject No: 12411471

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 11:46:48 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 12411471	Item copied from previous form

**2. Birth Date:**

Date	Location	User	Value	Reason
Aug-25-2020 11:46:43 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> (b) (6) 1986	Enrollment Entry

**3. Sex:**

Date	Location	User	Value	Reason
Aug-25-2020 11:47:12 (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 11:47:12 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NOT HISPANIC OR LATINO(A) OR OF SPANISH ORIGIN	Initial Entry

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

Date	Location	User	Value	Reason
Aug-25-2020 11:47:12 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BLACK OR AFRICAN AMERICAN WHITE	Initial Entry

090177e196ae3f32\Final\Final On: 01-Apr-2021 05:12 (GMT)

**Header Text:** c4591001

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

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

**Site No:** 1241

**Subject No:** 12411471

**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

[Back to Form](#)

*1. Date of Visit*

Date	Location	User	Value	Reason
Aug-25-2020 11:47:20 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Aug/25/2020	Initial Entry

090177e196ae3f32\Final\Final On: 01-Apr-2021 05:12 (GMT)

**Header Text:** c4591001**Visit:** V1\_DAY1\_VAX1\_L**Form:** INCLUSION/EXCLUSION CRITERIA - eCRF Audit Trail History**Form Version:** 21-Aug-2020 02:50**Form Status:** Data Complete, Locked, Frozen, Verified**Site No:** 1241**Site Name:** (1241) Hospital Irma Dulce**Subject No:** 12411471**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 19:09[Back to Form](#)*I.a*

Date	Location	User	Value	Reason
Aug-25-2020 11:47:42 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Inclusion Number:</b> <b>Criterion Description:</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) <b>Criterion met?:</b> <b>Criterion ID:</b> (F or Pfizer use only):	Initial Entry

*I.a Inclusion Number:*

Date	Location	User	Value	Reason
Aug-25-2020 11:47:42 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 1	Initial Entry

*I.a Criterion Description:*

Date	Location	User	Value	Reason
Aug-25-2020 11:47:42 (UTC-03:00) City of	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Male or female participants bet	Initial Entry

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form: INCLUSION/EXCLUSION CRITERIA - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:50

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1241

Site Name: (1241) Hospital Irma Dulce

Subject No: 12411471

Subject Initials: ---

Generated By: (b) (4)

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

Buenos Aires		(b) (4), (b) (6)	ween 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)	
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**1.a Criterion met?**

Date	Location	User	Value	Reason
Aug-25-2020 11:47:42 (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 11:47:42 (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 11:47:42 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Inclusion Number:</b> <b>Criteria:</b> Participants who are willing and able to comply with all scheduled visits, vaccination plan, laboratory tests, lifestyle considerations, and other study procedures <b>Criterion met?:</b> YES	Initial Entry

090177e196ae3f32\Final\Final On: 01-Apr-2021 05:12 (GMT)

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form: INCLUSION/EXCLUSION CRITERIA - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:50

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1241

Site Name: (1241) Hospital Irma Dulce

Subject No: 12411471

Subject Initials: ---

Generated By: (b) (4)

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

			Criterion ID : (For Pfizer use only):	
			IN02A00	

***1.b Inclusion Number:***

Date	Location	User	Value	Reason
Aug-25-2020 11:47:42 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> 2	Initial Entry

***1.b Criterion Description:***

Date	Location	User	Value	Reason
Aug-25-2020 11:47:42 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Participants who are willing and able to comply with all scheduled visits, vaccination plan, laboratory tests, lifestyle considerations, and other study procedures	Initial Entry

***1.b Criterion met?***

Date	Location	User	Value	Reason
Aug-25-2020 11:47:42 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> YES	Initial Entry

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

Date	Location	User	Value	Reason
Aug-25-2020 11:47:42 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> IN02A00	Initial Entry

***1.c***

090177e196ae3f32\Final\Final On: 01-Apr-2021 05:12 (GMT)

**Header Text:** c4591001

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

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

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

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

**Site No:** 1241

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

**Subject No:** 12411471

**Subject Initials:** ---

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

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

Date	Location	User	Value	Reason
Aug-25-2020 11:47:42 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Inclusion Number:</b> 3 <b>Criteria:</b> Healthy participants who are determined by medical history, physical examination, and clinical judgment of the investigator to be eligible for inclusion in the study. <b>Criterion ID:</b> IN03A00 <b>Use only:</b> (For Pfizer use only):	Initial Entry

090177e196ae3f32\Final\Final On: 01-Apr-2021 05:12 (GMT)

**Header Text:** c4591001**Visit:** V1\_DAY1\_VAX1\_L**Form:** INCLUSION/EXCLUSION CRITERIA - eCRF Audit Trail History**Form Version:** 21-Aug-2020 02:50**Form Status:** Data Complete, Locked, Frozen, Verified**Site No:** 1241**Site Name:** (1241) Hospital Irma Dulce**Subject No:** 12411471**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 19:09***I.c Inclusion Number:***

Date	Location	User	Value	Reason
Aug-25-2020 11:47:42 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 3	Initial Entry

***I.c Criterion Description:***

Date	Location	User	Value	Reason
Aug-25-2020 11:47:42 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Healthy participants who are determined by medical history, physical examination, and clinical judgment of the investigator to be eligible for inclusion in the study	Initial Entry

***I.c Criterion met?***

Date	Location	User	Value	Reason
Aug-25-2020 11:47:42 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

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

Date	Location	User	Value	Reason
Aug-25-2020 11:47:42 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> IN03A00	Initial Entry

***I.d***

Date	Location	User	Value	Reason
Aug-25-2020 11:47:42 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Inclus 4 ion N umbe r:	Initial Entry

**Header Text:** c4591001

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

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

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

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

**Site No:** 1241

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

**Subject No:** 12411471

**Subject Initials:** ---

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

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

			<p><b>Criterion Description:</b> Capable of giving personal signed informed consent, which includes compliance with the requirements and restrictions listed in the ICD and in this protocol</p> <p><b>Criterion Met?:</b> YES</p> <p><b>Criterion ID:</b> IN04A00</p> <p><b>Use Only:</b> (For Pfizer use only):</p>	
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090177e196ae3f32\Final\Final On: 01-Apr-2021 05:12 (GMT)

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form: INCLUSION/EXCLUSION CRITERIA - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:50

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1241

Site Name: (1241) Hospital Irma Dulce

Subject No: 12411471

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 11:47:42 (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 11:47:42 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Capable of giving personal signed informed consent, which includes compliance with the requirements and restrictions listed in the ICD and in this protocol	Initial Entry

**1.d Criterion met?**

Date	Location	User	Value	Reason
Aug-25-2020 11:47:42 (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
Aug-25-2020 11:47:42 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> IN04A00	Initial Entry

**2.a**

Date	Location	User	Value	Reason
Aug-25-2020 11:47:42 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Exclusion Number:	Initial Entry

090177e196ae3f32\Final\Final On: 01-Apr-2021 05:12 (GMT)

**Header Text:** c4591001

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

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

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

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

**Site No:** 1241

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

**Subject No:** 12411471

**Subject Initials:** ---

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

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

			<p><b>Criterion Description:</b> 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</p> <p><b>Criterion met?:</b> NO</p> <p><b>Criterion ID:</b> EX01A00</p> <p><b>Use only:</b> (For Pfizer use only):</p>
--	--	--	--

**2.a Exclusion Number:**

Date	Location	User	Value	Reason
Aug-25-2020 11:47:42 (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 11:47:42 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 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	Initial Entry

**2.a Criterion met?:**

Date	Location	User	Value	Reason
Aug-25-2020 11:47:42 (UTC-03:00) City of	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**Header Text:** c4591001

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

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

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

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

**Site No:** 1241

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

**Subject No:** 12411471

**Subject Initials:** ---

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

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

Buenos Aires

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

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

Date	Location	User	Value	Reason
Aug-25-2020 11:47:42 (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 11:47:42 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Exclusi 2 on Nu mber: <b>Criteria</b> Known infection with <b>on Desc</b> human immunodefici <b>ription:</b> ency virus (HIV), hep atitis C virus (HCV), or hepatitis B virus ( HBV) <b>Criteria</b> NO <b>on met</b> ?: <b>Criteria</b> EX02A00 <b>on ID: (</b> <b>For Pfi</b> <b>zer use</b> <b>only):</b>	Initial Entry

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Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form: INCLUSION/EXCLUSION CRITERIA - eCRF Audit Trail History

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Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1241

Site Name: (1241) Hospital Irma Dulce

Subject No: 12411471

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 11:47:42 (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 11:47:42 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Known infection with human immunodeficiency virus (HIV), hepatitis C virus (HCV), or hepatitis B virus (HBV)	Initial Entry

2.b Criterion met?

Date	Location	User	Value	Reason
Aug-25-2020 11:47:42 (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 11:47:42 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> EX02A00	Initial Entry

2.c

Date	Location	User	Value	Reason
Aug-25-2020 11:47:42 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Exclusion Number :	Initial Entry

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**Header Text:** c4591001

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

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

**Site No:** 1241

**Subject No:** 12411471

**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

			<p><b>Criterion Description:</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)</p> <p><b>Criterion Met?:</b> NO</p> <p><b>Criterion ID:</b> EX03A00</p> <p><b>Use Only:</b> (For Pfizer use only):</p>	
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Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

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Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1241

Site Name: (1241) Hospital Irma Dulce

Subject No: 12411471

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 11:47:42 (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 11:47:42 (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 11:47:42 (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
Aug-25-2020 11:47:42 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> EX03A00	Initial Entry

2.d

Date	Location	User	Value	Reason
Aug-25-2020 11:47:42 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Exclusion Number:</b> 4	Initial Entry

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Header Text: c4591001

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Site No: 1241

Site Name: (1241) Hospital Irma Dulce

Subject No: 12411471

Subject Initials: ---

Generated By: (b) (4)

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			<b>Criterion D</b> Receipt of medication intended to prevent COVID-19 <b>Criterion m</b> NO <b>et?:</b> <b>Criterion I</b> EX04A00 <b>D: (For Pfizer use only)</b> :	
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2.d Exclusion Number:

Date	Location	User	Value	Reason
Aug-25-2020 11:47:42 (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 11:47:42 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Receipt of medications intended to prevent COVID-19	Initial Entry

2.d Criterion met?

Date	Location	User	Value	Reason
Aug-25-2020 11:47:42 (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 11:47:42 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> EX04A00	Initial Entry

2.e

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Header Text: c4591001

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Site No: 1241

Site Name: (1241) Hospital Irma Dulce

Subject No: 12411471

Subject Initials: ---

Generated By: (b) (4)

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

Date	Location	User	Value	Reason
Aug-25-2020 11:47:42 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Exclusion Number:</b> <b>Criterion:</b> Immunocompromised individuals with known or suspected immunodeficiency, as determined by history and/or laboratory/physical examination <b>Criterion met?:</b> <b>Criterion ID:</b> EX08A00 (For Pfizer use only)	Initial Entry

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Site No: 1241

Site Name: (1241) Hospital Irma Dulce

Subject No: 12411471

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 11:47:42 (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 11:47:42 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Immunocompromised individuals with known or suspected immunodeficiency, as determined by history and/or laboratory/physical examination	Initial Entry

2.e Criterion met?

Date	Location	User	Value	Reason
Aug-25-2020 11:47:42 (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
Aug-25-2020 11:47:42 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> EX08A00	Initial Entry

2.f

Date	Location	User	Value	Reason
Aug-25-2020 11:47:42 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Exclus 10 ion Nu mber:	Initial Entry

090177e196ae3f32\Final\Final On: 01-Apr-2021 05:12 (GMT)

**Header Text:** c4591001

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

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

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

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

**Site No:** 1241

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

**Subject No:** 12411471

**Subject Initials:** ---

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

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

			<p><b>Criterion Description:</b> Bleeding diathesis or condition associated with prolonged bleeding that would, in the opinion of the investigator, contraindicate intramuscular injection</p> <p><b>Criterion ID:</b> NO</p> <p><b>Criterion ID:</b> EX10A00</p> <p><b>Criterion ID:</b> (For Pfizer use only):</p>	
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Header Text: c4591001

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Site No: 1241

Site Name: (1241) Hospital Irma Dulce

Subject No: 12411471

Subject Initials: ---

Generated By: (b) (4)

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

2.f Exclusion Number:

Date	Location	User	Value	Reason
Aug-25-2020 11:47:42 (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 11:47:42 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Bleeding diathesis or condition associated with prolonged bleeding that would, in the opinion of the investigator, contraindicate intramuscular injection	Initial Entry

2.f Criterion met?

Date	Location	User	Value	Reason
Aug-25-2020 11:47:42 (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
Aug-25-2020 11:47:42 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> EX10A00	Initial Entry

2.g

Date	Location	User	Value	Reason
Aug-25-2020 11:47:42 (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	Initial Entry

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Site No: 1241

Site Name: (1241) Hospital Irma Dulce

Subject No: 12411471

Subject Initials: ---

Generated By: (b) (4)

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			Criterion met?:	
			Criterion ID: EX11A00	
			(For Pfizer use only):	

2.g Exclusion Number:

Date	Location	User	Value	Reason
Aug-25-2020 11:47:42 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 11	Initial Entry

2.g Criterion Description:

Date	Location	User	Value	Reason
Aug-25-2020 11:47:42 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Women who are pregnant or breastfeeding	Initial Entry

2.g Criterion met?

Date	Location	User	Value	Reason
Aug-25-2020 11:47:42 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

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

Date	Location	User	Value	Reason
Aug-25-2020 11:47:42 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: EX11A00	Initial Entry

2.h

Date	Location	User	Value	Reason
Aug-25-2020 11:47:42 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Exclusion Number: 12	Initial Entry

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Site Name: (1241) Hospital Irma Dulce

Subject No: 12411471

Subject Initials: ---

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			<b>Criterion D description:</b> Previous vaccination with any coronavirus vaccine <b>Criterion met?:</b> NO <b>Criterion ID: (For Pfizer use only):</b> EX12A00	
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**2.h Exclusion Number:**

Date	Location	User	Value	Reason
Aug-25-2020 11:47:42 (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 11:47:42 (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 11:47:42 (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 11:47:42 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> EX12A00	Initial Entry

**2.i**

Date	Location	User	Value	Reason
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**Form Status:** Data Complete, Locked, Frozen, Verified

**Site No:** 1241

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

**Subject No:** 12411471

**Subject Initials:** ---

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

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

<p>Aug-25-2020 11:47:42 (UTC-03:00) City of Buenos Aires</p>	<p>ACV0PFEINFP6000</p>	<p>(b) (4), (b) (6)</p>	<p><b>Data Entry:</b>  <b>Exclusion Number:</b> 13  <b>Criterion Description:</b> Subjects who receive immunosuppressive therapy, such as cytotoxic agents or systemic corticosteroids  <b>Criterion met?:</b> NO  <b>Criterion ID: (For Pfizer use only):</b> EX13A01</p>	<p>Initial Entry</p>
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Site No: 1241

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2.i Exclusion Number:

Date	Location	User	Value	Reason
Aug-25-2020 11:47:42 (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 11:47:42 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Subjects who receive immunosuppressive therapy, such as cytotoxic agents or systemic corticosteroids	Initial Entry

2.i Criterion met?

Date	Location	User	Value	Reason
Aug-25-2020 11:47:42 (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 11:47:42 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> EX13A01	Initial Entry

2.j

Date	Location	User	Value	Reason
Aug-25-2020 11:47:42 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Exclusion Number: 15	Initial Entry

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

**Subject No:** 12411471

**Subject Initials:** ---

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

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			<p><b>Criterion Description:</b> Receipt of blood/plasma products or immunoglobulin, from 60 days before study intervention administration or planned receipt throughout the study</p> <p><b>Criterion met?:</b> NO</p> <p><b>Criterion ID:</b> EX14A01 : (For Pfizer use only):</p>
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Subject No: 12411471

Subject Initials: ---

Generated By: (b) (4)

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2.j Exclusion Number:

Date	Location	User	Value	Reason
Aug-25-2020 11:47:42 (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 11:47:42 (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 11:47:42 (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)

Date	Location	User	Value	Reason
Aug-25-2020 11:47:42 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> EX14A01	Initial Entry

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Subject Initials: ---

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Date	Location	User	Value	Reason
Aug-25-2020 11:47:42 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Exclusion Number:</b> 16 <b>Criterion Description:</b> Participation in other studies involving study intervention within 28 days prior to study entry and/or during study participation <b>Criterion Met?:</b> NO <b>Criterion ID:</b> EX15A01 <b>(For Pfizer use only):</b> :	Initial Entry

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Subject No: 12411471

Subject Initials: ---

Generated By: (b) (4)

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

2.k Exclusion Number:

Date	Location	User	Value	Reason
Aug-25-2020 11:47:42 (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 11:47:42 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Participation in other studies in involving study intervention with in 28 days prior to study entry and/or during study participatio n	Initial Entry

2.k Criterion met?

Date	Location	User	Value	Reason
Aug-25-2020 11:47:42 (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 11:47:42 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> EX15A01	Initial Entry

2.l

Date	Location	User	Value	Reason
Aug-25-2020 11:47:42 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Exclusio 17 n Num ber:	Initial Entry

090177e196ae3f32\Final\Final On: 01-Apr-2021 05:12 (GMT)

**Header Text:** c4591001

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

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

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

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

**Site No:** 1241

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

**Subject No:** 12411471

**Subject Initials:** ---

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

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

			<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: (Former Pfizer use only):</b> EX16A01</p>	
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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: 12411471

Subject Initials: ---

Generated By: (b) (4)

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

2.l Exclusion Number:

Date	Location	User	Value	Reason
Aug-25-2020 11:47:42 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 17	Initial Entry

2.l Criterion Description:

Date	Location	User	Value	Reason
Aug-25-2020 11:47:42 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Previous participation in other studies involving study intervention containing lipid nanoparticles	Initial Entry

2.l Criterion met?

Date	Location	User	Value	Reason
Aug-25-2020 11:47:42 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

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

Date	Location	User	Value	Reason
Aug-25-2020 11:47:42 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> EX16A01	Initial Entry

2.m

Date	Location	User	Value	Reason
Aug-25-2020 11:47:42 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Exclusion Number: 22	Initial Entry

090177e196ae3f32\Final\Final On: 01-Apr-2021 05:12 (GMT)

**Header Text:** c4591001

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

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

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

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

**Site No:** 1241

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

**Subject No:** 12411471

**Subject Initials:** ---

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

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

			<p><b>Crite</b> Investigator site staff o  <b>ri</b> r Pfizer employees dire  <b>Descr</b> ctly involved in the con  <b>ption</b> duct of the study, site st  <b>:</b> aff otherwise supervise  d by the investigator, a  nd their respective fami  ly members</p> <p><b>Crite</b> NO  <b>ri</b>  <b>on</b>  <b>met?:</b></p> <p><b>Crite</b> EX21A01  <b>ri</b>  <b>on I</b>  <b>D: (F</b>  <b>or Pfi</b>  <b>zer us</b>  <b>e only</b>  <b>):</b></p>	
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090177e196ae3f32\Final\Final On: 01-Apr-2021 05:12 (GMT)

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form: INCLUSION/EXCLUSION CRITERIA - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:50

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1241

Site Name: (1241) Hospital Irma Dulce

Subject No: 12411471

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 11:47:42 (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 11:47:42 (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 the conduct of the study, site staff otherwise supervised by the investigator, and their respective family members	Initial Entry

**2.m Criterion met?**

Date	Location	User	Value	Reason
Aug-25-2020 11:47:42 (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)**

Date	Location	User	Value	Reason
Aug-25-2020 11:47:42 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> EX21A01	Initial Entry

090177e196ae3f32\Final\Final On: 01-Apr-2021 05:12 (GMT)

**Header Text:** c4591001

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

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

**Site No:** 1241

**Subject No:** 12411471

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

**Form:** DISPOSITION - SCREENING - 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 Completion/Discontinuation/Death**

Date	Location	User	Value	Reason
Aug-25-2020 11:47:50 (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 11:47:50 (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 11:47:50 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> COMPLETED	Initial Entry

090177e196ae3f32\Final\Final On: 01-Apr-2021 05:12 (GMT)

**Header Text:** c4591001**Visit:** V1\_DAY1\_VAX1\_L**Form Version:** 22-Apr-2020 21:03**Site No:** 1241**Subject No:** 12411471**Generated By:** (b) (4)**Form:** GENERAL MEDICAL HISTORY - 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[Back to Form](#)*I.a*

Date	Location	User	Value	Reason
Oct-29-2020 11:07:44 (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> Headache <b>Start Date:</b> Aug/20/2020 <b>Ongoing:</b> NO End Date: Aug/20/2020	Initial Entry

*I.a Line/MH Number:*

Date	Location	User	Value	Reason
Oct-29-2020 11:07:44 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 1	Initial Entry

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

Date	Location	User	Value	Reason
Oct-29-2020 11:07:44 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Headache	Initial Entry

*I.a Start Date:*

Date	Location	User	Value	Reason
Oct-29-2020 11:07:44 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Aug/20/2020	Initial Entry

*I.a Ongoing:*

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

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

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

**Site No:** 1241

**Subject No:** 12411471

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

**Form:** GENERAL MEDICAL HISTORY - 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

Oct-29-2020 11:07:44 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO End Date:  Aug/20/2020	Initial Entry
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090177e196ae3f32\Final\Final On: 01-Apr-2021 05:12 (GMT)

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 21-Aug-2020 02:51

Site No: 1241

Subject No: 12411471

Generated By: (b) (4)

Form: VITAL SIGNS - BASELINE - 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
Aug-25-2020 11:48:32 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Aug/25/2020	Initial Entry

**2. Weight:**

Date	Location	User	Value	Reason
Aug-25-2020 11:48:32 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> 63.9	Initial Entry

**3. Unit:**

Date	Location	User	Value	Reason
Aug-25-2020 11:48:32 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> kg	Initial Entry

**4. Height:**

Date	Location	User	Value	Reason
Aug-25-2020 11:48:32 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> 164.5	Initial Entry

**5. Unit:**

Date	Location	User	Value	Reason
Aug-25-2020 11:48:32 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> cm	Initial Entry

**6. Body Mass Index:**

Date	Location	User	Value	Reason
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090177e196ae3f32\Final\Final On: 01-Apr-2021 05:12 (GMT)

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 21-Aug-2020 02:51

Site No: 1241

Subject No: 12411471

Generated By: (b) (4)

Form: VITAL SIGNS - BASELINE - 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

Aug-25-2020 11:48:32 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 23.6	Initial Entry
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7.a

Date	Location	User	Value	Reason
Aug-25-2020 11:48:32 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Record Identifier 1</b> :: <b>Temperature:</b> 36.9 <b>Temperature Uni C</b> <b>t:</b> <b>Temperature Loc ORAL CA</b> <b>ation::</b> VITY	Initial Entry

7.a Record Identifier:

Date	Location	User	Value	Reason
Aug-25-2020 11:48:32 (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 11:48:32 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 36.9	Initial Entry

7.a Unit:

Date	Location	User	Value	Reason
Aug-25-2020 11:48:32 (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
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090177e196ae3f32\Final\Final On: 01-Apr-2021 05:12 (GMT)

**Header Text:** c4591001

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

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

**Site No:** 1241

**Subject No:** 12411471

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

**Form:** VITAL SIGNS - BASELINE - 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

Aug-25-2020 11:48:32 (UTC-03:00) City of Buenos Aires	ACVOPFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> ORAL CAVITY	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: 12411471

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 11:48:42 (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 11:48:42 (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 11:48:42 (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 11:48:42 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> STUDY SITE	Initial Entry

**5. Specimen Type:**

Date	Location	User	Value	Reason
Aug-25-2020 11:48:42 (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
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090177e196ae3f32\Final\Final On: 01-Apr-2021 05:12 (GMT)

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

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

Form Version: 21-Aug-2020 02:49

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1241

Site Name: (1241) Hospital Irma Dulce

Subject No: 12411471

Subject Initials: ---

Generated By: (b) (4)

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

Aug-25-2020 11:48:42 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Sponsor-Defined Identifier:</b> 113 <b>Test::</b> Choriogonadotropin Beta_PX113 <b>Result::</b> NEGATIVE <b>Not Done::</b>	Initial Entry
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**6.a Sponsor ID:**

Date	Location	User	Value	Reason
Aug-25-2020 11:48:42 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 113	Initial Entry

**6.a Test:**

Date	Location	User	Value	Reason
Aug-25-2020 11:48:42 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Choriogonadotropin Beta_PX1 13	Initial Entry

**6.a Result:**

Date	Location	User	Value	Reason
Aug-25-2020 11:48:42 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NEGATIVE	Initial Entry

090177e196ae3f32\Final\Final On: 01-Apr-2021 05:12 (GMT)

**Header Text:** c4591001

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

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

**Site No:** 1241

**Subject No:** 12411471

**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 11:48:56 (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 11:48:56 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 65073	Initial Entry

090177e196ae3f32\Final\Final On: 01-Apr-2021 05:12 (GMT)

**Header Text:** c4591001**Visit:** V1\_DAY1\_VAX1\_L**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY  
- eCRF Audit Trail History**Form Version:** 22-Apr-2020 21:03**Form Status:** Data Complete, Locked, Frozen, Verified**Site No:** 1241**Site Name:** (1241) Hospital Irma Dulce**Subject No:** 12411471**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 19:09[Back to Form](#)**1. Data Origin**

Date	Location	User	Value	Reason
Aug-25-2020 13:33:25 (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 13:33:25 (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 13:33:41 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Aug-25-2020 13:33:25 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Aug-25-2020 13:33:25 (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 13:33:41 (UTC-03:00) City of	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample ID:</b> BPT0WH	Initial Entry

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1241

Site Name: (1241) Hospital Irma Dulce

Subject No: 12411471

Subject Initials: ---

Generated By: (b) (4)

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

Buenos Aires		(b) (4), (b) (6)		
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5.a Sample ID

Date	Location	User	Value	Reason
Aug-25-2020 13:33:41 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BPT0WH	Initial Entry

5.b

Date	Location	User	Value	Reason
Aug-25-2020 13:33:50 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sample ID: BPT0WJ	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Aug-25-2020 13:33:50 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BPT0WJ	Initial Entry

5.c

Date	Location	User	Value	Reason
Aug-25-2020 13:33:57 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sample ID: BPT0WK	Initial Entry

5.c Sample ID

Date	Location	User	Value	Reason
Aug-25-2020 13:33:57 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BPT0WK	Initial Entry

5.d

Date	Location	User	Value	Reason
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090177e196ae3f32\Final\Final On: 01-Apr-2021 05:12 (GMT)

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1241

Site Name: (1241) Hospital Irma Dulce

Subject No: 12411471

Subject Initials: ---

Generated By: (b) (4)

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

Aug-25-2020 13:34:23 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample ID:</b> BLCH4N	Initial Entry
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**5.d Sample ID**

Date	Location	User	Value	Reason
Aug-25-2020 13:34:23 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BLCH4N	Initial Entry

**5.e**

Date	Location	User	Value	Reason
Aug-25-2020 13:34:30 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample ID:</b> BLCH4P	Initial Entry

**5.e Sample ID**

Date	Location	User	Value	Reason
Aug-25-2020 13:34:30 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BLCH4P	Initial Entry

090177e196ae3f32\Final\Final On: 01-Apr-2021 05:12 (GMT)

**Header Text:** c4591001**Visit:** V1\_DAY1\_VAX1\_L**Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB - eCRF Audit Trail History**Form Version:** 22-Apr-2020 21:03**Form Status:** Data Complete, Locked, Frozen, Verified**Site No:** 1241**Site Name:** (1241) Hospital Irma Dulce**Subject No:** 12411471**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 19:09[Back to Form](#)**1. Data Origin**

Date	Location	User	Value	Reason
Aug-25-2020 13:34:44 (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 13:34:44 (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 13:35:00 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Aug-25-2020 13:34:44 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Aug-25-2020 13:34:44 (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 13:35:00 (UTC-03:00) City of	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample ID:</b> BPT0W2	Initial Entry

**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:** 12411471

**Subject Initials:** ---

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

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

Buenos Aires

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

**5.a Sample ID**

Date	Location	User	Value	Reason
Aug-25-2020 13:35:00 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BPT0W2	Initial Entry

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 22-Apr-2020 21:04

Site No: 1241

Subject No: 12411471

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 11:49:43 (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 11:49:43 (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 11:49:43 (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 11:49:43 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Aug/25/2020 09:57	Initial Entry

**5. Anatomical Location:**

Date	Location	User	Value	Reason
Aug-25-2020 11:49:43 (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
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090177e196ae3f32\Final\Final On: 01-Apr-2021 05:12 (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: 12411471

Subject Initials: ---

Generated By: (b) (4)

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

Aug-25-2020 11:49:43 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> LEFT	Initial Entry
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**7. Route:**

Date	Location	User	Value	Reason
Aug-25-2020 11:49:43 (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 11:49:43 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> THE PROTOCOL SPECIFIED O BSERVATION PERIOD	Initial Entry

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

Date	Location	User	Value	Reason
Aug-25-2020 11:49:43 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

090177e196ae3f32\Final\Final On: 01-Apr-2021 05:12 (GMT)

**Header Text:** c4591001

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

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

**Site No:** 1241

**Subject No:** 12411471

**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 11:49:49 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO - REACTOGENICITY E-D IARY NOT COLLECTED FO R THIS SUBJECT	Initial Entry

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

**Site No:** 1241

**Subject No:** 12411471

**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*

<b>Date</b>	<b>Location</b>	<b>User</b>	<b>Value</b>	<b>Reason</b>
Sep-15-2020 10:37:52 (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: 12411471

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 10:38:19 (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 10:38:19 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Record Identifier 1 :: Temperature: 36.5 Temperature Unit: Temperature Location: ORAL CAVITY	Initial Entry

**2.a Record Identifier:**

Date	Location	User	Value	Reason
Sep-15-2020 10:38:19 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 1	Initial Entry

**2.a Temperature:**

Date	Location	User	Value	Reason
Sep-15-2020 10:38:19 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 36.5	Initial Entry

**2.a Unit:**

Date	Location	User	Value	Reason
Sep-15-2020 10:38:19 (UTC-03:00) City of	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> C	Initial Entry

090177e196ae3f32\Final\Final On: 01-Apr-2021 05:12 (GMT)

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

**Site No:** 1241

**Subject No:** 12411471

**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

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

Date	Location	User	Value	Reason
Sep-15-2020 10:38:19 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> ORAL CAVITY	Initial Entry

Header Text: c4591001

Visit: V2\_VAX2\_L

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

Form Version: 21-Aug-2020 02:49

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1241

Site Name: (1241) Hospital Irma Dulce

Subject No: 12411471

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 10:38:30 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> URINALYSIS	Initial Entry

**2. Lab Sub-Panel:**

Date	Location	User	Value	Reason
Sep-15-2020 10:38:30 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> PREGNANCY	Initial Entry

**3. Collection Date:**

Date	Location	User	Value	Reason
Sep-15-2020 10:38:30 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Sep/15/2020	Initial Entry

**4. Laboratory Name and Address (Derived)**

Date	Location	User	Value	Reason
Sep-15-2020 10:38:30 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> STUDY SITE	Initial Entry

**5. Specimen Type:**

Date	Location	User	Value	Reason
Sep-15-2020 10:38:30 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> URINE	Initial Entry

**6.a**

Date	Location	User	Value	Reason
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090177e196ae3f32\Final\Final On: 01-Apr-2021 05:12 (GMT)

Header Text: c4591001

Visit: V2\_VAX2\_L

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

Form Version: 21-Aug-2020 02:49

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1241

Site Name: (1241) Hospital Irma Dulce

Subject No: 12411471

Subject Initials: ---

Generated By: (b) (4)

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

Sep-15-2020 10:38:30 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Sponsor-Defined Identifier:</b> 113 <b>Test::</b> Choriogonadotropin Beta_PX113 <b>Result::</b> NEGATIVE <b>Not Done::</b>	Initial Entry
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**6.a Sponsor ID:**

Date	Location	User	Value	Reason
Sep-15-2020 10:38:30 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 113	Initial Entry

**6.a Test:**

Date	Location	User	Value	Reason
Sep-15-2020 10:38:30 (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 10:38:30 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NEGATIVE	Initial Entry

090177e196ae3f32\Final\Final On: 01-Apr-2021 05:12 (GMT)

**Header Text:** c4591001**Visit:** V2\_VAX2\_L**Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB - eCRF Audit Trail History**Form Version:** 22-Apr-2020 21:03**Form Status:** Data Complete, Locked, Frozen, Verified**Site No:** 1241**Site Name:** (1241) Hospital Irma Dulce**Subject No:** 12411471**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 19:09[Back to Form](#)**1. Data Origin**

Date	Location	User	Value	Reason
Sep-15-2020 13:34:56 (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 13:34:56 (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 13:35:03 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Sep-15-2020 13:34:56 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Sep-15-2020 13:34:56 (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 13:35:03 (UTC-03:00) City of	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample ID:</b> BPWYLZ	Initial Entry

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

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

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

**Site No:** 1241

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

**Subject No:** 12411471

**Subject Initials:** ---

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

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

Buenos Aires	(b) (4), (b) (6)
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**5.a Sample ID**

Date	Location	User	Value	Reason
Sep-15-2020 13:35:03 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BPWYLZ	Initial Entry

Header Text: c4591001

Visit: V2\_VAX2\_L

Form Version: 22-Apr-2020 21:04

Site No: 1241

Subject No: 12411471

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 10:39:00 (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 10:39:00 (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 10:39:00 (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 10:39:00 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sep/15/2020 09:50	Initial Entry

**5. Anatomical Location:**

Date	Location	User	Value	Reason
Sep-15-2020 10:39:00 (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
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090177e196ae3f32\Final\Final On: 01-Apr-2021 05:12 (GMT)

Header Text: c4591001

Visit: V2\_VAX2\_L

Form Version: 22-Apr-2020 21:04

Site No: 1241

Subject No: 12411471

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

Sep-15-2020 10:39:00 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> LEFT	Initial Entry
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**7. Route:**

Date	Location	User	Value	Reason
Sep-15-2020 10:39:00 (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 10:39:00 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> THE PROTOCOL SPECIFIED O BSERVATION PERIOD	Initial Entry

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

Date	Location	User	Value	Reason
Sep-15-2020 10:39:00 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

090177e196ae3f32\Final\Final On: 01-Apr-2021 05:12 (GMT)

**Header Text:** c4591001

**Visit:** V3\_MONTH1\_POSTVAX2\_L

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

**Site No:** 1241

**Subject No:** 12411471

**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
Oct-13-2020 10:51:42 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Oct/13/2020	Initial Entry

090177e196ae3f32\Final\Final On: 01-Apr-2021 05:12 (GMT)

**Header Text:** c4591001**Visit:** V3\_MONTH1\_POSTVAX2\_L**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY  
- eCRF Audit Trail History**Form Version:** 22-Apr-2020 21:03**Form Status:** Data Complete, Locked, Frozen, Verified**Site No:** 1241**Site Name:** (1241) Hospital Irma Dulce**Subject No:** 12411471**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 19:09[Back to Form](#)**1. Data Origin**

Date	Location	User	Value	Reason
Oct-14-2020 08:52:47 (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 08:52:47 (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 08:53:00 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Oct-14-2020 08:52:47 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Oct-14-2020 08:52:47 (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 08:53:00 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample ID:</b> BRD3X2	Initial Entry

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: 12411471

Subject Initials: ---

Generated By: (b) (4)

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

Buenos Aires		(b) (4), (b) (6)		
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5.a Sample ID

Date	Location	User	Value	Reason
Oct-14-2020 08:53:00 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BRD3X2	Initial Entry

5.b

Date	Location	User	Value	Reason
Oct-14-2020 08:53:12 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sample ID: BRXGNN	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Oct-14-2020 08:53:12 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BRXGNN	Initial Entry

5.c

Date	Location	User	Value	Reason
Oct-14-2020 08:53:20 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sample ID: BRXGNN	Initial Entry

5.c Sample ID

Date	Location	User	Value	Reason
Oct-14-2020 08:53:20 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BRXGNN	Initial Entry

090177e196ae3f32\Final\Final On: 01-Apr-2021 05:12 (GMT)

**Header Text:** c4591001

**Visit:** V4\_MONTH6\_L

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

**Site No:** 1241

**Subject No:** 12411471

**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
Mar-09-2021 09:52:01 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Mar/9/2021	Initial Entry

Header Text: c4591001

Visit: V4\_MONTH6\_L

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1241

Site Name: (1241) Hospital Irma Dulce

Subject No: 12411471

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
Mar-09-2021 10:38:58 (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
Mar-09-2021 10:38:58 (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
Mar-09-2021 10:39:11 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Mar-09-2021 10:38:58 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Mar-09-2021 10:38:58 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES Date of Collection:  Mar/9/2021	Initial Entry

**5.a**

Date	Location	User	Value	Reason
Mar-09-2021 10:39:11 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample ID:</b> BRCFLW	Initial Entry

090177e196ae3f32\Final\Final On: 01-Apr-2021 05:12 (GMT)

Header Text: c4591001

Visit: V4\_MONTH6\_L

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1241

Site Name: (1241) Hospital Irma Dulce

Subject No: 12411471

Subject Initials: ---

Generated By: (b) (4)

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

Buenos Aires

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

5.a Sample ID

Date	Location	User	Value	Reason
Mar-09-2021 10:39:11 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BRCFLW	Initial Entry

5.b

Date	Location	User	Value	Reason
Mar-09-2021 10:39:21 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sample ID: BSCYM6	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Mar-09-2021 10:39:21 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BSCYM6	Initial Entry

5.c

Date	Location	User	Value	Reason
Mar-09-2021 10:39:29 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sample ID: BSCYM7	Initial Entry

5.c Sample ID

Date	Location	User	Value	Reason
Mar-09-2021 10:39:29 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BSCYM7	Initial Entry

090177e196ae3f32\Final\Final On: 01-Apr-2021 05:12 (GMT)

**Header Text:** c4591001

**Visit:** End of Treatment - Unscheduled

**Form:** DISPOSITION - TREATMENT - eCRF Audit Trail History

**Form Version:** 15-Sep-2020 21:55

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

**Site No:** 1241

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

**Subject No:** 12411471

**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 10:52:41 (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 10:52:41 (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 10:52:41 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> COMPLETED	Initial Entry

090177e196ae3f32\Final\Final On: 01-Apr-2021 05:12 (GMT)

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1241

**Subject No:** 12411471

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

**Form:** ADVERSE EVENT REPORT - Audit Trail

**Form Status:**

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

**Subject Initials:** ---

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

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Date	Location	User	Value	Reason
Aug-25-2020 12:08:12 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Created	

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1241

**Subject No:** 12411471

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

**Form:** ADVERSE EVENT REPORT - Audit Trail

**Form Status:**

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

**Subject Initials:** ---

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

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Date	Location	User	Value	Reason
Oct-13-2020 10:54:30 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Created	

090177e196ae3f32\Final\Final On: 01-Apr-2021 05:12 (GMT)

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1241

**Subject No:** 12411471

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

**Form:** ADVERSE EVENT REPORT - Audit Trail

**Form Status:**

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

**Subject Initials:** ---

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

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Date	Location	User	Value	Reason
Oct-13-2020 10:55:45 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Created	

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1241

**Subject No:** 12411471

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

**Form:** ADVERSE EVENT REPORT - Audit Trail

**Form Status:**

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

**Subject Initials:** ---

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

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Date	Location	User	Value	Reason
Oct-13-2020 10:56:44 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Created	

090177e196ae3f32\Final\Final On: 01-Apr-2021 05:12 (GMT)

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1241

**Subject No:** 12411471

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

**Form:** ADVERSE EVENT REPORT - Audit Trail

**Form Status:**

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

**Subject Initials:** ---

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

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Date	Location	User	Value	Reason
Oct-13-2020 10:57:47 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Created	

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1241

**Subject No:** 12411471

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

**Form:** ADVERSE EVENT REPORT - Audit Trail

**Form Status:**

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

**Subject Initials:** ---

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

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Date	Location	User	Value	Reason
Oct-13-2020 10:58:54 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Created	

090177e196ae3f32\Final\Final On: 01-Apr-2021 05:12 (GMT)

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1241

**Subject No:** 12411471

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

**Form:** ADVERSE EVENT REPORT - Audit Trail

**Form Status:**

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

**Subject Initials:** ---

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

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Date	Location	User	Value	Reason
Oct-13-2020 10:59:47 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Created	

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1241

**Subject No:** 12411471

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

**Form:** ADVERSE EVENT REPORT - Audit Trail

**Form Status:**

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

**Subject Initials:** ---

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

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Date	Location	User	Value	Reason
Oct-13-2020 11:00:40 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Created	

090177e196ae3f32\Final\Final On: 01-Apr-2021 05:12 (GMT)

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1241

**Subject No:** 12411471

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

**Form:** ADVERSE EVENT REPORT - Audit Trail

**Form Status:**

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

**Subject Initials:** ---

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

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Date	Location	User	Value	Reason
Oct-13-2020 11:01:47 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Created	

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1241

**Subject No:** 12411471

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

**Form:** ADVERSE EVENT REPORT - Audit Trail

**Form Status:**

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

**Subject Initials:** ---

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

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Date	Location	User	Value	Reason
Oct-13-2020 11:15:33 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Created	

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1241

**Subject No:** 12411471

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

**Form:** ADVERSE EVENT REPORT - Audit Trail

**Form Status:**

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

**Subject Initials:** ---

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

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Date	Location	User	Value	Reason
Mar-09-2021 10:09:48 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Created	

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1241

Subject No: 12411471

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen

Site Name: (1241) Hospital Irma Dulce

Subject Initials: ---

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

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**1. Category:**

Date	Location	User	Value	Reason
Aug-25-2020 12:08:12 (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
Aug-25-2020 12:08:12 (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
Aug-25-2020 12:08:12 (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
Aug-25-2020 12:08:12 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Aug/25/2020 09:58	Initial Entry

**5. Is the adverse event still ongoing?**

Date	Location	User	Value	Reason
Aug-27-2020 16:01:39 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO End Date Time: Aug/26/2020 UNK:UNK	New Information
Aug-25-2020 12:08:12 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

090177e196ae3f32\Final\Final On: 01-Apr-2021 05:12 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1241

Subject No: 12411471

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen

Site Name: (1241) Hospital Irma Dulce

Subject Initials: ---

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

6. Toxicity Grade:

Date	Location	User	Value	Reason
Aug-25-2020 12:08:12 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> 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
Aug-25-2020 12:08:12 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NO	Initial Entry

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

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

Date	Location	User	Value	Reason
Aug-25-2020 12:08:12 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NO	Initial Entry

9. Is this event related to study treatment:

Date	Location	User	Value	Reason
Aug-25-2020 12:08:12 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> RELATED	Initial Entry

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Aug-25-2020 12:08:12 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NOT APPLICABLE	Initial Entry

090177e196ae3f32\Final\Final On: 01-Apr-2021 05:12 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1241

Subject No: 12411471

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen

Site Name: (1241) Hospital Irma Dulce

Subject Initials: ---

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

11. Was a Concomitant Medication given?

Date	Location	User	Value	Reason
Aug-25-2020 12:08:12 (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
Aug-25-2020 12:08:12 (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
Aug-27-2020 16:01:59 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Aug-27-2020 16:01:59 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> RECOVERED/RESOLVED	New Information
Aug-27-2020 16:01:39 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	For AE Injection site pain: Response to "What was the outcome of this adverse event?" is 'Recovering/Resolving' but AE End Date/Time is present.
Aug-25-2020 12:08:12 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> RECOVERING/RESOLVING	Initial Entry

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

Date	Location	User	Value	Reason
Aug-25-2020 12:08:12 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

090177e196ae3f32\Final\Final On: 01-Apr-2021 05:12 (GMT)

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1241

**Subject No:** 12411471

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

**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History

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

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

**Subject Initials:** ---

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

Buenos Aires

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

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Header Text: c4591001

Visit: Logs - Unscheduled

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Site No: 1241

Subject No: 12411471

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen

Site Name: (1241) Hospital Irma Dulce

Subject Initials: ---

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

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**1. Category:**

Date	Location	User	Value	Reason
Oct-13-2020 10:54:30 (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
Oct-13-2020 10:54:30 (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
Oct-13-2020 10:54:30 (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
Oct-13-2020 10:54:30 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sep/15/2020 12:00	Initial Entry

**5. Is the adverse event still ongoing?**

Date	Location	User	Value	Reason
Oct-13-2020 10:54:30 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO End Date Time: Sep/21/2020 UNK:UNK	Initial Entry

**6. Toxicity Grade:**

090177e196ae3f32\Final\Final On: 01-Apr-2021 05:12 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Locked, Frozen

Site No: 1241

Site Name: (1241) Hospital Irma Dulce

Subject No: 12411471

Subject Initials: ---

Generated By: (b) (4)

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

Date	Location	User	Value	Reason
Oct-13-2020 10:54:30 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 2	Initial Entry

7. Is the adverse event serious?

If Yes, NOTIFY PFIZER IMMEDIATELY.

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

Date	Location	User	Value	Reason
Oct-13-2020 10:54:30 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

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

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

Date	Location	User	Value	Reason
Oct-13-2020 10:54:30 (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
Oct-13-2020 10:54:30 (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
Oct-13-2020 10:54:30 (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?

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Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Locked, Frozen

Site No: 1241

Site Name: (1241) Hospital Irma Dulce

Subject No: 12411471

Subject Initials: ---

Generated By: (b) (4)

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

Date	Location	User	Value	Reason
Oct-13-2020 10:54:30 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

*12. Was a Non-Drug Treatment given?*

Date	Location	User	Value	Reason
Oct-13-2020 10:54:30 (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
Oct-13-2020 10:54:30 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> RECOVERED/RESOLVED	Initial Entry

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

Date	Location	User	Value	Reason
Oct-13-2020 10:54:30 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

090177e196ae3f32\Final\Final On: 01-Apr-2021 05:12 (GMT)

Header Text: c4591001

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Site No: 1241

Subject No: 12411471

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen

Site Name: (1241) Hospital Irma Dulce

Subject Initials: ---

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

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**1. Category:**

Date	Location	User	Value	Reason
Oct-13-2020 10:55:45 (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
Oct-13-2020 10:55:45 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 3	Initial Entry

**3. Adverse Event:**

*(If possible specify diagnosis, not individual symptoms)*

Date	Location	User	Value	Reason
Oct-13-2020 10:55:45 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Injection site swelling	Initial Entry

**4. Start Date Time:**

Date	Location	User	Value	Reason
Oct-13-2020 10:55:45 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sep/15/2020 12:00	Initial Entry

**5. Is the adverse event still ongoing?**

Date	Location	User	Value	Reason
Oct-13-2020 10:55:45 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO End Date Time: Sep/21/2020 UNK:UNK	Initial Entry

**6. Toxicity Grade:**

090177e196ae3f32\Final\Final On: 01-Apr-2021 05:12 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Locked, Frozen

Site No: 1241

Site Name: (1241) Hospital Irma Dulce

Subject No: 12411471

Subject Initials: ---

Generated By: (b) (4)

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

Date	Location	User	Value	Reason
Oct-13-2020 10:55:45 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 2	Initial Entry

**7. Is the adverse event serious?**

**If Yes, NOTIFY PFIZER IMMEDIATELY.**

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

Date	Location	User	Value	Reason
Oct-13-2020 10:55:45 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

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

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

Date	Location	User	Value	Reason
Oct-13-2020 10:55:45 (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
Oct-13-2020 10:55:45 (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
Oct-13-2020 10:55:45 (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?**

090177e196ae3f32\Final\Final On: 01-Apr-2021 05:12 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Locked, Frozen

Site No: 1241

Site Name: (1241) Hospital Irma Dulce

Subject No: 12411471

Subject Initials: ---

Generated By: (b) (4)

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

Date	Location	User	Value	Reason
Oct-13-2020 10:55:45 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

**12. Was a Non-Drug Treatment given?**

Date	Location	User	Value	Reason
Oct-13-2020 10:55:45 (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
Oct-13-2020 10:55:45 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> RECOVERED/RESOLVED	Initial Entry

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

Date	Location	User	Value	Reason
Oct-13-2020 10:55:45 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

090177e196ae3f32\Final\Final On: 01-Apr-2021 05:12 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1241

Subject No: 12411471

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen

Site Name: (1241) Hospital Irma Dulce

Subject Initials: ---

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

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**1. Category:**

Date	Location	User	Value	Reason
Oct-13-2020 10:56:44 (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
Oct-13-2020 10:56:44 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 4	Initial Entry

**3. Adverse Event:**

*(If possible specify diagnosis, not individual symptoms)*

Date	Location	User	Value	Reason
Oct-13-2020 10:56:44 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Fever	Initial Entry

**4. Start Date Time:**

Date	Location	User	Value	Reason
Oct-13-2020 10:56:44 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sep/15/2020 18:00	Initial Entry

**5. Is the adverse event still ongoing?**

Date	Location	User	Value	Reason
Oct-13-2020 10:56:44 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO End Date Time: Sep/18/2020 UNK:UNK	Initial Entry

**6. Toxicity Grade:**

090177e196ae3f32\Final\Final On: 01-Apr-2021 05:12 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Locked, Frozen

Site No: 1241

Site Name: (1241) Hospital Irma Dulce

Subject No: 12411471

Subject Initials: ---

Generated By: (b) (4)

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

Date	Location	User	Value	Reason
Oct-13-2020 10:56:44 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 2	Initial Entry

7. Is the adverse event serious?

If Yes, NOTIFY PFIZER IMMEDIATELY.

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

Date	Location	User	Value	Reason
Oct-13-2020 10:56:44 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

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

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

Date	Location	User	Value	Reason
Oct-13-2020 10:56:44 (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
Oct-13-2020 10:56:44 (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
Oct-13-2020 10:56:44 (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?

090177e196ae3f32\Final\Final On: 01-Apr-2021 05:12 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Locked, Frozen

Site No: 1241

Site Name: (1241) Hospital Irma Dulce

Subject No: 12411471

Subject Initials: ---

Generated By: (b) (4)

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

Date	Location	User	Value	Reason
Oct-13-2020 10:56:44 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

**12. Was a Non-Drug Treatment given?**

Date	Location	User	Value	Reason
Oct-13-2020 10:56:44 (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
Oct-13-2020 10:56:44 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> RECOVERED/RESOLVED	Initial Entry

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

Date	Location	User	Value	Reason
Oct-13-2020 10:56:44 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

090177e196ae3f32\Final\Final On: 01-Apr-2021 05:12 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1241

Subject No: 12411471

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen

Site Name: (1241) Hospital Irma Dulce

Subject Initials: ---

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

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**1. Category:**

Date	Location	User	Value	Reason
Oct-13-2020 10:57:47 (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
Oct-13-2020 10:57:47 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 5	Initial Entry

**3. Adverse Event:**

*(If possible specify diagnosis, not individual symptoms)*

Date	Location	User	Value	Reason
Oct-13-2020 10:57:47 (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
Oct-13-2020 10:57:47 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sep/15/2020 18:00	Initial Entry

**5. Is the adverse event still ongoing?**

Date	Location	User	Value	Reason
Oct-13-2020 10:57:47 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO End Date Time: Sep/18/2020 UNK:UNK	Initial Entry

**6. Toxicity Grade:**

090177e196ae3f32\Final\Final On: 01-Apr-2021 05:12 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Locked, Frozen

Site No: 1241

Site Name: (1241) Hospital Irma Dulce

Subject No: 12411471

Subject Initials: ---

Generated By: (b) (4)

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

Date	Location	User	Value	Reason
Oct-13-2020 10:57:47 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> 2	Initial Entry

7. Is the adverse event serious?

If Yes, NOTIFY PFIZER IMMEDIATELY.

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

Date	Location	User	Value	Reason
Oct-13-2020 10:57:47 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NO	Initial Entry

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

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

Date	Location	User	Value	Reason
Oct-13-2020 10:57:47 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NO	Initial Entry

9. Is this event related to study treatment:

Date	Location	User	Value	Reason
Oct-13-2020 10:57:47 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> RELATED	Initial Entry

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Oct-13-2020 10:57:47 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NOT APPLICABLE	Initial Entry

11. Was a Concomitant Medication given?

090177e196ae3f32\Final\Final On: 01-Apr-2021 05:12 (GMT)

Header Text: c4591001

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Form Version: 22-Apr-2020 21:02

Site No: 1241

Subject No: 12411471

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen

Site Name: (1241) Hospital Irma Dulce

Subject Initials: ---

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

Date	Location	User	Value	Reason
Oct-13-2020 10:57:47 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

**12. Was a Non-Drug Treatment given?**

Date	Location	User	Value	Reason
Oct-13-2020 10:57:47 (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
Oct-13-2020 10:57:47 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> RECOVERED/RESOLVED	Initial Entry

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

Date	Location	User	Value	Reason
Oct-13-2020 10:57:47 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

090177e196ae3f32\Final\Final On: 01-Apr-2021 05:12 (GMT)

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Site No: 1241

Subject No: 12411471

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen

Site Name: (1241) Hospital Irma Dulce

Subject Initials: ---

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

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**1. Category:**

Date	Location	User	Value	Reason
Oct-13-2020 10:58:54 (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
Oct-13-2020 10:58:54 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 6	Initial Entry

**3. Adverse Event:**

*(If possible specify diagnosis, not individual symptoms)*

Date	Location	User	Value	Reason
Oct-13-2020 10:58:54 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Headache	Initial Entry

**4. Start Date Time:**

Date	Location	User	Value	Reason
Oct-13-2020 10:58:54 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sep/15/2020 18:00	Initial Entry

**5. Is the adverse event still ongoing?**

Date	Location	User	Value	Reason
Oct-13-2020 10:58:54 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO End Date Time: Sep/18/2020 UNK:UNK	Initial Entry

**6. Toxicity Grade:**

090177e196ae3f32\Final\Final On: 01-Apr-2021 05:12 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Locked, Frozen

Site No: 1241

Site Name: (1241) Hospital Irma Dulce

Subject No: 12411471

Subject Initials: ---

Generated By: (b) (4)

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

Date	Location	User	Value	Reason
Oct-13-2020 10:58:54 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 2	Initial Entry

**7. Is the adverse event serious?**

**If Yes, NOTIFY PFIZER IMMEDIATELY.**

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

Date	Location	User	Value	Reason
Oct-13-2020 10:58:54 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

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

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

Date	Location	User	Value	Reason
Oct-13-2020 10:58:54 (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
Oct-13-2020 10:58:54 (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
Oct-13-2020 10:58:54 (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?**

090177e196ae3f32\Final\Final On: 01-Apr-2021 05:12 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1241

Subject No: 12411471

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen

Site Name: (1241) Hospital Irma Dulce

Subject Initials: ---

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

Date	Location	User	Value	Reason
Oct-13-2020 10:58:54 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

**12. Was a Non-Drug Treatment given?**

Date	Location	User	Value	Reason
Oct-13-2020 10:58:54 (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
Oct-13-2020 10:58:54 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> RECOVERED/RESOLVED	Initial Entry

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

Date	Location	User	Value	Reason
Oct-13-2020 10:58:54 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

090177e196ae3f32\Final\Final On: 01-Apr-2021 05:12 (GMT)

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Site No: 1241

Subject No: 12411471

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen

Site Name: (1241) Hospital Irma Dulce

Subject Initials: ---

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

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**1. Category:**

Date	Location	User	Value	Reason
Oct-13-2020 10:59:47 (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
Oct-13-2020 10:59:47 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 7	Initial Entry

**3. Adverse Event:**

*(If possible specify diagnosis, not individual symptoms)*

Date	Location	User	Value	Reason
Oct-13-2020 10:59:47 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Fatigue	Initial Entry

**4. Start Date Time:**

Date	Location	User	Value	Reason
Oct-13-2020 10:59:47 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sep/15/2020 18:00	Initial Entry

**5. Is the adverse event still ongoing?**

Date	Location	User	Value	Reason
Oct-13-2020 10:59:47 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO End Date Time: Sep/18/2020 UNK:UNK	Initial Entry

**6. Toxicity Grade:**

090177e196ae3f32\Final\Final On: 01-Apr-2021 05:12 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Locked, Frozen

Site No: 1241

Site Name: (1241) Hospital Irma Dulce

Subject No: 12411471

Subject Initials: ---

Generated By: (b) (4)

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

Date	Location	User	Value	Reason
Oct-13-2020 10:59:47 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 2	Initial Entry

7. Is the adverse event serious?

If Yes, NOTIFY PFIZER IMMEDIATELY.

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

Date	Location	User	Value	Reason
Oct-13-2020 10:59:47 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

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

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

Date	Location	User	Value	Reason
Oct-13-2020 10:59:47 (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
Oct-13-2020 10:59:47 (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
Oct-13-2020 10:59:47 (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?

090177e196ae3f32\Final\Final On: 01-Apr-2021 05:12 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

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Site No: 1241

Site Name: (1241) Hospital Irma Dulce

Subject No: 12411471

Subject Initials: ---

Generated By: (b) (4)

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

Date	Location	User	Value	Reason
Oct-13-2020 10:59:47 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

**12. Was a Non-Drug Treatment given?**

Date	Location	User	Value	Reason
Oct-13-2020 10:59:47 (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
Oct-13-2020 10:59:47 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> RECOVERED/RESOLVED	Initial Entry

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

Date	Location	User	Value	Reason
Oct-13-2020 10:59:47 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

090177e196ae3f32\Final\Final On: 01-Apr-2021 05:12 (GMT)

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Form Status: Data Complete, Locked, Frozen

Site Name: (1241) Hospital Irma Dulce

Subject Initials: ---

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

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**1. Category:**

Date	Location	User	Value	Reason
Oct-13-2020 11:00:40 (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
Oct-13-2020 11:00:40 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 8	Initial Entry

**3. Adverse Event:**

*(If possible specify diagnosis, not individual symptoms)*

Date	Location	User	Value	Reason
Oct-13-2020 11:00:40 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Myalgia	Initial Entry

**4. Start Date Time:**

Date	Location	User	Value	Reason
Oct-13-2020 11:00:40 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sep/15/2020 18:00	Initial Entry

**5. Is the adverse event still ongoing?**

Date	Location	User	Value	Reason
Oct-13-2020 11:00:40 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO End Date Time: Sep/18/2020 UNK:UNK	Initial Entry

**6. Toxicity Grade:**

090177e196ae3f32\Final\Final On: 01-Apr-2021 05:12 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Locked, Frozen

Site No: 1241

Site Name: (1241) Hospital Irma Dulce

Subject No: 12411471

Subject Initials: ---

Generated By: (b) (4)

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

Date	Location	User	Value	Reason
Oct-13-2020 11:00:40 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> 2	Initial Entry

7. Is the adverse event serious?

If Yes, NOTIFY PFIZER IMMEDIATELY.

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

Date	Location	User	Value	Reason
Oct-13-2020 11:00:40 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NO	Initial Entry

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

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

Date	Location	User	Value	Reason
Oct-13-2020 11:00:40 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NO	Initial Entry

9. Is this event related to study treatment:

Date	Location	User	Value	Reason
Oct-13-2020 11:00:40 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> RELATED	Initial Entry

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Oct-13-2020 11:00:40 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NOT APPLICABLE	Initial Entry

11. Was a Concomitant Medication given?

090177e196ae3f32\Final\Final On: 01-Apr-2021 05:12 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Locked, Frozen

Site No: 1241

Site Name: (1241) Hospital Irma Dulce

Subject No: 12411471

Subject Initials: ---

Generated By: (b) (4)

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

Date	Location	User	Value	Reason
Oct-13-2020 11:00:40 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

**12. Was a Non-Drug Treatment given?**

Date	Location	User	Value	Reason
Oct-13-2020 11:00:40 (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
Oct-13-2020 11:00:40 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> RECOVERED/RESOLVED	Initial Entry

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

Date	Location	User	Value	Reason
Oct-13-2020 11:00:40 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

090177e196ae3f32\Final\Final On: 01-Apr-2021 05:12 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1241

Subject No: 12411471

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen

Site Name: (1241) Hospital Irma Dulce

Subject Initials: ---

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

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**1. Category:**

Date	Location	User	Value	Reason
Oct-13-2020 11:01:47 (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
Oct-13-2020 11:01:47 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 9	Initial Entry

**3. Adverse Event:**

*(If possible specify diagnosis, not individual symptoms)*

Date	Location	User	Value	Reason
Oct-13-2020 11:01:47 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Nausea	Initial Entry

**4. Start Date Time:**

Date	Location	User	Value	Reason
Oct-13-2020 11:01:47 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sep/15/2020 18:00	Initial Entry

**5. Is the adverse event still ongoing?**

Date	Location	User	Value	Reason
Oct-13-2020 11:01:47 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO End Date Time: Sep/18/2020 UNK:UNK	Initial Entry

**6. Toxicity Grade:**

090177e196ae3f32\Final\Final On: 01-Apr-2021 05:12 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Locked, Frozen

Site No: 1241

Site Name: (1241) Hospital Irma Dulce

Subject No: 12411471

Subject Initials: ---

Generated By: (b) (4)

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

Date	Location	User	Value	Reason
Oct-13-2020 11:01:47 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 2	Initial Entry

7. Is the adverse event serious?

If Yes, NOTIFY PFIZER IMMEDIATELY.

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

Date	Location	User	Value	Reason
Oct-13-2020 11:01:47 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

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

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

Date	Location	User	Value	Reason
Oct-13-2020 11:01:47 (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
Oct-13-2020 11:01:47 (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
Oct-13-2020 11:01:47 (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?

090177e196ae3f32\Final\Final On: 01-Apr-2021 05:12 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1241

Subject No: 12411471

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen

Site Name: (1241) Hospital Irma Dulce

Subject Initials: ---

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

Date	Location	User	Value	Reason
Oct-13-2020 11:01:47 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

**12. Was a Non-Drug Treatment given?**

Date	Location	User	Value	Reason
Oct-13-2020 11:01:47 (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
Oct-13-2020 11:01:47 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> RECOVERED/RESOLVED	Initial Entry

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

Date	Location	User	Value	Reason
Oct-13-2020 11:01:47 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

090177e196ae3f32\Final\Final On: 01-Apr-2021 05:12 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1241

Subject No: 12411471

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen

Site Name: (1241) Hospital Irma Dulce

Subject Initials: ---

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

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**1. Category:**

Date	Location	User	Value	Reason
Oct-13-2020 11:15:33 (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
Oct-13-2020 11:15:33 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 10	Initial Entry

**3. Adverse Event:**

*(If possible specify diagnosis, not individual symptoms)*

Date	Location	User	Value	Reason
Oct-13-2020 11:15:33 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Reactive axillary lymph node in the left arm	Initial Entry

**4. Start Date Time:**

Date	Location	User	Value	Reason
Oct-13-2020 11:15:33 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sep/16/2020 UNK:UNK	Initial Entry

**5. Is the adverse event still ongoing?**

Date	Location	User	Value	Reason
Oct-13-2020 11:15:33 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO End Date Time: Sep/26/2020 UNK:UNK	Initial Entry

**6. Toxicity Grade:**

090177e196ae3f32\Final\Final On: 01-Apr-2021 05:12 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Locked, Frozen

Site No: 1241

Site Name: (1241) Hospital Irma Dulce

Subject No: 12411471

Subject Initials: ---

Generated By: (b) (4)

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

Date	Location	User	Value	Reason
Oct-13-2020 11:15:33 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 2	Initial Entry

7. Is the adverse event serious?

If Yes, NOTIFY PFIZER IMMEDIATELY.

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

Date	Location	User	Value	Reason
Oct-13-2020 11:15:33 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

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

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

Date	Location	User	Value	Reason
Oct-13-2020 11:15:33 (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
Oct-13-2020 11:15:33 (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
Oct-13-2020 11:15:33 (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?

090177e196ae3f32\Final\Final On: 01-Apr-2021 05:12 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1241

Subject No: 12411471

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen

Site Name: (1241) Hospital Irma Dulce

Subject Initials: ---

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

Date	Location	User	Value	Reason
Oct-13-2020 11:15:33 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

*12. Was a Non-Drug Treatment given?*

Date	Location	User	Value	Reason
Oct-13-2020 11:15:33 (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
Oct-13-2020 11:15:33 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> RECOVERED/RESOLVED	Initial Entry

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

Date	Location	User	Value	Reason
Oct-13-2020 11:15:33 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

090177e196ae3f32\Final\Final On: 01-Apr-2021 05:12 (GMT)

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History

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

**Form Status:** Data Complete

**Site No:** 1241

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

**Subject No:** 12411471

**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
Mar-09-2021 10:09:48 (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
Mar-09-2021 10:09:48 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 11	Initial Entry

**3. Adverse Event:**

*(If possible specify diagnosis, not individual symptoms)*

Date	Location	User	Value	Reason
Mar-09-2021 10:09:48 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Left mumps	Initial Entry

**4. Start Date Time:**

Date	Location	User	Value	Reason
Mar-09-2021 10:10:14 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Closed	Close Auto Query
Mar-09-2021 10:10:14 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Mar-09-2021 10:10:14 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Feb/UNK/2021 UNK:UNK	Transcription Error
Mar-09-2021 10:09:48 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Opened	For Left mumps: Start date UNK/Feb/2020 is before V1D1VX1L

090177e196ae3f32\Final\Final On: 01-Apr-2021 05:12 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

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Site No: 1241

Site Name: (1241) Hospital Irma Dulce

Subject No: 12411471

Subject Initials: ---

Generated By: (b) (4)

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

				visit date 25/Aug /2020. Please review and update as appropriate.
Mar-09-2021 10:09:48 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	Start date is before Consent Date 25/Aug/2020.
Mar-09-2021 10:09:48 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Feb/UNK/2020 UNK:UNK	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Mar-09-2021 10:09:48 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

6. Toxicity Grade:

Date	Location	User	Value	Reason
Mar-09-2021 10:09:48 (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
Mar-09-2021 10:09:48 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

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

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

Date	Location	User	Value	Reason
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090177e196ae3f32\Final\Final On: 01-Apr-2021 05:12 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

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Site No: 1241

Site Name: (1241) Hospital Irma Dulce

Subject No: 12411471

Subject Initials: ---

Generated By: (b) (4)

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

Mar-09-2021 10:09:48 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry
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9. Is this event related to study treatment:

Date	Location	User	Value	Reason
Mar-11-2021 11:10:42 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1 : Closed	Response satisfies query
Mar-11-2021 08:20:32 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1 : Answered	This was suspected and is not related to a pre-existing condition
Mar-11-2021 07:10:38 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000.InFormAdapter.Discrepancy	PFE SDQ PROD (b) (4)	Query 1 : Opened	Please review "If not related to study treatment other" field, the following text was indicated in the comment field [Sjogren syndrome]. Kindly confirm this condition is related to any pre existing event, if so please review and update the Medical History, else clarify. (b) (4)
Mar-09-2021	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data E</b>	Initial Entry

090177e196ae3f32\Final\Final On: 01-Apr-2021 05:12 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

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Site No: 1241

Subject No: 12411471

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete

Site Name: (1241) Hospital Irma Dulce

Subject Initials: ---

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

<p>10:09:48 (UTC-03:00) City of Buenos Aires</p>		(b) (4), (b) (6)	<p><b>ntry:</b> NOT R ELATE D If Not Relate d to st udy tre atment (s), thi s event is due to:  OTH ER  <i>If Oth er, spe cify :</i>  Sj o gr en sy n dr o m e</p>
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<b>10. Latest Action Taken with Study Treatment:</b>				
Date	Location	User	Value	Reason
Mar-09-2021 10:09:48 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NOT APPLICABLE	Initial Entry
<b>11. Was a Concomitant Medication given?</b>				

090177e196ae3f32\Final\Final On: 01-Apr-2021 05:12 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

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Site No: 1241

Site Name: (1241) Hospital Irma Dulce

Subject No: 12411471

Subject Initials: ---

Generated By: (b) (4)

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

Date	Location	User	Value	Reason
Mar-09-2021 10:09:48 (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
Mar-09-2021 10:09:48 (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
Mar-09-2021 10:09:48 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> RECOVERING/RESOLVING	Initial Entry

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

Date	Location	User	Value	Reason
Mar-09-2021 10:09:48 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

090177e196ae3f32\Final\Final On: 01-Apr-2021 05:12 (GMT)

**Header Text:** c4591001

**Visit:** Potential ReVax Initial Contact -  
Unscheduled

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

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

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

**Site No:** 1241

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

**Subject No:** 12411471

**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
Jan-29-2021 08:58:30 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6) [Redacted] [Redacted]	<b>Data Entry:</b> Jan/21/2021	Initial Entry

**Header Text:** c4591001

**Visit:** Potential ReVax Initial Contact -  
Unscheduled

**Form Version:** 10-Dec-2020 02:25

**Site No:** 1241

**Subject No:** 12411471

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

**Form:** FURTHER VACCINATION CONFIRMATION - eCRF Audit  
Trail History

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

Date	Location	User	Value	Reason
Jan-29-2021 08:58:41 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6) [Redacted] [Redacted]	<b>Data Entry:</b> Participant is willing to return for Vaccination 3 Participant is:  eligible and NOT confirme d to have received only pla cebo at Vaccination 1/2	Initial Entry

**Header Text:** c4591001

**Visit:** Disposition - Unscheduled

**Form:** TREATMENT UNBLINDED - eCRF Audit Trail History

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

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

**Site No:** 1241

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

**Subject No:** 12411471

**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-29-2021 08:58:21 (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-29-2021 08:58:21 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> ASSESS ELIGIBILITY FOR ADDITIONAL VACCINATION	Initial Entry

090177e196ae3f32\Final\Final On: 01-Apr-2021 05:12 (GMT)

**Header Text:** c4591001

**Visit:** Subject Status - Unscheduled

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

**Site No:** 1241

**Subject No:** 12411471

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

**Form:** SUBJECT STATUS - eCRF Audit Trail History

**Form Status:** Data Complete, Verified

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

**Subject Initials:** ---

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

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**1. Subject Status**

Date	Location	User	Value	Reason
Oct-13-2020 10:52:41 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> FOLLOW-UP	Initial Entry
Aug-25-2020 11:48:56 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> ENROLLED/RANDOMIZED	Initial Entry
Aug-25-2020 11:47:50 (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 10:52:41 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> Oct/13/2020	Initial Entry
Aug-25-2020 11:48:56 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> Aug/25/2020	Initial Entry
Aug-25-2020 11:47:50 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> Aug/25/2020	Initial Entry

090177e196ae3f32\Final\Final On: 01-Apr-2021 05:12 (GMT)

**Header Text:** c4591001

**Visit:** Investigator Signature - Unscheduled

**Form:** CASEBOOK SIGNATURE FORM - eCRF Audit Trail History

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

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

**Site No:** 1241

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

**Subject No:** 12411471

**Subject Initials:** ---

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

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

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*1. Casebook Signature*

Date	Location	User	Value	Reason
Oct-22-2020 19:40:10 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6) [Redacted] [Redacted]	<b>Data Entry:</b> Click Here to Enable	Initial Entry