

Header Text: c4591001

Visit: COHORT_SELECTION

Form Version: 30-Jul-2020 21:29

Site No: 1241

Subject No: 12411279

Generated By: (b) (4)

Form: COHORT_SELECTION

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](#)

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: 12411279

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/19/2020
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Header Text: c4591001

Visit: COHORT_SELECTION

Form Version: 06-Jul-2020 21:55

Site No: 1241

Subject No: 12411279

Generated By: (b) (4)

Form: DEMOGRAPHY

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](#)

Demography

1.	Subject ID	[12411279]
2.	Birth Date:	(b) (6) 1985
3.	Sex:	FEMALE
4.	Ethnicity:	NOT HISPANIC OR LATINO(A) OR OF SPANISH ORIGIN
5.	Race: (Check X all that apply):	BLACK OR AFRICAN AMERICAN
6.	Racial Designation:	

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:02

Site No: 1241

Subject No: 12411279

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/19/2020
2.	Erroneous Visit	

Header Text: c4591001**Visit:** V1_DAY1_VAX1_L**Form Version:** 30-Jul-2020 21:27**Site No:** 1241**Subject No:** 12411279**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

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

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 30-Jul-2020 21:27

Site No: 1241

Subject No: 12411279

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

	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
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

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Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 30-Jul-2020 21:27

Site No: 1241

Subject No: 12411279

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.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
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: 12411279

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/19/2020
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: 12411279

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1241) Hospital Irma Dulce

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Medical History Details

1.a	Line/MH Number:	[1]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Bariatric surgery]
	Start Date:	Jan/5/2013
	Ongoing:	NO End Date: Jan/5/2013
1.b	Line/MH Number:	[2]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[chronic low back pain]
	Start Date:	UNK/UNK/2013
	Ongoing:	YES

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Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 30-Jul-2020 21:28

Site No: 1241

Subject No: 12411279

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/19/2020
2.	Weight:	[76.5]
3.	Unit:	kg
4.	Height:	[168.0]
5.	Unit:	cm
6.	Body Mass Index:	[27.1]

Vital Signs Details

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

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Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 30-Jul-2020 21:27

Site No: 1241

Subject No: 12411279

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/19/2020
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: 12411279

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/19/2020
2.	Randomization Number:	[56038]
3.	Randomization Group:	[]

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1241

Subject No: 12411279

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/19/2020
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	[BP5S9S]
5.b	Sample ID	[BP5S9T]
5.c	Sample ID	[BP5S9V]
5.d	Sample ID	[BLCHFN]
5.e	Sample ID	[BLCHFP]

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Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1241

Subject No: 12411279

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/19/2020
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	[BP5S8K]
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090177e196ae3f38\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: 12411279

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/19/2020 12:25
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

090177e196ae3f38\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: 12411279

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: 12411279

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/10/2020
2.	Erroneous Visit	

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 21-Aug-2020 02:51

Site No: 1241

Subject No: 12411279

Generated By: (b) (4)

Form: VITAL SIGNS - TEMP

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:	Sep/10/2020
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Vital Signs Details

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

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 30-Jul-2020 21:27

Site No: 1241

Subject No: 12411279

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/10/2020
4.	Laboratory Name and Address (Derived)	[STUDY SITE]
5.	Specimen Type:	URINE

Lab Result

6.a	Sponsor ID:	[113]
	Test:	Choriogonadotropin Beta_PX113
	Result:	POSITIVE
	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: 12411279

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/10/2020
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	[BPX0TR]
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090177e196ae3f38\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: 12411279

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

[Form Comments](#)

[eCRF Audit Trail History](#)

Vaccination

1.	Was there a temporary delay of vaccination?	Not Done _____	Comments
2.	Treatment Name	Not Done _____ []	Comments
3.	Formulation:	Not Done _____	Comments
4.	Dose Date Time:	Not Done _____ //	Comments
5.	Anatomical Location:	Not Done _____	Comments
6.	Body Side:	Not Done _____	Comments
7.	Route:	Not Done _____	Comments
8.	Actual Dose:	Not Done _____ []	Comments
9.	Unit:	Not Done _____	Comments
10.	Timeframe Subject Was Observed	Not Done _____	Comments
11.	Was the subject observed for at least the protocol specified observation period after investigational product administration?	Not Done _____	Comments

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Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form Version: 22-Apr-2020 21:02

Site No: 1241

Subject No: 12411279

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/8/2020
2.	Erroneous Visit	

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form Version: 22-Apr-2020 21:03

Site No: 1241

Subject No: 12411279

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: Oct/8/2020
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	[BPWXW8]
5.b	Sample ID	[BHHZZM]
5.c	Sample ID	[BHHZZN]

090177e196ae3f38\Final\Final On: 01-Apr-2021 05:12 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit
on Nov/27/2020

Form: DATE OF VISIT - ILLNESS ONSET

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1241

Site Name: (1241) Hospital Irma Dulce

Subject No: 12411279

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	Nov/27/2020
2.	Erroneous Visit	

COVID-19 Illness Visit

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

Visit: POT_COVID_ILL 1 - Unscheduled Visit
on Nov/27/2020

Form: SIGNS AND SYMPTOMS OF POTENTIAL COVID-19

Form Version: 10-Oct-2020 16:02

Form Status: Data Complete, Frozen, Verified

Site No: 1241

Site Name: (1241) Hospital Irma Dulce

Subject No: 12411279

Subject Initials: ---

Generated By: (b) (4)

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

[eCRF Audit Trail History](#)

Signs and Symptoms

1.	Date of Assessment:	Nov/27/2020
2.	Date of First Symptom Started:	Nov/25/2020
3.	Symptoms Ongoing?	NO Date of Last Symptom Resolved: Nov/30/2020

Symptoms

4.a	Symptoms:	FEVER
	Was symptom present?	YES
4.b	Symptoms:	NEW OR INCREASED COUGH
	Was symptom present?	YES
4.c	Symptoms:	NEW OR INCREASED SHORTNESS OF BREATH
	Was symptom present?	NO
4.d	Symptoms:	CHILLS
	Was symptom present?	NO
4.e	Symptoms:	NEW OR INCREASED MUSCLE PAIN
	Was symptom present?	YES
4.f	Symptoms:	NEW LOSS OF TASTE OR SMELL
	Was symptom present?	NO
4.g	Symptoms:	NEW OR INCREASED SORE THROAT
	Was symptom present?	YES
4.h	Symptoms:	DIARRHEA
	Was symptom present?	NO
4.i	Symptoms:	VOMITING
	Was symptom present?	NO

090177e196ae3f38\Final\Final On: 01-Apr-2021 05:12 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit
on Nov/27/2020

Form: SIGNS AND SYMPTOMS OF POTENTIAL COVID-19

Form Version: 10-Oct-2020 16:02

Form Status: Data Complete, Frozen, Verified

Site No: 1241

Site Name: (1241) Hospital Irma Dulce

Subject No: 12411279

Subject Initials: ---

Generated By: (b) (4)

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

Symptoms - Other

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

Visit: POT_COVID_ILL 1

Form: MICROBIOLOGY SPECIMEN

Form Version: 06-Jul-2020 21:54

Site No: 1241

Site Name: (1241) Hospital Irma Dulce

Subject No: 12411279

Subject Initials: ---

Generated By: (b) (4)

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

#	Date of Collection	Specimen Type	Specimen Collection Location	Assay Code and Description	Device Type	Form Instance
1.	Not Applicable	Not Applicable	Not Applicable	Not Applicable	Not Applicable	Repeating Pages

090177e196ae3f38\Final\Final On: 01-Apr-2021 05:12 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** MICROBIOLOGY SPECIMEN
on Nov/27/2020

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen, Verified

Site No: 1241

Site Name: (1241) Hospital Irma Dulce

Subject No: 12411279

Subject Initials: ---

Generated By: (b) (4)

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

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[Form Comments](#)

[eCRF Audit Trail History](#)

Microbiology Specimen

1.	Actual Date of Collection:	Not Applicable _____ //	Comments
2.	Specimen Type:	Not Applicable _____	Comments
3.	Specimen Collection Location:	Not Applicable _____	Comments
4.	Assay Code and Description:	Not Applicable _____	Comments
5.	Device Type:	Not Applicable _____	Comments
6.	Trade Name:	Not Applicable _____	Comments
7.	Test Result:	Not Applicable _____	Comments
8.	Comments/Findings/Details:	Not Applicable _____ []	Comments
9.	Trade Name Other, Specify:	Not Applicable _____ []	Comments

090177e196ae3f38\Final\Final On: 01-Apr-2021 05:12 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit
on Nov/27/2020

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB SELF

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1241

Site Name: (1241) Hospital Irma Dulce

Subject No: 12411279

Subject Initials: ---

Generated By: (b) (4)

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

[eCRF Audit Trail History](#)

Electronic Sample Tracking

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB_SELF
3.	Sample Collected?	YES Date of Collection: Nov/27/2020
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	[RW92922]
-----	-----------	-----------

090177e196ae3f38\Final\Final On: 01-Apr-2021 05:12 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit
on Nov/27/2020

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1241

Site Name: (1241) Hospital Irma Dulce

Subject No: 12411279

Subject Initials: ---

Generated By: (b) (4)

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

[eCRF Audit Trail History](#)

Electronic Sample Tracking

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

Aliquot

Please enter barcode for each aliquot.

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

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** HEALTH CARE UTILIZATION
on Nov/27/2020

Form Version: 10-Oct-2020 15:59

Form Status: Data Complete, Frozen, Verified

Site No: 1241

Site Name: (1241) Hospital Irma Dulce

Subject No: 12411279

Subject Initials: ---

Generated By: (b) (4)

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

[eCRF Audit Trail History](#)

Health Care Utilization

1.a	Physician or Healthcare Professional:	SPECIALIST
	Occurrence of Visits or Contacts:	NO
1.b	Physician or Healthcare Professional:	EMERGENCY ROOM
	Occurrence of Visits or Contacts:	NO
1.c	Physician or Healthcare Professional:	PRIMARY CARE PHYSICIAN
	Occurrence of Visits or Contacts:	NO
1.d	Physician or Healthcare Professional:	URGENT CARE
	Occurrence of Visits or Contacts:	NO
1.e	Physician or Healthcare Professional:	TELEPHONE CONSULTATION
	Occurrence of Visits or Contacts:	NO
1.f	Physician or Healthcare Professional:	OTHER
	Occurrence of Visits or Contacts:	NO

Health Care Utilization Other

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

Health Care Utilization

3.	Has the subject been hospitalized due to potential COVID-19 illness?	NO
----	--	----

090177e196ae3f38\Final\Final On: 01-Apr-2021 05:12 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1

Form: RESPIRATORY TREATMENT

Form Version: 06-Jul-2020 21:53

Site No: 1241

Site Name: (1241) Hospital Irma Dulce

Subject No: 12411279

Subject Initials: ---

Generated By: (b) (4)

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

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

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** RESPIRATORY TREATMENT
on Nov/27/2020

Form Version: 06-Jul-2020 21:53

Form Status: Not Started

Site No: 1241

Site Name: (1241) Hospital Irma Dulce

Subject No: 12411279

Subject Initials: ---

Generated By: (b) (4)

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

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Respiratory Treatment

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

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** ILLNESS DETAILS
on Nov/27/2020

Form Version: 06-Jul-2020 21:52

Form Status: Data Complete, Frozen, Verified

Site No: 1241

Site Name: (1241) Hospital Irma Dulce

Subject No: 12411279

Subject Initials: ---

Generated By: (b) (4)

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

[eCRF Audit Trail History](#)

Illness Details

1.	Category of Clinical Event:	POTENTIAL COVID-19 ILLNESS
2.	Was a diagnosis obtained for Potential COVID-19 Illness?	YES Respiratory Illness Diagnosis: [Laryngotonsillitis] Date of Diagnosis: Nov/27/2020
3.	Toxicity Grade:	1

Header Text: c4591001

Visit: POT_COVID_ILL 1

Form: ILLNESS DETAILS - SEVERE

Form Version: 17-Jul-2020 21:55

Site No: 1241

Site Name: (1241) Hospital Irma Dulce

Subject No: 12411279

Subject Initials: ---

Generated By: (b) (4)

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

#	Category of Clinical Event:	Subcategory of Clinical Event	Diagnosis Obtained	Toxicity Grade	Form Instance
1.					Repeating Pages

090177e196ae3f38\Final\Final On: 01-Apr-2021 05:12 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** ILLNESS DETAILS - SEVERE
on Nov/27/2020

Form Version: 17-Jul-2020 21:55

Form Status: Not Started

Site No: 1241

Site Name: (1241) Hospital Irma Dulce

Subject No: 12411279

Subject Initials: ---

Generated By: (b) (4)

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

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Illness Details

1.	Category of Clinical Event:	
2.	Subcategory of Clinical Event:	
3.	Was a diagnosis obtained?	
4.	Toxicity Grade:	

Header Text: c4591001

Visit: POT_COVID_ILL 1

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY

Form Version: 30-Jul-2020 21:27

Site No: 1241

Site Name: (1241) Hospital Irma Dulce

Subject No: 12411279

Subject Initials: ---

Generated By: (b) (4)

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

#	Category for Lab Test	Vendor Name	Collection Date:	Specimen Type	Lab Result			Form Instance
1.					Sponsor-Defined Identifier	Test :	Result :	Repeating Pages

090177e196ae3f38\Final\Final On: 01-Apr-2021 05:12 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit
on Nov/27/2020

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY

Form Version: 30-Jul-2020 21:27

Form Status: Not Started

Site No: 1241

Site Name: (1241) Hospital Irma Dulce

Subject No: 12411279

Subject Initials: ---

Generated By: (b) (4)

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

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Lab Chemistry Details

1.	Lab Panel:	
2.	Laboratory Name and Address	[]
3.	Collection Date:	//
4.	Specimen Type:	

Lab Result

5.	Sponsor ID:	[]
	Test:	
	Result:	[]
	Not Done:	
	LNMT	Low [] High [] Unit

090177e196ae3f38\Final\Final On: 01-Apr-2021 05:12 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1

Form: LOCAL LABORATORY DATA - REPEATING Hematology

Form Version: 30-Jul-2020 21:28

Site No: 1241

Site Name: (1241) Hospital Irma Dulce

Subject No: 12411279

Subject Initials: ---

Generated By: (b) (4)

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

#	Category for Lab Test	Vendor Name (DERIVED)	Collection Date:	Specimen Type	Lab Result			Form Instance
1.					Sponsor-Defined Identifier	Test:	Result:	Repeating Pages

090177e196ae3f38\Final\Final On: 01-Apr-2021 05:12 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit
on Nov/27/2020

Form: LOCAL LABORATORY DATA - REPEATING Hematology

Form Version: 30-Jul-2020 21:28

Form Status: Not Started

Site No: 1241

Site Name: (1241) Hospital Irma Dulce

Subject No: 12411279

Subject Initials: ---

Generated By: (b) (4)

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

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Laboratory Data Hematology

1.	Lab Panel:	
2.	Laboratory Name and Address	[]
3.	Collection Date:	//
4.	Specimen Type:	

Lab Result

5.	Sponsor ID:	[]
	Test:	
	Result:	[]
	Not Done:	
	LNMT	Low [] High [] Unit

090177e196ae3f38\Final\Final On: 01-Apr-2021 05:12 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1

Form: VITAL SIGNS - COVID

Form Version: 30-Jul-2020 21:27

Site No: 1241

Site Name: (1241) Hospital Irma Dulce

Subject No: 12411279

Subject Initials: ---

Generated By: (b) (4)

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

#	Date:	Vital Signs Details			Form Instance
1.		Record Identifier:	Systolic:	Diastolic:	Repeating Pages

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** VITAL SIGNS - COVID
on Nov/27/2020

Form Version: 30-Jul-2020 21:27

Form Status: Not Started

Site No: 1241

Site Name: (1241) Hospital Irma Dulce

Subject No: 12411279

Subject Initials: ---

Generated By: (b) (4)

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

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Vital Signs

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

Vital Signs Details

2.	Record Identifier:	
	Systolic:	[]
	Diastolic:	[]
	Respiratory Rate in respirations/minute:	[]
	Heart Rate in beats/minute:	[]

Header Text: c4591001

Visit: POT_COVID_ILL 1

Form: VITAL SIGNS - PULSE OX ROOM AIR

Form Version: 30-Jul-2020 21:28

Site No: 1241

Site Name: (1241) Hospital Irma Dulce

Subject No: 12411279

Subject Initials: ---

Generated By: (b) (4)

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

#	Date:	Vital Signs Details		Form Instance
1.		Record Identifier:	Oxygen Saturation	Repeating Pages

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit
on Nov/27/2020

Form: VITAL SIGNS - PULSE OX ROOM AIR

Form Version: 30-Jul-2020 21:28

Form Status: Not Started

Site No: 1241

Site Name: (1241) Hospital Irma Dulce

Subject No: 12411279

Subject Initials: ---

Generated By: (b) (4)

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

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Vital Signs

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

Vital Signs Details

2.	Record Identifier:	
	SPO2 Pulse Oximetry %	[]

Header Text: c4591001

Visit: POT_COVID_ILL 1

Form: OXYGENATION PARAMETERS

Form Version: 06-Jul-2020 21:52

Site No: 1241

Site Name: (1241) Hospital Irma Dulce

Subject No: 12411279

Subject Initials: ---

Generated By: (b) (4)

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

#	Date Time of Assessment	Arterial Blood Gases PaO2	FiO2 (Fraction of Inhaled Oxygen)	Form Instance
1.				Repeating Pages

090177e196ae3f38\Final\Final On: 01-Apr-2021 05:12 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit
on Nov/27/2020

Form: OXYGENATION PARAMETERS

Form Version: 06-Jul-2020 21:52

Form Status: Not Started

Site No: 1241

Site Name: (1241) Hospital Irma Dulce

Subject No: 12411279

Subject Initials: ---

Generated By: (b) (4)

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

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Oxygenation Parameters

1.	Date Time of Assessment:	//
2.	Arterial Blood Gases PaO2 (mmHg):	[]
3.	FiO2 (Fraction of Inhaled Oxygen):	[]

Header Text: c4591001

Visit: POT_COVID_ILL 1

Form: CONCOMITANT MEDICATIONS - VASOPRESSORS

Form Version: 06-Jul-2020 21:55

Site No: 1241

Site Name: (1241) Hospital Irma Dulce

Subject No: 12411279

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.						Repeating Pages

090177e196ae3f38\Final\Final On: 01-Apr-2021 05:12 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit
on Nov/27/2020

Form: CONCOMITANT MEDICATIONS - VASOPRESSORS

Form Version: 06-Jul-2020 21:55

Form Status: Not Started

Site No: 1241

Site Name: (1241) Hospital Irma Dulce

Subject No: 12411279

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.	Start Date:	//
6.	Ongoing?	

090177e196ae3f38\Final\Final On: 01-Apr-2021 05:12 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1

Form: IMAGING

Form Version: 06-Jul-2020 21:53

Site No: 1241

Site Name: (1241) Hospital Irma Dulce

Subject No: 12411279

Subject Initials: ---

Generated By: (b) (4)

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

#	Date of Assessment	Location of Assessment	Imaging Method	Overall Assessment	Form Instance
1.					Repeating Pages

090177e196ae3f38\Final\Final On: 01-Apr-2021 05:12 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** IMAGING
on Nov/27/2020

Form Version: 06-Jul-2020 21:53

Form Status: Not Started

Site No: 1241

Site Name: (1241) Hospital Irma Dulce

Subject No: 12411279

Subject Initials: ---

Generated By: (b) (4)

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

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Imaging

1.	Date of Assessment:	//
2.	Location of Assessment:	
3.	Type of Imaging Exam:	
4.	Assessment:	

Header Text: c4591001

Visit: POT_COVID_CONVA 1 - Unscheduled
Visit on Dec/28/2020

Form: DATE OF VISIT - ILLNESS CONVALESCENT

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Frozen, Verified

Site No: 1241

Site Name: (1241) Hospital Irma Dulce

Subject No: 12411279

Subject Initials: ---

Generated By: (b) (4)

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

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Date of Visit

1.	Date of Visit	Dec/28/2020
2.	Erroneous Visit	

COVID-19 Illness Visit

3.	COVID-19 Illness Visit:	COVID_A1
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Header Text: c4591001

Visit: POT_COVID_CONVA 1 - Unscheduled
Visit on Dec/28/2020

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1241

Site Name: (1241) Hospital Irma Dulce

Subject No: 12411279

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: Dec/28/2020
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	[BR797H]
5.b	Sample ID	[BS2JVC]
5.c	Sample ID	[BS2JVD]

090177e196ae3f38\Final\Final On: 01-Apr-2021 05:12 (GMT)

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: 12411279

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: 12411279

Subject Initials: ---

Generated By: (b) (4)

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

Unplanned Assessments

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

Header Text: c4591001

Visit: End of Treatment - Unscheduled

Form Version: 22-Apr-2020 21:05

Site No: 1241

Subject No: 12411279

Generated By: (b) (4)

Form: DISPOSITION - TREATMENT

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 - Treatment

1.	Date of Completion/Discontinuation /Death :	Sep/10/2020
2.	Phase of Disposition:	VACCINATION
3.	Status:	PREGNANCY
4.	Specify Status:	[]

Header Text: c4591001

Visit: Follow-Up - Unscheduled

Form Version: 15-Sep-2020 21:53

Site No: 1241

Subject No: 12411279

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
Unscheduled Visit

Form: DATE OF VISIT - REPEAT SWAB

Form Version: 10-Oct-2020 15:57

Form Status: Not Started

Site No: 1241

Site Name: (1241) Hospital Irma Dulce

Subject No: 12411279

Subject Initials: ---

Generated By: (b) (4)

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

Date of Visit

1.	Date of Visit	//
2.	Erroneous Visit	

COVID-19 Repeat Swab

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

Header Text: c4591001

Visit: POT_COVID_REPEAT_SWAB - New
Unscheduled Visit

Form: ELECTRONIC SAMPLE TRACKING - REPEAT SWAB

Form Version: 10-Oct-2020 15:57

Form Status: Not Started

Site No: 1241

Site Name: (1241) Hospital Irma Dulce

Subject No: 12411279

Subject Initials: ---

Generated By: (b) (4)

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

Electronic Sample Tracking

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

Aliquot

Please enter barcode for each aliquot.

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

Header Text: c4591001

Visit: Logs

Form: ADVERSE EVENT REPORT

Form Version: 22-Apr-2020 21:02

Site No: 1241

Site Name: (1241) Hospital Irma Dulce

Subject No: 12411279

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	Exposure during pregnancy	Sep/10/2020 UNK:UNK	NO End Date Time: Oct/14/2020 UNK:UNK	Repeating Pages
2.	ADVERSE EVENT	2	Vaginal bleeding	Oct/5/2020 UNK:UNK	NO End Date Time: Oct/14/2020 UNK:UNK	Repeating Pages
3.	ADVERSE EVENT	3	RETAINED PRODUCTS OF CONCEPTION	Oct/14/2020 UNK:UNK	NO End Date Time: Oct/14/2020 UNK:UNK	Repeating Pages
4.	ADVERSE EVENT	4	Myalgia	Feb/16/2021 20:00	NO End Date Time: Feb/19/2021 UNK:UNK	Repeating Pages
5.	ADVERSE EVENT	5	Chills	Feb/16/2021 20:00	NO End Date Time: Feb/19/2021 UNK:UNK	Repeating Pages
6.	ADVERSE EVENT	6	Injection site pain	Feb/16/2021 20:00	NO End Date Time: Feb/19/2021 UNK:UNK	Repeating Pages

090177e196ae3f38\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: 12411279

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Locked, Frozen, Not 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:	[1]	
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[Exposure during pregnancy]	
4.	Start Date Time:	Sep/10/2020 UNK:UNK	
5.	Is the adverse event still ongoing?	NO End Date Time: Oct/14/2020 UNK:UNK	
6.	Toxicity Grade:	Not Applicable	Comments
7.	Is the adverse event serious? If Yes, NOTIFY PFIZER IMMEDIATELY. Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).	NO	
8.	Is this adverse event the result of a study Medication Error? If Yes, record the type of medication error on the Medication Error Log.	NO	
9.	Is this event related to study treatment:	NOT RELATED If Not Related to study treatment(s), this event is due to: OTHER If Other, specify: [Pregnancy]	
10.	Latest Action Taken with Study Treatment:	DRUG WITHDRAWN	

090177e196ae3f38\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: 12411279

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Locked, Frozen, Not Complete

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	[]

090177e196ae3f38\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: 12411279

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Locked, Frozen, Not 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:	[2]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[Vaginal bleeding]
4.	Start Date Time:	Oct/5/2020 UNK:UNK
5.	Is the adverse event still ongoing?	NO End Date Time: Oct/14/2020 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:	NOT RELATED If Not Related to study treatment(s), this event is due to: OTHER If Other, specify: [threat of abortion]
10.	Latest Action Taken with Study Treatment:	NOT APPLICABLE

090177e196ae3f38\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: 12411279

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Locked, Frozen, Not Complete

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	[]

090177e196ae3f38\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: 12411279

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

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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Adverse Event Report

1.	Category:	ADVERSE EVENT
2.	AE ID:	[3]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[RETAINED PRODUCTS OF CONCEPTION]
4.	Start Date Time:	Oct/14/2020 UNK:UNK
5.	Is the adverse event still ongoing?	NO End Date Time: Oct/14/2020 UNK:UNK
6.	Toxicity Grade:	3
7.	Is the adverse event serious? If Yes, NOTIFY PFIZER IMMEDIATELY. Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).	YES Is this serious event associated with congenital anomaly or birth defect? NO Did this serious event result in death? NO Did this serious event require or prolong hospitalization? YES Did this serious event result in persistent or significant disability/incapacity? NO Is this serious event life threatening? NO Other medically important serious event YES
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

090177e196ae3f38\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: 12411279

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1241) Hospital Irma Dulce

Subject Initials: ---

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

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: [Vaginal bleeding]
10.	Latest Action Taken with Study Treatment:	NOT APPLICABLE
11.	Was a Concomitant Medication given?	YES
12.	Was a Non-Drug Treatment given?	NO
13.	What was the outcome of this adverse event?:	RECOVERED/RESOLVED
14.	Did the adverse event cause the subject to be discontinued from the study?	NO
15.	Serious Adverse Event Number: For Pfizer Use Only	[2020352761]

090177e196ae3f38\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: 12411279

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Frozen

Site Name: (1241) Hospital Irma Dulce

Subject Initials: ---

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

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Adverse Event Report

1.	Category:	ADVERSE EVENT
2.	AE ID:	[4]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[Myalgia]
4.	Start Date Time:	Feb/16/2021 20:00
5.	Is the adverse event still ongoing?	NO End Date Time: Feb/19/2021 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
11.	Was a Concomitant Medication given?	NO
12.	Was a Non-Drug Treatment given?	NO

090177e196ae3f38\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: 12411279

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Frozen

Site Name: (1241) Hospital Irma Dulce

Subject Initials: ---

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

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	[]

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Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1241

Subject No: 12411279

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Frozen

Site Name: (1241) Hospital Irma Dulce

Subject Initials: ---

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

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Adverse Event Report

1.	Category:	ADVERSE EVENT
2.	AE ID:	[5]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[Chills]
4.	Start Date Time:	Feb/16/2021 20:00
5.	Is the adverse event still ongoing?	NO End Date Time: Feb/19/2021 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
11.	Was a Concomitant Medication given?	NO
12.	Was a Non-Drug Treatment given?	NO

090177e196ae3f38\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: 12411279

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Frozen

Site Name: (1241) Hospital Irma Dulce

Subject Initials: ---

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

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	[]

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Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1241

Subject No: 12411279

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Frozen

Site Name: (1241) Hospital Irma Dulce

Subject Initials: ---

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

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Adverse Event Report

1.	Category:	ADVERSE EVENT
2.	AE ID:	[6]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[Injection site pain]
4.	Start Date Time:	Feb/16/2021 20:00
5.	Is the adverse event still ongoing?	NO End Date Time: Feb/19/2021 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
11.	Was a Concomitant Medication given?	NO
12.	Was a Non-Drug Treatment given?	NO

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Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1241

Subject No: 12411279

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Frozen

Site Name: (1241) Hospital Irma Dulce

Subject Initials: ---

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

13.	What was the outcome of this adverse event?:	RECOVERED/RESOLVED
14.	Did the adverse event cause the subject to be discontinued from the study?	NO
15.	Serious Adverse Event Number: For Pfizer Use Only	[]

Header Text: c4591001

Visit: Logs

Form: MEDICATION ERROR

Form Version: 17-Jul-2020 21:54

Site No: 1241

Site Name: (1241) Hospital Irma Dulce

Subject No: 12411279

Subject Initials: ---

Generated By: (b) (4)

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

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

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 17-Jul-2020 21:54

Site No: 1241

Subject No: 12411279

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	[]

090177e196ae3f38\Final\Final On: 01-Apr-2021 05:12 (GMT)

Header Text: c4591001

Visit: Logs

Form: CONCOMITANT MEDICATIONS - NON STUDY VACCINATIONS

Form Version: 22-Apr-2020 21:03

Site No: 1241

Site Name: (1241) Hospital Irma Dulce

Subject No: 12411279

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.						Repeating Pages

Header Text: c4591001

Visit: Logs - Unscheduled

Form: CONCOMITANT MEDICATIONS - NON STUDY VACCINATIONS

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1241

Site Name: (1241) Hospital Irma Dulce

Subject No: 12411279

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:	//

090177e196ae3f38\Final\Final On: 01-Apr-2021 05:12 (GMT)

Header Text: c4591001

Visit: Logs

Form: CONCOMITANT MEDICATIONS - PROHIBITED

Form Version: 22-Apr-2020 21:03

Site No: 1241

Site Name: (1241) Hospital Irma Dulce

Subject No: 12411279

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.						Repeating Pages

090177e196ae3f38\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: 12411279

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?	

090177e196ae3f38\Final\Final On: 01-Apr-2021 05:12 (GMT)

Header Text: c4591001

Visit: Logs

Form: RADIATION TREATMENT

Form Version: 22-Apr-2020 21:02

Site No: 1241

Site Name: (1241) Hospital Irma Dulce

Subject No: 12411279

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.						Repeating Pages

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1241

Subject No: 12411279

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: 12411279

Subject Initials: ---

Generated By: (b) (4)

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

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

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1241

Subject No: 12411279

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: 12411279

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: 12411279

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: 12411279

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:	

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: 12411279

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?	

090177e196ae3f38\Final\Final On: 01-Apr-2021 05:12 (GMT)

Header Text: c4591001

Visit: Unplanned Vaccination - Unscheduled

Form: CONTACT OUTCOME - MONTH 1

Form Version: 10-Oct-2020 15:57

Form Status: Not Started

Site No: 1241

Site Name: (1241) Hospital Irma Dulce

Subject No: 12411279

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: 12411279

Subject Initials: ---

Generated By: (b) (4)

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

Contact Outcome

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

Header Text: c4591001

Visit: Potential ReVax Initial Contact -
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: 12411279

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/29/2021
2.	Erroneous Visit	

Header Text: c4591001

Visit: Potential ReVax Initial Contact -
Unscheduled

Form: FURTHER VACCINATION CONFIRMATION

Form Version: 10-Dec-2020 02:25

Form Status: Data Complete, Frozen

Site No: 1241

Site Name: (1241) Hospital Irma Dulce

Subject No: 12411279

Subject Initials: ---

Generated By: (b) (4)

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

[eCRF Audit Trail History](#)

Further Vaccination Confirmation

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

090177e196ae3f38\Final\Final On: 01-Apr-2021 05:12 (GMT)

Header Text: c4591001

Visit: Disposition - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1241

Subject No: 12411279

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/29/2021
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: 12411279

Subject Initials: ---

Generated By: (b) (4)

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

Withdrawal Of Consent

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

090177e196ae3f38\Final\Final On: 01-Apr-2021 05:12 (GMT)

Header Text: c4591001

Visit: Disposition - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1241

Subject No: 12411279

Generated By: (b) (4)

Form: DEATH DETAILS CODED

Form Status: Not Started

Site Name: (1241) Hospital Irma Dulce

Subject Initials: ---

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

Death Details

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

Cause of Death

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

Header Text: c4591001

Visit: V101_VAX3

Form Version: 22-Apr-2020 21:02

Site No: 1241

Subject No: 12411279

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	Feb/16/2021
2.	Erroneous Visit	

Header Text: c4591001

Visit: V101_VAX3

Form Version: 10-Dec-2020 02:31

Site No: 1241

Subject No: 12411279

Generated By: (b) (4)

Form: INFORMED CONSENT - FURTHER VACCINATION

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](#)

Informed Consent - Further Vaccination

1.	Consent Was:	OBTAINED Date Written Consent Obtained Feb/11/2021
----	--------------	--

Header Text: c4591001

Visit: V101_VAX3

Form: INCLUSION/EXCLUSION CRITERIA - FURTHER VACCINATION

Form Version: 10-Dec-2020 02:30

Form Status: Data Complete, Frozen, Verified

Site No: 1241

Site Name: (1241) Hospital Irma Dulce

Subject No: 12411279

Subject Initials: ---

Generated By: (b) (4)

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

Form Comments

Inclusion Criteria Not Met

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

Exclusion Criteria Met

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

Header Text: c4591001

Visit: V101_VAX3

Form Version: 10-Dec-2020 02:31

Site No: 1241

Subject No: 12411279

Generated By: (b) (4)

Form: DISPOSITION - SCREENING FOR FURTHER VACCINATION

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](#)

Disposition - Screening for Further Vaccination

1.	Date of Completion/Discontinuation /Death :	Feb/16/2021
2.	Phase of Disposition:	REPEAT SCREENING 1
3.	Status:	COMPLETED
4.	Specify Status:	[]

Header Text: c4591001

Visit: V101_VAX3

Form Version: 14-Jan-2021 02:21

Site No: 1241

Subject No: 12411279

Generated By: (b) (4)

Form: LAB URINALYSIS - PREGNANCY TEST

Form Status: Data Complete, Frozen, Verified

Site Name: (1241) Hospital Irma Dulce

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Lab Urinalysis

1.	Lab Panel:	URINALYSIS
2.	Lab Sub-Panel:	PREGNANCY
3.	Collection Date:	Feb/16/2021
4.	Laboratory Name and Address (Derived)	[STUDY SITE]
5.	Specimen Type:	URINE

Lab Result

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

090177e196ae3f38\Final\Final On: 01-Apr-2021 05:12 (GMT)

Header Text: c4591001

Visit: V101_VAX3

Form Version: 22-Apr-2020 21:03

Site No: 1241

Subject No: 12411279

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: Feb/16/2021
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	[BRKF3D]
5.b	Sample ID	[BS2Y73]
5.c	Sample ID	[BS2Y74]

Header Text: c4591001

Visit: V101_VAX3

Form Version: 22-Apr-2020 21:03

Site No: 1241

Subject No: 12411279

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB

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	NASAL_SWAB
3.	Sample Collected?	YES Date of Collection: Feb/16/2021
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	[BRKF65]
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090177e196ae3f38\Final\Final On: 01-Apr-2021 05:12 (GMT)

Header Text: c4591001

Visit: V101_VAX3

Form Version: 10-Dec-2020 02:26

Site No: 1241

Subject No: 12411279

Generated By: (b) (4)

Form: VACCINATION

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](#)

Vaccination

1.	Was there a temporary delay of vaccination?	NO
2.	Treatment Name	[BNT162b2]
3.	Formulation:	INJECTION
4.	Dose Date Time:	Feb/16/2021 11:46
5.	Anatomical Location:	DELTOID MUSCLE
6.	Body Side:	LEFT
7.	Route:	INTRAMUSCULAR
8.	Actual Dose:	[30.0]
9.	Unit:	ug
10.	Timeframe Subject Was Observed	30 MINUTES
11.	Was the subject observed for at least the protocol specified observation period after investigational product administration?	YES

090177e196ae3f38\Final\Final On: 01-Apr-2021 05:12 (GMT)

Header Text: c4591001

Visit: V102_VAX4

Form Version: 22-Apr-2020 21:02

Site No: 1241

Subject No: 12411279

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: V102_VAX4

Form Version: 14-Jan-2021 02:21

Site No: 1241

Subject No: 12411279

Generated By: (b) (4)

Form: LAB URINALYSIS - PREGNANCY TEST

Form Status: Data Complete, Frozen, Verified

Site Name: (1241) Hospital Irma Dulce

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Lab Urinalysis

1.	Lab Panel:	URINALYSIS
2.	Lab Sub-Panel:	PREGNANCY
3.	Collection Date:	Mar/9/2021
4.	Laboratory Name and Address (Derived)	[STUDY SITE]
5.	Specimen Type:	URINE

Lab Result

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

090177e196ae3f38\Final\Final On: 01-Apr-2021 05:12 (GMT)

Header Text: c4591001

Visit: V102_VAX4

Form Version: 22-Apr-2020 21:03

Site No: 1241

Subject No: 12411279

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB

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	NASAL_SWAB
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	[BRCFLC]
-----	-----------	----------

090177e196ae3f38\Final\Final On: 01-Apr-2021 05:12 (GMT)

Header Text: c4591001

Visit: V102_VAX4

Form Version: 10-Dec-2020 02:26

Site No: 1241

Subject No: 12411279

Generated By: (b) (4)

Form: VACCINATION

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](#)

Vaccination

1.	Was there a temporary delay of vaccination?	NO
2.	Treatment Name	[BNT162b2]
3.	Formulation:	INJECTION
4.	Dose Date Time:	Mar/9/2021 08:33
5.	Anatomical Location:	DELTOID MUSCLE
6.	Body Side:	LEFT
7.	Route:	INTRAMUSCULAR
8.	Actual Dose:	[30.0]
9.	Unit:	ug
10.	Timeframe Subject Was Observed	30 MINUTES
11.	Was the subject observed for at least the protocol specified observation period after investigational product administration?	YES

090177e196ae3f38\Final\Final On: 01-Apr-2021 05:12 (GMT)

Header Text: c4591001

Visit: V103_MONTH1

Form Version: 22-Apr-2020 21:02

Site No: 1241

Subject No: 12411279

Generated By: (b) (4)

Form: DATE OF VISIT

Form Status: Not Started

Site Name: (1241) Hospital Irma Dulce

Subject Initials: ---

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

Date of Visit

1.	Date of Visit	//
2.	Erroneous Visit	

Header Text: c4591001

Visit: V103_MONTH1

Form Version: 22-Apr-2020 21:04

Site No: 1241

Subject No: 12411279

Generated By: (b) (4)

Form: CONTACT OUTCOME

Form Status: Not Started

Site Name: (1241) Hospital Irma Dulce

Subject Initials: ---

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

Contact Outcome

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

Header Text: c4591001

Visit: V104_MONTH6

Form Version: 22-Apr-2020 21:02

Site No: 1241

Subject No: 12411279

Generated By: (b) (4)

Form: DATE OF VISIT

Form Status: Not Started

Site Name: (1241) Hospital Irma Dulce

Subject Initials: ---

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

Date of Visit

1.	Date of Visit	//
2.	Erroneous Visit	

Header Text: c4591001

Visit: V104_MONTH6

Form Version: 22-Apr-2020 21:04

Site No: 1241

Subject No: 12411279

Generated By: (b) (4)

Form: CONTACT OUTCOME

Form Status: Not Started

Site Name: (1241) Hospital Irma Dulce

Subject Initials: ---

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

Contact Outcome

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

Header Text: c4591001

Visit: V105_MONTH18

Form Version: 22-Apr-2020 21:02

Site No: 1241

Subject No: 12411279

Generated By: (b) (4)

Form: DATE OF VISIT

Form Status: Not Started

Site Name: (1241) Hospital Irma Dulce

Subject Initials: ---

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

Date of Visit

1.	Date of Visit	//
2.	Erroneous Visit	

Header Text: c4591001

Visit: V105_MONTH18

Form Version: 22-Apr-2020 21:04

Site No: 1241

Subject No: 12411279

Generated By: (b) (4)

Form: CONTACT OUTCOME

Form Status: Not Started

Site Name: (1241) Hospital Irma Dulce

Subject Initials: ---

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

Contact Outcome

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

Header Text: c4591001

Visit: FURTHER_VACCINATION_EOT -
Unscheduled

Form: DISPOSITION - TREATMENT

Form Version: 20-Feb-2021 02:26

Form Status: Not Started

Site No: 1241

Site Name: (1241) Hospital Irma Dulce

Subject No: 12411279

Subject Initials: ---

Generated By: (b) (4)

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

Disposition - Treatment

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

Header Text: c4591001

Visit: Subject Status - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1241

Subject No: 12411279

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	DISCONTINUED
2.	Subject Status Date	Sep/10/2020

Header Text: c4591001

Visit: Investigator Signature - Unscheduled

Form Version: 22-Apr-2020 21:04

Site No: 1241

Subject No: 12411279

Generated By: (b) (4)

Form: CASEBOOK SIGNATURE FORM

Form Status: Data Complete, Signed, Verified

Site Name: (1241) Hospital Irma Dulce

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Casebook Signature Form

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

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: 12411279

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 17:36:32 (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.

090177e196ae3f38\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: 12411279

Generated By: (b) (4)

Form: VACCINATION - Comments

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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Item	Date	User	Comment
Form	Sep-10-2020 13:01:55 (UTC-03:00) City of Buenos Aires	(b) (4), (b) (6)	Not Done

090177e196ae3f38\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: 12411279

Generated By: (b) (4)

Form: VACCINATION - Comments

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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Item	Date	User	Comment
1	Sep-10-2020 13:01:55 (UTC-03:00) City of Buenos Aires	(b) (4), (b) (6)	Not Done

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:04

Site No: 1241

Subject No: 12411279

Generated By: (b) (4)

Form: VACCINATION - Comments

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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Item	Date	User	Comment
2	Sep-10-2020 13:01:55 (UTC-03:00) City of Buenos Aires	(b) (4), (b) (6)	Not Done

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:04

Site No: 1241

Subject No: 12411279

Generated By: (b) (4)

Form: VACCINATION - Comments

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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Item	Date	User	Comment
3	Sep-10-2020 13:01:55 (UTC-03:00) City of Buenos Aires	(b) (4), (b) (6)	Not Done

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:04

Site No: 1241

Subject No: 12411279

Generated By: (b) (4)

Form: VACCINATION - Comments

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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Item	Date	User	Comment
4	Sep-10-2020 13:01:55 (UTC-03:00) City of Buenos Aires	(b) (4), (b) (6)	Not Done

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:04

Site No: 1241

Subject No: 12411279

Generated By: (b) (4)

Form: VACCINATION - Comments

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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Item	Date	User	Comment
5	Sep-10-2020 13:01:55 (UTC-03:00) City of Buenos Aires	(b) (4), (b) (6)	Not Done

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:04

Site No: 1241

Subject No: 12411279

Generated By: (b) (4)

Form: VACCINATION - Comments

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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Item	Date	User	Comment
6	Sep-10-2020 13:01:55 (UTC-03:00) City of Buenos Aires	(b) (4), (b) (6)	Not Done

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:04

Site No: 1241

Subject No: 12411279

Generated By: (b) (4)

Form: VACCINATION - Comments

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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Item	Date	User	Comment
7	Sep-10-2020 13:01:55 (UTC-03:00) City of Buenos Aires	(b) (4), (b) (6)	Not Done

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:04

Site No: 1241

Subject No: 12411279

Generated By: (b) (4)

Form: VACCINATION - Comments

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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Item	Date	User	Comment
8	Sep-10-2020 13:01:55 (UTC-03:00) City of Buenos Aires	(b) (4), (b) (6)	Not Done

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:04

Site No: 1241

Subject No: 12411279

Generated By: (b) (4)

Form: VACCINATION - Comments

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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Item	Date	User	Comment
9	Sep-10-2020 13:01:55 (UTC-03:00) City of Buenos Aires	(b) (4), (b) (6)	Not Done

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:04

Site No: 1241

Subject No: 12411279

Generated By: (b) (4)

Form: VACCINATION - Comments

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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Item	Date	User	Comment
10	Sep-10-2020 13:01:55 (UTC-03:00) City of Buenos Aires	(b) (4), (b) (6)	Not Done

090177e196ae3f38\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: 12411279

Generated By: (b) (4)

Form: VACCINATION - Comments

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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Item	Date	User	Comment
11	Sep-10-2020 13:01:55 (UTC-03:00) City of Buenos Aires	(b) (4), (b) (6)	Not Done

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** MICROBIOLOGY SPECIMEN - Comments
on Nov/27/2020

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen, Verified

Site No: 1241

Site Name: (1241) Hospital Irma Dulce

Subject No: 12411279

Subject Initials: ---

Generated By: (b) (4)

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

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Item	Date	User	Comment
Form	Dec-23-2020 10:09:04 (UTC-03:00) City of Buenos Aires	(b) (4), (b) (6)	Subject refused collection at the local lab Not Applicable
Form	Dec-23-2020 09:41:50 (UTC-03:00) City of Buenos Aires	(b) (4), (b) (6)	Subject refused collection at the local lab Not Done

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** MICROBIOLOGY SPECIMEN - Comments
on Nov/27/2020

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen, Verified

Site No: 1241

Site Name: (1241) Hospital Irma Dulce

Subject No: 12411279

Subject Initials: ---

Generated By: (b) (4)

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

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Item	Date	User	Comment
1	Dec-23-2020 10:09:04 (UTC-03:00) City of Buenos Aires	(b) (4), (b) (6)	Subject refused collection at the local lab Not Applicable
1	Dec-23-2020 09:41:50 (UTC-03:00) City of Buenos Aires	(b) (4), (b) (6)	Subject refused collection at the local lab Not Done

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** MICROBIOLOGY SPECIMEN - Comments
on Nov/27/2020

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen, Verified

Site No: 1241

Site Name: (1241) Hospital Irma Dulce

Subject No: 12411279

Subject Initials: ---

Generated By: (b) (4)

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

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Item	Date	User	Comment
2	Dec-23-2020 10:09:04 (UTC-03:00) City of Buenos Aires	(b) (4), (b) (6)	Subject refused collection at the local lab Not Applicable
2	Dec-23-2020 09:41:50 (UTC-03:00) City of Buenos Aires	(b) (4), (b) (6)	Subject refused collection at the local lab Not Done

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/27/2020 **Form:** MICROBIOLOGY SPECIMEN - Comments

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen, Verified

Site No: 1241

Site Name: (1241) Hospital Irma Dulce

Subject No: 12411279

Subject Initials: ---

Generated By: (b) (4)

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

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Item	Date	User	Comment
3	Dec-23-2020 10:09:04 (UTC-03:00) City of Buenos Aires	(b) (4), (b) (6)	Subject refused collection at the local lab Not Applicable
3	Dec-23-2020 09:41:50 (UTC-03:00) City of Buenos Aires	(b) (4), (b) (6)	Subject refused collection at the local lab Not Done

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/27/2020 **Form:** MICROBIOLOGY SPECIMEN - Comments

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen, Verified

Site No: 1241

Site Name: (1241) Hospital Irma Dulce

Subject No: 12411279

Subject Initials: ---

Generated By: (b) (4)

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

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Item	Date	User	Comment
4	Dec-23-2020 10:09:04 (UTC-03:00) City of Buenos Aires	(b) (4), (b) (6)	Subject refused collection at the local lab Not Applicable
4	Dec-23-2020 09:41:50 (UTC-03:00) City of Buenos Aires	(b) (4), (b) (6)	Subject refused collection at the local lab Not Done

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/27/2020 **Form:** MICROBIOLOGY SPECIMEN - Comments

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen, Verified

Site No: 1241

Site Name: (1241) Hospital Irma Dulce

Subject No: 12411279

Subject Initials: ---

Generated By: (b) (4)

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

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Item	Date	User	Comment
5	Dec-23-2020 10:09:04 (UTC-03:00) City of Buenos Aires	(b) (4), (b) (6)	Subject refused collection at the local lab Not Applicable
5	Dec-23-2020 09:41:50 (UTC-03:00) City of Buenos Aires	(b) (4), (b) (6)	Subject refused collection at the local lab Not Done

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/27/2020 **Form:** MICROBIOLOGY SPECIMEN - Comments

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen, Verified

Site No: 1241

Site Name: (1241) Hospital Irma Dulce

Subject No: 12411279

Subject Initials: ---

Generated By: (b) (4)

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

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Item	Date	User	Comment
6	Dec-23-2020 10:09:04 (UTC-03:00) City of Buenos Aires	(b) (4), (b) (6)	Subject refused collection at the local lab Not Applicable
6	Dec-23-2020 09:41:50 (UTC-03:00) City of Buenos Aires	(b) (4), (b) (6)	Subject refused collection at the local lab Not Done

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** MICROBIOLOGY SPECIMEN - Comments
on Nov/27/2020

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen, Verified

Site No: 1241

Site Name: (1241) Hospital Irma Dulce

Subject No: 12411279

Subject Initials: ---

Generated By: (b) (4)

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

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Item	Date	User	Comment
7	Dec-23-2020 10:09:04 (UTC-03:00) City of Buenos Aires	(b) (4), (b) (6)	Subject refused collection at the local lab Not Applicable
7	Dec-23-2020 09:41:50 (UTC-03:00) City of Buenos Aires	(b) (4), (b) (6)	Subject refused collection at the local lab Not Done

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/27/2020 **Form:** MICROBIOLOGY SPECIMEN - Comments

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen, Verified

Site No: 1241

Site Name: (1241) Hospital Irma Dulce

Subject No: 12411279

Subject Initials: ---

Generated By: (b) (4)

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

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Item	Date	User	Comment
8	Dec-23-2020 10:09:04 (UTC-03:00) City of Buenos Aires	(b) (4), (b) (6)	Subject refused collection at the local lab Not Applicable
8	Dec-23-2020 09:41:50 (UTC-03:00) City of Buenos Aires	(b) (4), (b) (6)	Subject refused collection at the local lab Not Done

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/27/2020 **Form:** MICROBIOLOGY SPECIMEN - Comments

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen, Verified

Site No: 1241

Site Name: (1241) Hospital Irma Dulce

Subject No: 12411279

Subject Initials: ---

Generated By: (b) (4)

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

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Item	Date	User	Comment
9	Dec-23-2020 10:09:04 (UTC-03:00) City of Buenos Aires	(b) (4), (b) (6)	Subject refused collection at the local lab Not Applicable
9	Dec-23-2020 09:41:50 (UTC-03:00) City of Buenos Aires	(b) (4), (b) (6)	Subject refused collection at the local lab Not Done

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1241

Subject No: 12411279

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - Comments

Form Status: Data Complete, Locked, Frozen, Not Complete

Site Name: (1241) Hospital Irma Dulce

Subject Initials: ---

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

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Item	Date	User	Comment
6	Sep-14-2020 08:13:24 (UTC-03:00) City of Buenos Aires	(b) (4), (b) (6)	Not Applicable

Header Text: c4591001

Visit: V101_VAX3

Form: INCLUSION/EXCLUSION CRITERIA - FURTHER
VACCINATION - Comments

Form Version: 10-Dec-2020 02:30

Form Status: Data Complete, Frozen, Verified

Site No: 1241

Site Name: (1241) Hospital Irma Dulce

Subject No: 12411279

Subject Initials: ---

Generated By: (b) (4)

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

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Item	Date	User	Comment
Form	Feb-16-2021 12:43:26 (UTC-03:00) City of Buenos Aires	(b) (4), (b) (6)	Not Applicable

Header Text: c4591001

Visit: Investigator Signature - Unscheduled

Form: CASEBOOK SIGNATURE FORM - Signature History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Signed, Verified

Site No: 1241

Site Name: (1241) Hospital Irma Dulce

Subject No: 12411279

Subject Initials: ---

Generated By: (b) (4)

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

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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 17:36:32 (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 09:20:23 (UTC-03:00) City of Buenos Aires		Edit - All signatures invalidated
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Affidavit:

N/A

(b) (6)	Approved	Feb-24-2021 15:01:37 (UTC-03:00) City of Buenos Aires	BOOK	Signed
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Affidavit:

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

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

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

(b) (6)	N/A	Feb-16-2021 12:41:58 (UTC-03:00) City of Buenos Aires		Edit - All signatures invalidated
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Affidavit:

N/A

Edson Moreira	Approved	Jan-21-2021 17:31:14 (UTC-03:00) City of Buenos Aires	BOOK	Signed
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090177e196ae3f38\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: 12411279

Subject Initials: ---

Generated By: (b) (4)

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

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	Nov-30-2020 15:43:03 (UTC-03:00) City of Buenos Aires		Edit - All signatures invalidated
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Affidavit:

N/A

Edson Moreira	Approved	Nov-04-2020 16:55:34 (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	Nov-02-2020 11:06:30 (UTC-03:00) City of Buenos Aires		Edit - All signatures invalidated
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Affidavit:

N/A

(b) (6)	Approved	Oct-30-2020 18:54:53 (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.

090177e196ae3f38\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: 12411279

Subject Initials: ---

Generated By: (b) (4)

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

(b) (6)	N/A	Oct-30-2020 18:29:20 (UTC-03:00) City of Buenos Aires		Edit - All signatures invalidated
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Affidavit:
N/A

Edson Moreira	Approved	Oct-30-2020 16:28:49 (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-30-2020 16:07:41 (UTC-03:00) City of Buenos Aires		Edit - All signatures invalidated
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Affidavit:
N/A

Edson Moreira	Approved	Oct-26-2020 21:02:03 (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-23-2020 20:11:56 (UTC-03:00) City of Buenos Aires		Edit - All signatures invalidated
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Affidavit:
N/A

Edson Moreira	Approved	Oct-22-2020 23:32:53 (UTC-03:00) City of Buenos Aires	BOOK	Signed
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090177e196ae3f38\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: 12411279

Subject Initials: ---

Generated By: (b) (4)

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

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.

Header Text: c4591001

Visit: COHORT_SELECTION

Form Version: 30-Jul-2020 21:29

Site No: 1241

Subject No: 12411279

Generated By: (b) (4)

Form: COHORT SELECTION - 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 - Protocol version

Date	Location	User	Value	Reason
Aug-19-2020 13:39:50 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 30 JUN 2020	Initial Entry

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

Date	Location	User	Value	Reason
Aug-19-2020 13:39:50 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: STAGE 3 COHORTS	Initial Entry

Header Text: c4591001

Visit: COHORT_SELECTION

Form Version: 22-Apr-2020 21:02

Site No: 1241

Subject No: 12411279

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-19-2020 13:39:59 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: OBTAINED Date Written Consent Obtained Aug/19/2020	Initial Entry

Header Text: c4591001

Visit: COHORT_SELECTION

Form Version: 06-Jul-2020 21:55

Site No: 1241

Subject No: 12411279

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
Sep-15-2020 06:58:39 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	event added
Sep-14-2020 08:14:37 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	data updated
Sep-14-2020 07:10:16 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	SAE RECON:AER#2020352761 Pregnancy(onset date:10Sep2020)was reported as serious in Safety database but missing in AE CRF. Please confirm and update CRF. If safety update is required, submit a follow-up SAE Form.
Aug-19-2020 13:39:37 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 12411279	Item copied from previous form

2. Birth Date:

Date	Location	User	Value	Reason
Aug-19-2020 13:39:29 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: (b) (6) 1985	Enrollment Entry

3. Sex:

Date	Location	User	Value	Reason
Aug-19-2020 13:40:16 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: FEMALE	Initial Entry

4. Ethnicity:

Date	Location	User	Value	Reason
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090177e196ae3f38\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: 12411279

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

Aug-19-2020 13:40:16 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NOT HISPANIC OR LATINO(A) OR OF SPANISH ORIGIN	Initial Entry
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5. Race: (Check X all that apply):

Date	Location	User	Value	Reason
Aug-19-2020 13:40:16 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BLACK OR AFRICAN AMERIC AN	Initial Entry

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:02

Site No: 1241

Subject No: 12411279

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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I. Date of Visit

Date	Location	User	Value	Reason
Aug-19-2020 13:40:47 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Aug/19/2020	Initial Entry

090177e196ae3f38\Final\Final On: 01-Apr-2021 05:12 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 30-Jul-2020 21:27

Site No: 1241

Subject No: 12411279

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

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I.a

Date	Location	User	Value	Reason
Aug-19-2020 13:41:10 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Inclusion Number: Criterion Description: Criterion ID: (For Pfizer use only):	Initial Entry

I.a Inclusion Number:

Date	Location	User	Value	Reason
Aug-19-2020 13:41:10 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 1	Initial Entry

I.a Criterion Description:

Date	Location	User	Value	Reason
Aug-19-2020 13:41:10 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Male or female participants between the ages of 18 and 55 years, inclusive, 65 and 85 years, inclusive, or 18 and 85 years, inclusive, at randomization (dependent upon study stage)	Initial Entry

090177e196ae3f38\Final\Final On: 01-Apr-2021 05:12 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 30-Jul-2020 21:27

Site No: 1241

Subject No: 12411279

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

1.a Criterion met?

Date	Location	User	Value	Reason
Aug-19-2020 13:41:10 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

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

Date	Location	User	Value	Reason
Aug-19-2020 13:41:10 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: IN01A00	Initial Entry

1.b

Date	Location	User	Value	Reason
Aug-19-2020 13:41:10 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Inclusion Number: 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	Initial Entry

090177e196ae3f38\Final\Final On: 01-Apr-2021 05:12 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 30-Jul-2020 21:27

Site No: 1241

Subject No: 12411279

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

I.b Inclusion Number:

Date	Location	User	Value	Reason
Aug-19-2020 13:41:10 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 2	Initial Entry

I.b Criterion Description:

Date	Location	User	Value	Reason
Aug-19-2020 13:41:10 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Participants who are willing and able to comply with all scheduled visits, vaccination plan, laboratory tests, lifestyle considerations, and other study procedures	Initial Entry

I.b Criterion met?

Date	Location	User	Value	Reason
Aug-19-2020 13:41:10 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

I.b Criterion ID: (For Pfizer use only)

Date	Location	User	Value	Reason
Aug-19-2020 13:41:10 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: IN02A00	Initial Entry

I.c

Date	Location	User	Value	Reason
Aug-19-2020 13:41:10 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Inclusion Number:	Initial Entry

090177e196ae3f38\Final\Final On: 01-Apr-2021 05:12 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 30-Jul-2020 21:27

Site No: 1241

Subject No: 12411279

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>Criteria Healthy participants who on Des are determined by medica criptio l history, physical examin n: ation, and clinical judgme nt of the investigator to be eligible for inclusion in th e study</p> <p>Criteria YES on met ?:</p> <p>Criteria IN03A00 on ID: (For P fizer u se only):</p>	
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090177e196ae3f38\Final\Final On: 01-Apr-2021 05:12 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 30-Jul-2020 21:27

Site No: 1241

Subject No: 12411279

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

I.c Inclusion Number:

Date	Location	User	Value	Reason
Aug-19-2020 13:41:10 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 3	Initial Entry

I.c Criterion Description:

Date	Location	User	Value	Reason
Aug-19-2020 13:41:10 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 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-19-2020 13:41:10 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

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

Date	Location	User	Value	Reason
Aug-19-2020 13:41:10 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: IN03A00	Initial Entry

I.d

Date	Location	User	Value	Reason
Aug-19-2020 13:41:10 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Inclusi 4 on Nu mber:	Initial Entry

090177e196ae3f38\Final\Final On: 01-Apr-2021 05:12 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 30-Jul-2020 21:27

Site No: 1241

Subject No: 12411279

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>Criterion Description: Capable of giving person signed informed consent, which includes compliance with the requirements and restrictions listed in the ICD and in this protocol</p> <p>Criterion Met: YES</p> <p>Criterion ID: IN04A00 (For Pfizer use only)</p>	
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090177e196ae3f38\Final\Final On: 01-Apr-2021 05:12 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 30-Jul-2020 21:27

Site No: 1241

Subject No: 12411279

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

1.d Inclusion Number:

Date	Location	User	Value	Reason
Aug-19-2020 13:41:10 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 4	Initial Entry

1.d Criterion Description:

Date	Location	User	Value	Reason
Aug-19-2020 13:41:10 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 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-19-2020 13:41:10 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

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

Date	Location	User	Value	Reason
Aug-19-2020 13:41:10 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: IN04A00	Initial Entry

2.a

Date	Location	User	Value	Reason
Aug-19-2020 13:41:10 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Exclus 1 ion Nu mber:	Initial Entry

090177e196ae3f38\Final\Final On: 01-Apr-2021 05:12 (GMT)

Header Text: c4591001

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Subject No: 12411279

Generated By: (b) (4)

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Site Name: (1241) Hospital Irma Dulce

Subject Initials: ---

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			<p>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</p> <p>Criterion met?: NO</p> <p>Criterion ID: EX01A00 (For Pfizer use only):</p>	
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2.a Exclusion Number:

Date	Location	User	Value	Reason
Aug-19-2020 13:41:10 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 1	Initial Entry

2.a Criterion Description:

Date	Location	User	Value	Reason
Aug-19-2020 13:41:10 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 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-19-2020 13:41:10 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

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

Date	Location	User	Value	Reason
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Visit: V1_DAY1_VAX1_L

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Site No: 1241

Subject No: 12411279

Generated By: (b) (4)

Form: INCLUSION/EXCLUSION CRITERIA - eCRF Audit Trail History

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Aug-19-2020 13:41:10 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: EX01A00	Initial Entry
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2.b

Date	Location	User	Value	Reason
Aug-19-2020 13:41:10 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Exclusion Number: Criterion Description: Known infection with human immunodeficiency virus (HIV), hepatitis C virus (HCV), or hepatitis B virus (HBV) Criterion met?: NO Criterion ID: (Former Pfizer use only): EX02A00	Initial Entry

090177e196ae3f38\Final\Final On: 01-Apr-2021 05:12 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

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Site No: 1241

Subject No: 12411279

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

2.b Exclusion Number:

Date	Location	User	Value	Reason
Aug-19-2020 13:41:10 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 2	Initial Entry

2.b Criterion Description:

Date	Location	User	Value	Reason
Aug-19-2020 13:41:10 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 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-19-2020 13:41:10 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

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

Date	Location	User	Value	Reason
Aug-19-2020 13:41:10 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: EX02A00	Initial Entry

2.c

Date	Location	User	Value	Reason
Aug-19-2020 13:41:10 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Exclusion Number: Criteria 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

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Header Text: c4591001

Visit: V1_DAY1_VAX1_L

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Site No: 1241

Subject No: 12411279

Generated By: (b) (4)

Form: INCLUSION/EXCLUSION CRITERIA - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

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Subject Initials: ---

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			Criteria NO on met ?: Criteria EX03A00 on ID: (For Pfizer use only):	
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2.c Exclusion Number:

Date	Location	User	Value	Reason
Aug-19-2020 13:41:10 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 3	Initial Entry

2.c Criterion Description:

Date	Location	User	Value	Reason
Aug-19-2020 13:41:10 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 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-19-2020 13:41:10 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

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

Date	Location	User	Value	Reason
Aug-19-2020 13:41:10 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: EX03A00	Initial Entry

2.d

Date	Location	User	Value	Reason
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Header Text: c4591001

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Subject No: 12411279

Generated By: (b) (4)

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Subject Initials: ---

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

Aug-19-2020 13:41:10 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Exclusion Number: 4 Criterion Description: Receipt of medications intended to prevent COVID-19 Criterion met?: NO Criterion ID: EX04A00 (For Pfizer use only):	Initial Entry
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2.d Exclusion Number:

Date	Location	User	Value	Reason
Aug-19-2020 13:41:10 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 4	Initial Entry

2.d Criterion Description:

Date	Location	User	Value	Reason
Aug-19-2020 13:41:10 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Receipt of medications intended to prevent COVID-19	Initial Entry

2.d Criterion met?

Date	Location	User	Value	Reason
Aug-19-2020 13:41:10 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

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

Date	Location	User	Value	Reason
Aug-19-2020 13:41:10 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: EX04A00	Initial Entry

2.e

Date	Location	User	Value	Reason
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Subject No: 12411279

Generated By: (b) (4)

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Subject Initials: ---

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Aug-19-2020 13:41:10 (UTC-03:00) City of Buenos Aires	ACVOPFEINFP6000	(b) (4), (b) (6)	Data Entry: 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: EX08A00 (For Pfizer use only):	Initial Entry
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Generated By: (b) (4)

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Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1241) Hospital Irma Dulce

Subject Initials: ---

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2.e Exclusion Number:

Date	Location	User	Value	Reason
Aug-19-2020 13:41:10 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 8	Initial Entry

2.e Criterion Description:

Date	Location	User	Value	Reason
Aug-19-2020 13:41:10 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Immunocompromised individuals with known or suspected immunod efficiency, as determined by history and/or laboratory/physical examination	Initial Entry

2.e Criterion met?

Date	Location	User	Value	Reason
Aug-19-2020 13:41:10 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

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

Date	Location	User	Value	Reason
Aug-19-2020 13:41:10 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: EX08A00	Initial Entry

2.f

Date	Location	User	Value	Reason
Aug-19-2020 13:41:10 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Exclusion Number: Criterion: Bleeding diathesis or condition associated with prolonged bleeding that would, in the opinion of the investigator, contraindicate intramuscular injection	Initial Entry

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			Criteria NO on met ?: Criteria EX10A00 on ID: (For Pfizer use only) :	
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2.f Exclusion Number:

Date	Location	User	Value	Reason
Aug-19-2020 13:41:10 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 10	Initial Entry

2.f Criterion Description:

Date	Location	User	Value	Reason
Aug-19-2020 13:41:10 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 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-19-2020 13:41:10 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

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

Date	Location	User	Value	Reason
Aug-19-2020 13:41:10 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: EX10A00	Initial Entry

2.g

Date	Location	User	Value	Reason
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Subject No: 12411279

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Aug-19-2020 13:41:10 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Exclusion Number: 11 Criterion Description: Women who are pregnant or breastfeeding Criterion met? NO Criterion ID: (EX11A00 For Pfizer use only):	Initial Entry
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2.g Exclusion Number:

Date	Location	User	Value	Reason
Aug-19-2020 13:41:10 (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-19-2020 13:41:10 (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-19-2020 13:41:10 (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-19-2020 13:41:10 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: EX11A00	Initial Entry

2.h

Date	Location	User	Value	Reason
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Aug-19-2020 13:41:10 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Exclusion Number: 12 Criterion Description: Previous vaccination with any coronavirus vaccine Criterion met NO ?: Criterion ID: EX12A00 (For Pfizer use only):	Initial Entry
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2.h Exclusion Number:

Date	Location	User	Value	Reason
Aug-19-2020 13:41:10 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 12	Initial Entry

2.h Criterion Description:

Date	Location	User	Value	Reason
Aug-19-2020 13:41:10 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Previous vaccination with any coronavirus vaccine	Initial Entry

2.h Criterion met?

Date	Location	User	Value	Reason
Aug-19-2020 13:41:10 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

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

Date	Location	User	Value	Reason
Aug-19-2020 13:41:10 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: EX12A00	Initial Entry

2.i

Date	Location	User	Value	Reason
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Aug-19-2020 13:41:10 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Exclusion Number: 13 Criteria Description: Subjects who receive immunosuppressive therapy, such as cytotoxic agents or systemic corticosteroids Criterion met?: NO Criteria ID: (For Pfizer use only): EX13A01	Initial Entry
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2.i Exclusion Number:

Date	Location	User	Value	Reason
Aug-19-2020 13:41:10 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 13	Initial Entry

2.i Criterion Description:

Date	Location	User	Value	Reason
Aug-19-2020 13:41:10 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Subjects who receive immunosuppressive therapy, such as cytotoxic agents or systemic corticosteroids	Initial Entry

2.i Criterion met?

Date	Location	User	Value	Reason
Aug-19-2020 13:41:10 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

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

Date	Location	User	Value	Reason
Aug-19-2020 13:41:10 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: EX13A01	Initial Entry

2.j

Date	Location	User	Value	Reason
Aug-19-2020 13:41:10 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Exclusion Number: Criterion Description: Receipt of blood/plasma products or immunoglobulin, from 60 days before study intervention administration or planned receipt throughout the study	Initial Entry

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Subject No: 12411279

Generated By: (b) (4)

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Subject Initials: ---

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			Criteria NO on met ?: Criteria EX14A01 on ID: (For Pfizer use only) :	
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2.j Exclusion Number:

Date	Location	User	Value	Reason
Aug-19-2020 13:41:10 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 15	Initial Entry

2.j Criterion Description:

Date	Location	User	Value	Reason
Aug-19-2020 13:41:10 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 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-19-2020 13:41:10 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

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

Date	Location	User	Value	Reason
Aug-19-2020 13:41:10 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: EX14A01	Initial Entry

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2.k

Date	Location	User	Value	Reason
Aug-19-2020 13:41:10 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 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	Initial Entry

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2.k Exclusion Number:

Date	Location	User	Value	Reason
Aug-19-2020 13:41:10 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 16	Initial Entry

2.k Criterion Description:

Date	Location	User	Value	Reason
Aug-19-2020 13:41:10 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Participation in other studies involving study intervention within 28 days prior to study entry and/or during study participation	Initial Entry

2.k Criterion met?

Date	Location	User	Value	Reason
Aug-19-2020 13:41:10 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

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

Date	Location	User	Value	Reason
Aug-19-2020 13:41:10 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: EX15A01	Initial Entry

2.l

Date	Location	User	Value	Reason
Aug-19-2020 13:41:10 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Exclusion Number: 17 Criterion Description: Previous participation in other studies involving study intervention containing lipid nanoparticles Criterion met?: NO	Initial Entry

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Subject No: 12411279

Generated By: (b) (4)

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Subject Initials: ---

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			Criterion EX16A01 ID: (For Pfizer use only):	
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2.l Exclusion Number:

Date	Location	User	Value	Reason
Aug-19-2020 13:41:10 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> 17	Initial Entry

2.l Criterion Description:

Date	Location	User	Value	Reason
Aug-19-2020 13:41:10 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Previous participation in other studies involving study intervention containing lipid nanoparticles	Initial Entry

2.l Criterion met?

Date	Location	User	Value	Reason
Aug-19-2020 13:41:10 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NO	Initial Entry

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

Date	Location	User	Value	Reason
Aug-19-2020 13:41:10 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> EX16A01	Initial Entry

2.m

Date	Location	User	Value	Reason
Aug-19-2020 13:41:10 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Exclusion Number :	Initial Entry

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Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 30-Jul-2020 21:27

Site No: 1241

Subject No: 12411279

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>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</p> <p>Criterion ID: NO</p> <p>Criterion ID: EX21A01</p> <p>Criterion ID: (For Pfizer use only):</p>	
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090177e196ae3f38\Final\Final On: 01-Apr-2021 05:12 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 30-Jul-2020 21:27

Site No: 1241

Subject No: 12411279

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

2.m Exclusion Number:				
Date	Location	User	Value	Reason
Aug-19-2020 13:41:10 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 22	Initial Entry

2.m Criterion Description:				
Date	Location	User	Value	Reason
Aug-19-2020 13:41:10 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 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-19-2020 13:41:10 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2.m Criterion ID: (For Pfizer use only)				
Date	Location	User	Value	Reason
Aug-19-2020 13:41:10 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: EX21A01	Initial Entry

090177e196ae3f38\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: 12411279

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-19-2020 13:41:19 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Aug/19/2020	Initial Entry

2. Phase of Disposition:

Date	Location	User	Value	Reason
Aug-19-2020 13:41:19 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SCREENING	Initial Entry

3. Status:

Date	Location	User	Value	Reason
Aug-19-2020 13:41:19 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: COMPLETED	Initial Entry

090177e196ae3f38\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: 12411279

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

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I.a

Date	Location	User	Value	Reason
Aug-19-2020 13:44:32 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Line/MH Number 1 : Medical History Term: Bariatric surgery Start Date: Jan/5/2013 Ongoing: NO End Date: Jan/5/2013	Transcription Error
Aug-19-2020 13:43:53 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number 1 Medical History Term: Allergic rhinosinusitis Start Date: Jan/5/2013 Ongoing: NO End Date: Jan/5/2013	Initial Entry

I.a Line/MH Number:

Date	Location	User	Value	Reason
Aug-19-2020 13:43:53 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 1	Initial Entry

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

Date	Location	User	Value	Reason
Aug-19-2020 13:44:32 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Bariatric surgery	Transcription Error
Aug-19-2020 13:43:53 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Allergic rhinosinusitis	Initial Entry

090177e196ae3f38\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: 12411279

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

Buenos Aires		(b) (4), (b) (6)	
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1.a Start Date:

Date	Location	User	Value	Reason
Aug-19-2020 13:43:53 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Jan/5/2013	Initial Entry

1.a Ongoing:

Date	Location	User	Value	Reason
Aug-19-2020 13:43:53 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO End Date: Jan/5/2013	Initial Entry

1.b

Date	Location	User	Value	Reason
Oct-20-2020 13:40:27 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: Medical History chronic low back pain Term: Start Date: UNK/UNK/2013 Ongoing: YES	Initial Entry

090177e196ae3f38\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: 12411279

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

I.b Line/MH Number:

Date	Location	User	Value	Reason
Oct-20-2020 13:40:27 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 2	Initial Entry

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

Date	Location	User	Value	Reason
Oct-20-2020 13:40:27 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: chronic low back pain	Initial Entry

I.b Start Date:

Date	Location	User	Value	Reason
Oct-20-2020 13:40:27 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: UNK/UNK/2013	Initial Entry

I.b Ongoing:

Date	Location	User	Value	Reason
Oct-20-2020 13:40:27 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

090177e196ae3f38\Final\Final On: 01-Apr-2021 05:12 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 30-Jul-2020 21:28

Site No: 1241

Subject No: 12411279

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-19-2020 13:44:56 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Aug/19/2020	Initial Entry

2. Weight:

Date	Location	User	Value	Reason
Aug-19-2020 13:44:56 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 76.5	Initial Entry

3. Unit:

Date	Location	User	Value	Reason
Aug-19-2020 13:44:56 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: kg	Initial Entry

4. Height:

Date	Location	User	Value	Reason
Aug-19-2020 13:44:56 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 168.0	Initial Entry

5. Unit:

Date	Location	User	Value	Reason
Aug-19-2020 13:44:56 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: cm	Initial Entry

6. Body Mass Index:

Date	Location	User	Value	Reason
Aug-19-2020 13:44:56 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 27.1	Initial Entry

090177e196ae3f38\Final\Final On: 01-Apr-2021 05:12 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 30-Jul-2020 21:28

Site No: 1241

Subject No: 12411279

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

7.a

Date	Location	User	Value	Reason
Aug-19-2020 13:44:56 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Record Identifier:: 1 Temperature: 36.4 Temperature Unit: C Temperature Location:: ORAL CAVITY	Initial Entry

7.a Record Identifier:

Date	Location	User	Value	Reason
Aug-19-2020 13:44:56 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 1	Initial Entry

7.a Temperature:

Date	Location	User	Value	Reason
Aug-19-2020 13:44:56 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 36.4	Initial Entry

7.a Unit:

Date	Location	User	Value	Reason
Aug-19-2020 13:44:56 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: C	Initial Entry

7.a Temperature Location:

Date	Location	User	Value	Reason
Aug-19-2020 13:44:56 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: ORAL CAVITY	Initial Entry

090177e196ae3f38\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: 30-Jul-2020 21:27

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1241

Site Name: (1241) Hospital Irma Dulce

Subject No: 12411279

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-19-2020 13:45:05 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: URINALYSIS	Initial Entry

2. Lab Sub-Panel:

Date	Location	User	Value	Reason
Aug-19-2020 13:45:05 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: PREGNANCY	Initial Entry

3. Collection Date:

Date	Location	User	Value	Reason
Aug-19-2020 13:45:05 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Aug/19/2020	Initial Entry

4. Laboratory Name and Address (Derived)

Date	Location	User	Value	Reason
Aug-19-2020 13:45:05 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: STUDY SITE	Initial Entry

5. Specimen Type:

Date	Location	User	Value	Reason
Aug-19-2020 13:45:05 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: URINE	Initial Entry

6.a

Date	Location	User	Value	Reason
Aug-19-2020 13:45:05 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sponsor-Define 113	Initial Entry

090177e196ae3f38\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: 30-Jul-2020 21:27

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1241

Site Name: (1241) Hospital Irma Dulce

Subject No: 12411279

Subject Initials: ---

Generated By: (b) (4)

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

Buenos Aires			d Identifier:	
			Test::	Choriogonadotrop in Beta_PX113
			Result::	NEGATIVE
			Not Done::	

6.a Sponsor ID:

Date	Location	User	Value	Reason
Aug-19-2020 13:45:05 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 113	Initial Entry

6.a Test:

Date	Location	User	Value	Reason
Aug-19-2020 13:45:05 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) [redacted] (4), [redacted] (b) (6) [redacted]	Data Entry: Choriogonadotropin Beta_PX113	Initial Entry

6.a Result:

Date	Location	User	Value	Reason
Aug-19-2020 13:45:05 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) [redacted] (4), [redacted] (b) (6) [redacted]	Data Entry: NEGATIVE	Initial Entry

090177e196ae3f38\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: 12411279

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-19-2020 13:45:27 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Aug/19/2020	Initial Entry

2. Randomization Number:

Date	Location	User	Value	Reason
Aug-19-2020 13:45:27 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 56038	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: 12411279

Subject Initials: ---

Generated By: (b) (4)

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

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1. Data Origin

Date	Location	User	Value	Reason
Aug-20-2020 07:21:11 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Aug-20-2020 07:21:11 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SERUM	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Aug-20-2020 07:21:18 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Aug-20-2020 07:21:11 (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-20-2020 07:21:11 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Date of Collection: Aug/19/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Aug-20-2020 07:21:18 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BP5S9S	Initial Entry

5.a Sample ID

090177e196ae3f38\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: 12411279

Subject Initials: ---

Generated By: (b) (4)

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

Date	Location	User	Value	Reason
Aug-20-2020 07:21:18 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BP5S9S	Initial Entry

5.b

Date	Location	User	Value	Reason
Aug-20-2020 07:21:26 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BP5S9T	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Aug-20-2020 07:21:26 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BP5S9T	Initial Entry

5.c

Date	Location	User	Value	Reason
Aug-20-2020 07:21:35 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BP5S9V	Initial Entry

5.c Sample ID

Date	Location	User	Value	Reason
Aug-20-2020 07:21:35 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BP5S9V	Initial Entry

5.d

Date	Location	User	Value	Reason
Aug-20-2020 07:21:58 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BLCHFN	Initial Entry

090177e196ae3f38\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: 12411279

Subject Initials: ---

Generated By: (b) (4)

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

5.d Sample ID

Date	Location	User	Value	Reason
Aug-20-2020 07:21:58 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BLCHFV	Initial Entry

5.e

Date	Location	User	Value	Reason
Aug-20-2020 07:22:07 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BLCHFV	Initial Entry

5.e Sample ID

Date	Location	User	Value	Reason
Aug-20-2020 07:22:07 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BLCHFV	Initial Entry

090177e196ae3f38\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: 12411279

Subject Initials: ---

Generated By: (b) (4)

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

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1. Data Origin

Date	Location	User	Value	Reason
Aug-20-2020 07:22:29 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Aug-20-2020 07:22:29 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: NASAL_SWAB	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Aug-20-2020 07:22:36 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Aug-20-2020 07:22:29 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Aug-20-2020 07:22:29 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Date of Collection: Aug/19/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Aug-20-2020 07:22:36 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BP5S8K	Initial Entry

5.a Sample ID

090177e196ae3f38\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: 12411279

Subject Initials: ---

Generated By: (b) (4)

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

Date	Location	User	Value	Reason
Aug-20-2020 07:22:36 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BP5S8K	Initial Entry

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:04

Site No: 1241

Subject No: 12411279

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-19-2020 13:45:51 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2. Treatment Name

Date	Location	User	Value	Reason
Aug-19-2020 13:45:51 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: BLINDED THERAPY	Initial Entry

3. Formulation:

Date	Location	User	Value	Reason
Aug-19-2020 13:45:51 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: INJECTION	Initial Entry

4. Dose Date Time:

Date	Location	User	Value	Reason
Aug-19-2020 13:45:51 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Aug/19/2020 12:25	Initial Entry

5. Anatomical Location:

Date	Location	User	Value	Reason
Aug-19-2020 13:45:51 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: DELTOID MUSCLE	Initial Entry

6. Body Side:

Date	Location	User	Value	Reason
Aug-19-2020 13:45:51 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: LEFT	Initial Entry

090177e196ae3f38\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: 12411279

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

7. Route:

Date	Location	User	Value	Reason
Aug-19-2020 13:45:51 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: INTRAMUSCULAR	Initial Entry

10. Timeframe Subject Was Observed

Date	Location	User	Value	Reason
Aug-19-2020 13:45:51 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: THE PROTOCOL SPECIFIED OBSERVATION PERIOD	Initial Entry

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

Date	Location	User	Value	Reason
Aug-19-2020 13:45:51 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

090177e196ae3f38\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: 12411279

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-19-2020 13:45:56 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO - REACTOGENICITY E-DIARY NOT COLLECTED FOR THIS SUBJECT	Initial Entry

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:02

Site No: 1241

Subject No: 12411279

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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I. Date of Visit

Date	Location	User	Value	Reason
Sep-10-2020 12:56:56 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sep/10/2020	Initial Entry

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 21-Aug-2020 02:51

Site No: 1241

Subject No: 12411279

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-10-2020 13:01:30 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sep/10/2020	Initial Entry

2.a

Date	Location	User	Value	Reason
Sep-10-2020 13:01:30 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Record Identifier:: 1 Temperature: 37.1 Temperature Unit: C Temperature Locat ion:: ORAL CAVI TY	Initial Entry

2.a Record Identifier:

Date	Location	User	Value	Reason
Sep-10-2020 13:01:30 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 1	Initial Entry

2.a Temperature:

Date	Location	User	Value	Reason
Sep-10-2020 13:01:30 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 37.1	Initial Entry

2.a Unit:

Date	Location	User	Value	Reason
Sep-10-2020 13:01:30 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: C	Initial Entry

2.a Temperature Location:

Date	Location	User	Value	Reason
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090177e196ae3f38\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: 12411279

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

Sep-10-2020 13:01:30 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: ORAL CAVITY	Initial Entry
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Header Text: c4591001

Visit: V2_VAX2_L

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

Form Version: 30-Jul-2020 21:27

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1241

Site Name: (1241) Hospital Irma Dulce

Subject No: 12411279

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-10-2020 13:01:40 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: URINALYSIS	Initial Entry

2. Lab Sub-Panel:

Date	Location	User	Value	Reason
Sep-10-2020 13:01:40 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: PREGNANCY	Initial Entry

3. Collection Date:

Date	Location	User	Value	Reason
Sep-10-2020 13:01:40 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sep/10/2020	Initial Entry

4. Laboratory Name and Address (Derived)

Date	Location	User	Value	Reason
Sep-10-2020 13:01:40 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: STUDY SITE	Initial Entry

5. Specimen Type:

Date	Location	User	Value	Reason
Sep-10-2020 13:01:40 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: URINE	Initial Entry

6.a

Date	Location	User	Value	Reason
Sep-10-2020 13:01:40 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sponsor-Define 113	Initial Entry

090177e196ae3f38\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: 30-Jul-2020 21:27

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1241

Site Name: (1241) Hospital Irma Dulce

Subject No: 12411279

Subject Initials: ---

Generated By: (b) (4)

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

Buenos Aires			d Identifier:	
			Test::	Choriogonadotropin in Beta_PX113
			Result::	POSITIVE
			Not Done::	

6.a Sponsor ID:

Date	Location	User	Value	Reason
Sep-10-2020 13:01:40 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 113	Initial Entry

6.a Test:

Date	Location	User	Value	Reason
Sep-10-2020 13:01:40 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Choriogonadotropin Beta_PX113	Initial Entry

6.a Result:

Date	Location	User	Value	Reason
Sep-17-2020 07:45:46 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Closed	Closed per SITE response
Sep-16-2020 09:56:31 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Answered	It was Positive at V2 and was reported as SAE
Sep-16-2020 06:56:56 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Opened	PDQ: Result is POSITIVE however, Subject is Randomized. Please review and correct or confirm."
Sep-11-2020 06:22:00 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Sep-10-2020 13:08:42 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	The vaccination is "Not Done" at this visit

090177e196ae3f38\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: 30-Jul-2020 21:27

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1241

Site Name: (1241) Hospital Irma Dulce

Subject No: 12411279

Subject Initials: ---

Generated By: (b) (4)

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

Sep-10-2020 13:01:40 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	Lab result is "Positive", but subject has been vaccinated. Please review and update as appropriate. Else explain.
Sep-10-2020 13:01:40 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: POSITIVE	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: 12411279

Subject Initials: ---

Generated By: (b) (4)

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

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1. Data Origin

Date	Location	User	Value	Reason
Sep-10-2020 18:52:59 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Sep-10-2020 18:52:59 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: NASAL_SWAB	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Sep-10-2020 18:53:09 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Sep-10-2020 18:52:59 (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-10-2020 18:52:59 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Date of Collection: Sep/10/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Sep-10-2020 18:53:09 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BPX0TR	Initial Entry

5.a Sample ID

090177e196ae3f38\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: 12411279

Subject Initials: ---

Generated By: (b) (4)

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

Date	Location	User	Value	Reason
Sep-10-2020 18:53:09 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BPX0TR	Initial Entry

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:04

Site No: 1241

Subject No: 12411279

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-10-2020 13:01:55 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

2. Treatment Name

Date	Location	User	Value	Reason
Sep-10-2020 13:01:55 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

3. Formulation:

Date	Location	User	Value	Reason
Sep-10-2020 13:01:55 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

4. Dose Date Time:

Date	Location	User	Value	Reason
Sep-10-2020 13:01:55 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

5. Anatomical Location:

Date	Location	User	Value	Reason
Sep-10-2020 13:01:55 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

6. Body Side:

Date	Location	User	Value	Reason
Sep-10-2020 13:01:55 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

090177e196ae3f38\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: 12411279

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

7. Route:

Date	Location	User	Value	Reason
Sep-10-2020 13:01:55 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

8. Actual Dose:

Date	Location	User	Value	Reason
Sep-10-2020 13:01:55 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

9. Unit:

Date	Location	User	Value	Reason
Sep-10-2020 13:01:55 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

10. Timeframe Subject Was Observed

Date	Location	User	Value	Reason
Sep-10-2020 13:01:55 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	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-10-2020 13:01:55 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

090177e196ae3f38\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: 12411279

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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I. Date of Visit

Date	Location	User	Value	Reason
Oct-09-2020 14:39:56 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Oct/8/2020	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: 12411279

Subject Initials: ---

Generated By: (b) (4)

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

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1. Data Origin

Date	Location	User	Value	Reason
Oct-09-2020 11:43:11 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Oct-09-2020 11:43:11 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SERUM	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Oct-09-2020 11:43:19 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Oct-09-2020 11:43:11 (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-09-2020 11:43:11 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Date of Collection: Oct/8/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Oct-09-2020 11:43:19 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BPWXW8	Initial Entry

5.a Sample ID

090177e196ae3f38\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: 12411279

Subject Initials: ---

Generated By: (b) (4)

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

Date	Location	User	Value	Reason
Oct-09-2020 11:43:19 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> BPWXW8	Initial Entry

5.b

Date	Location	User	Value	Reason
Oct-09-2020 11:43:38 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Sample ID: BHHZZM	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Oct-09-2020 11:43:38 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> BHHZZM	Initial Entry

5.c

Date	Location	User	Value	Reason
Oct-09-2020 11:43:52 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Sample ID: BHHZZN	Initial Entry

5.c Sample ID

Date	Location	User	Value	Reason
Oct-09-2020 11:43:52 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> BHHZZN	Initial Entry

090177e196ae3f38\Final\Final On: 01-Apr-2021 05:12 (GMT)

Header Text: c4591001**Visit:** POT_COVID_ILL 1 - Unscheduled Visit
on Nov/27/2020**Form:** DATE OF VISIT - ILLNESS ONSET - 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:** 12411279**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 19:09[Back to Form](#)**I. Date of Visit**

Date	Location	User	Value	Reason
Nov-30-2020 15:44:06 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Nov-30-2020 15:43:42 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Deleted	Close Auto Query
Nov-30-2020 15:43:01 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Candidate	Date of Visit is completed but Date of Assessment in the Signs and Symptoms form is missing. Please review and update as appropriate.
Nov-30-2020 15:43:01 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	Date of Visit is completed but Date of Collection in both Nasal Swab Self and Nasal Swab are missing. Please review and update as appropriate.
Nov-30-2020 15:43:01 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Nov/27/2020	Initial Entry

3. COVID-19 Illness Visit:

Date	Location	User	Value	Reason
Nov-30-2020 15:43:01 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: COVID_A	Initial Entry

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/27/2020

Form Version: 10-Oct-2020 16:02

Site No: 1241

Subject No: 12411279

Generated By: (b) (4)

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

Date	Location	User	Value	Reason
Nov-30-2020 15:43:42 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Nov/27/2020	Initial Entry

2. Date of First Symptom Started:

Date	Location	User	Value	Reason
Nov-30-2020 15:43:42 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Nov/25/2020	Initial Entry

3. Symptoms Ongoing?

Date	Location	User	Value	Reason
Jan-04-2021 16:25:47 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Jan-04-2021 16:21:45 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	Patient chart is not clear if symptoms were resolved on 27Nov2020 or 30Nov2020. Please review and correct, if necessary.
Dec-28-2020 11:04:54 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO Date of Last Symptom Resolved: Nov/30/2020	New Information
Nov-30-2020 15:43:42 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

4.a

Date	Location	User	Value	Reason
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090177e196ae3f38\Final\Final On: 01-Apr-2021 05:12 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/27/2020

Form: SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - eCRF Audit Trail History

Form Version: 10-Oct-2020 16:02

Form Status: Data Complete, Frozen, Verified

Site No: 1241

Site Name: (1241) Hospital Irma Dulce

Subject No: 12411279

Subject Initials: ---

Generated By: (b) (4)

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

Nov-30-2020 15:43:22 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptoms: FEVER Symptom Present: YES	Initial Entry
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4.a Symptoms:

Date	Location	User	Value	Reason
Nov-30-2020 15:43:42 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: FEVER	Initial Entry

4.a Was symptom present?

Date	Location	User	Value	Reason
Nov-30-2020 15:43:42 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

4.b

Date	Location	User	Value	Reason
Nov-30-2020 15:43:42 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptoms: NEW OR INCREASED COUGH Symptom Present: YES	Initial Entry

4.b Symptoms:

Date	Location	User	Value	Reason
Nov-30-2020 15:43:42 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NEW OR INCREASED COUGH	Initial Entry

4.b Was symptom present?

Date	Location	User	Value	Reason
Nov-30-2020 15:43:42 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

4.c

090177e196ae3f38\Final\Final On: 01-Apr-2021 05:12 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/27/2020

Form: SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - eCRF Audit Trail History

Form Version: 10-Oct-2020 16:02

Form Status: Data Complete, Frozen, Verified

Site No: 1241

Site Name: (1241) Hospital Irma Dulce

Subject No: 12411279

Subject Initials: ---

Generated By: (b) (4)

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

Date	Location	User	Value	Reason
Nov-30-2020 15:43:42 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptoms: NEW OR INCREASED SHORTNESS OF BREATH Symptom Present: NO	Initial Entry

4.c Symptoms:

Date	Location	User	Value	Reason
Nov-30-2020 15:43:42 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NEW OR INCREASED SHORTNESS OF BREATH	Initial Entry

4.c Was symptom present?

Date	Location	User	Value	Reason
Nov-30-2020 15:43:42 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

4.d

Date	Location	User	Value	Reason
Nov-30-2020 15:43:42 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptoms: CHILLS Symptom Present: NO	Initial Entry

090177e196ae3f38\Final\Final On: 01-Apr-2021 05:12 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/27/2020

Form: SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - eCRF Audit Trail History

Form Version: 10-Oct-2020 16:02

Form Status: Data Complete, Frozen, Verified

Site No: 1241

Site Name: (1241) Hospital Irma Dulce

Subject No: 12411279

Subject Initials: ---

Generated By: (b) (4)

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

4.d Symptoms:

Date	Location	User	Value	Reason
Nov-30-2020 15:43:42 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: CHILLS	Initial Entry

4.d Was symptom present?

Date	Location	User	Value	Reason
Nov-30-2020 15:43:42 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

4.e

Date	Location	User	Value	Reason
Nov-30-2020 15:43:42 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom NEW OR INCREASED MUSCLE PAIN Symptom YES Present:	Initial Entry

4.e Symptoms:

Date	Location	User	Value	Reason
Nov-30-2020 15:43:42 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NEW OR INCREASED MUSCLE PAIN	Initial Entry

4.e Was symptom present?

Date	Location	User	Value	Reason
Nov-30-2020 15:43:42 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

4.f

Date	Location	User	Value	Reason
Nov-30-2020 15:43:42 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptoms NEW LOSS OF TA	Initial Entry

090177e196ae3f38\Final\Final On: 01-Apr-2021 05:12 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/27/2020

Form: SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - eCRF Audit Trail History

Form Version: 10-Oct-2020 16:02

Form Status: Data Complete, Frozen, Verified

Site No: 1241

Site Name: (1241) Hospital Irma Dulce

Subject No: 12411279

Subject Initials: ---

Generated By: (b) (4)

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

			: STE OR SMELL Symptom NO Present:	
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4.f Symptoms:

Date	Location	User	Value	Reason
Nov-30-2020 15:43:42 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NEW LOSS OF TASTE OR SMELL	Initial Entry

4.f Was symptom present?

Date	Location	User	Value	Reason
Nov-30-2020 15:43:42 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NO	Initial Entry

4.g

Date	Location	User	Value	Reason
Nov-30-2020 15:43:42 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Symptom NEW OR INCREASED SORE THROAT Symptom YES Present:	Initial Entry

4.g Symptoms:

Date	Location	User	Value	Reason
Nov-30-2020 15:43:42 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NEW OR INCREASED SORE THROAT	Initial Entry

4.g Was symptom present?

Date	Location	User	Value	Reason
Nov-30-2020 15:43:42 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> YES	Initial Entry

4.h

090177e196ae3f38\Final\Final On: 01-Apr-2021 05:12 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/27/2020

Form: SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - eCRF Audit Trail History

Form Version: 10-Oct-2020 16:02

Form Status: Data Complete, Frozen, Verified

Site No: 1241

Site Name: (1241) Hospital Irma Dulce

Subject No: 12411279

Subject Initials: ---

Generated By: (b) (4)

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

Date	Location	User	Value	Reason
Nov-30-2020 15:43:42 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptoms: DIARRHEA A Symptom Present NO :	Initial Entry

4.h Symptoms:

Date	Location	User	Value	Reason
Nov-30-2020 15:43:42 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: DIARRHEA	Initial Entry

4.h Was symptom present?

Date	Location	User	Value	Reason
Nov-30-2020 15:43:42 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

4.i

Date	Location	User	Value	Reason
Nov-30-2020 15:43:42 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptoms: VOMITING Symptom Present: NO	Initial Entry

4.i Symptoms:

Date	Location	User	Value	Reason
Nov-30-2020 15:43:42 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: VOMITING	Initial Entry

4.i Was symptom present?

Date	Location	User	Value	Reason
Nov-30-2020 15:43:42 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

090177e196ae3f38\Final\Final On: 01-Apr-2021 05:12 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/27/2020

Form: MICROBIOLOGY SPECIMEN - eCRF Audit Trail History

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen, Verified

Site No: 1241

Site Name: (1241) Hospital Irma Dulce

Subject No: 12411279

Subject Initials: ---

Generated By: (b) (4)

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

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1. Actual Date of Collection:

Date	Location	User	Value	Reason
Dec-23-2020 10:09:04 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry
Dec-23-2020 09:41:50 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

2. Specimen Type:

Date	Location	User	Value	Reason
Dec-23-2020 10:09:04 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry
Dec-23-2020 09:41:50 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

3. Specimen Collection Location:

Date	Location	User	Value	Reason
Dec-23-2020 10:09:04 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry
Dec-23-2020 09:41:50 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

4. Assay Code and Description:

Date	Location	User	Value	Reason
Dec-23-2020 10:09:04 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry
Dec-23-2020 09:41:50 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

090177e196ae3f38\Final\Final On: 01-Apr-2021 05:12 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit Form: MICROBIOLOGY SPECIMEN - eCRF Audit Trail History on Nov/27/2020

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen, Verified

Site No: 1241

Site Name: (1241) Hospital Irma Dulce

Subject No: 12411279

Subject Initials: ---

Generated By: (b) (4)

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

5. Device Type:

Date	Location	User	Value	Reason
Dec-23-2020 10:09:04 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry
Dec-23-2020 09:41:50 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

6. Trade Name:

Date	Location	User	Value	Reason
Dec-23-2020 10:09:04 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry
Dec-23-2020 09:41:50 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

7. Test Result:

Date	Location	User	Value	Reason
Dec-23-2020 10:09:04 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry
Dec-23-2020 09:41:50 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

8. Comments/Findings/Details:

Date	Location	User	Value	Reason
Dec-23-2020 10:09:04 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry
Dec-23-2020 09:41:50 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

9. Trade Name Other, Specify:

090177e196ae3f38\Final\Final On: 01-Apr-2021 05:12 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** MICROBIOLOGY SPECIMEN - eCRF Audit Trail History
on Nov/27/2020

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen, Verified

Site No: 1241

Site Name: (1241) Hospital Irma Dulce

Subject No: 12411279

Subject Initials: ---

Generated By: (b) (4)

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

Date	Location	User	Value	Reason
Dec-23-2020 10:09:04 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry
Dec-23-2020 09:41:50 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

Header Text: c4591001**Visit:** POT_COVID_ILL 1 - Unscheduled Visit on Nov/27/2020**Form Version:** 22-Apr-2020 21:03**Site No:** 1241**Subject No:** 12411279**Generated By:** (b) (4)**Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB SELF - 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[Back to Form](#)**1. Data Origin**

Date	Location	User	Value	Reason
Nov-30-2020 15:44:06 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Nov-30-2020 15:44:06 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: NASAL_SWAB_SELF	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Nov-30-2020 15:44:22 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Nov-30-2020 15:44:06 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Nov-30-2020 15:44:06 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Date of Collection: Nov/27/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Nov-30-2020 15:44:22 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: RW92922	Initial Entry

5.a Sample ID

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/27/2020

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB SELF - 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: 12411279

Subject Initials: ---

Generated By: (b) (4)

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

Date	Location	User	Value	Reason
Nov-30-2020 15:44:22 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: RW92922	Initial Entry

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/27/2020

Form Version: 22-Apr-2020 21:03

Site No: 1241

Subject No: 12411279

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB - 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. Data Origin

Date	Location	User	Value	Reason
Nov-30-2020 15:44:35 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Nov-30-2020 15:44:35 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: NASAL_SWAB	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Nov-30-2020 15:44:35 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

4. If no sample was collected or sample was not collected according to protocol, please provide reason:

Date	Location	User	Value	Reason
Nov-30-2020 15:44:35 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Subject used self swab	Initial Entry

090177e196ae3f38\Final\Final On: 01-Apr-2021 05:12 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/27/2020

Form: HEALTH CARE UTILIZATION - eCRF Audit Trail History

Form Version: 10-Oct-2020 15:59

Form Status: Data Complete, Frozen, Verified

Site No: 1241

Site Name: (1241) Hospital Irma Dulce

Subject No: 12411279

Subject Initials: ---

Generated By: (b) (4)

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

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1.a

Date	Location	User	Value	Reason
Nov-30-2020 15:44:51 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Type of Practitioner: SPECIALIST Occurrence of Visits or Contacts: NO	Initial Entry

1.a Physician or Healthcare Professional:

Date	Location	User	Value	Reason
Nov-30-2020 15:44:51 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: SPECIALIST	Initial Entry

1.a Occurrence of Visits or Contacts:

Date	Location	User	Value	Reason
Nov-30-2020 15:44:51 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

1.b

Date	Location	User	Value	Reason
Nov-30-2020 15:44:51 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Type of Practitioner: EMERGENCY ROOM Occurrence of Visits or Contacts: NO	Initial Entry

090177e196ae3f38\Final\Final On: 01-Apr-2021 05:12 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit Form: HEALTH CARE UTILIZATION - eCRF Audit Trail History on Nov/27/2020

Form Version: 10-Oct-2020 15:59

Form Status: Data Complete, Frozen, Verified

Site No: 1241

Site Name: (1241) Hospital Irma Dulce

Subject No: 12411279

Subject Initials: ---

Generated By: (b) (4)

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

1.b Physician or Healthcare Professional:

Date	Location	User	Value	Reason
Nov-30-2020 15:44:51 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: EMERGENCY ROOM	Initial Entry

1.b Occurrence of Visits or Contacts:

Date	Location	User	Value	Reason
Nov-30-2020 15:44:51 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

1.c

Date	Location	User	Value	Reason
Nov-30-2020 15:44:51 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Type of Practitioner: PRIMARY CARE PHYSICIAN Occurrence of Visits or Contacts: NO	Initial Entry

1.c Physician or Healthcare Professional:

Date	Location	User	Value	Reason
Nov-30-2020 15:44:51 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: PRIMARY CARE PHYSICIAN	Initial Entry

1.c Occurrence of Visits or Contacts:

Date	Location	User	Value	Reason
Nov-30-2020 15:44:51 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

1.d

Date	Location	User	Value	Reason
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090177e196ae3f38\Final\Final On: 01-Apr-2021 05:12 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit Form: HEALTH CARE UTILIZATION - eCRF Audit Trail History on Nov/27/2020

Form Version: 10-Oct-2020 15:59

Form Status: Data Complete, Frozen, Verified

Site No: 1241

Site Name: (1241) Hospital Irma Dulce

Subject No: 12411279

Subject Initials: ---

Generated By: (b) (4)

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

Nov-30-2020 15:44:51 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Type of Practitioner: URGENT CARE Occurrence of Visits or Contacts: NO	Initial Entry
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1.d Physician or Healthcare Professional:

Date	Location	User	Value	Reason
Nov-30-2020 15:44:51 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: URGENT CARE	Initial Entry

1.d Occurrence of Visits or Contacts:

Date	Location	User	Value	Reason
Nov-30-2020 15:44:51 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

1.e

Date	Location	User	Value	Reason
Dec-22-2020 12:32:01 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Type of Practitioner: TELEPHONE CONSULTATION Occurrence of Visits or Contacts: NO	Transcription Error
Nov-30-2020 15:44:51 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Type of Practitioner: TELEPHONE CONSULTATION Occurrence of Visits or Contacts: YES <i>Number of Visits or Contacts:</i> 1	Initial Entry

090177e196ae3f38\Final\Final On: 01-Apr-2021 05:12 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit Form: HEALTH CARE UTILIZATION - eCRF Audit Trail History on Nov/27/2020

Form Version: 10-Oct-2020 15:59

Form Status: Data Complete, Frozen, Verified

Site No: 1241

Site Name: (1241) Hospital Irma Dulce

Subject No: 12411279

Subject Initials: ---

Generated By: (b) (4)

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

I.e Physician or Healthcare Professional:

Date	Location	User	Value	Reason
Nov-30-2020 15:44:51 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: TELEPHONE CONSULTATION	Initial Entry

I.e Occurrence of Visits or Contacts:

Date	Location	User	Value	Reason
Dec-22-2020 14:32:43 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Dec-22-2020 12:32:01 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Transcription Error
Dec-22-2020 12:32:01 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Transcription Error
Dec-22-2020 11:36:29 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	As per source, question is No. Study visits should not be reported in Health Care Utilization page. Please verify and update, if applicable. Thank you.
Nov-30-2020 15:44:51 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES <i>Number of Visits or Contacts:</i> 1	Initial Entry

I.f

Date	Location	User	Value	Reason
Nov-30-2020 15:44:51 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Type of Practitioner: OTH ER Occurrence of Visits or Contacts: NO	Initial Entry

090177e196ae3f38\Final\Final On: 01-Apr-2021 05:12 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit Form: HEALTH CARE UTILIZATION - eCRF Audit Trail History
on Nov/27/2020

Form Version: 10-Oct-2020 15:59

Form Status: Data Complete, Frozen, Verified

Site No: 1241

Site Name: (1241) Hospital Irma Dulce

Subject No: 12411279

Subject Initials: ---

Generated By: (b) (4)

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

1.f Physician or Healthcare Professional:

Date	Location	User	Value	Reason
Nov-30-2020 15:44:51 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> OTHER	Initial Entry

1.f Occurrence of Visits or Contacts:

Date	Location	User	Value	Reason
Nov-30-2020 15:44:51 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NO	Initial Entry

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

Date	Location	User	Value	Reason
Nov-30-2020 15:44:51 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NO	Initial Entry

090177e196ae3f38\Final\Final On: 01-Apr-2021 05:12 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/27/2020

Form: ILLNESS DETAILS - eCRF Audit Trail History

Form Version: 06-Jul-2020 21:52

Form Status: Data Complete, Frozen, Verified

Site No: 1241

Site Name: (1241) Hospital Irma Dulce

Subject No: 12411279

Subject Initials: ---

Generated By: (b) (4)

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

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1. Category of Clinical Event:

Date	Location	User	Value	Reason
Dec-23-2020 07:53:18 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Dec-22-2020 15:35:24 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	data updated
Dec-22-2020 14:34:02 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reissued:Opened	Please verify diagnosis as pharyngotonsillitis on 27Nov2020. Thank you.
Dec-22-2020 11:55:04 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	data updated
Dec-22-2020 11:54:46 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: POTENTIAL COVID-19 ILLNESS	Initial Entry
Dec-22-2020 11:38:18 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	Please verify and complete page as per symptoms reported as grade 1 and possible diagnosis as pharyngotonsillitis on 27Nov2020. Thank you.

2. Was a diagnosis obtained for Potential COVID-19 Illness?

Date	Location	User	Value	Reason
Dec-22-2020 15:35:06 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES <i>Respiratory Illness Diagnosis:</i> Laryngotonsillitis Date of Diagnosis:	New Information

090177e196ae3f38\Final\Final On: 01-Apr-2021 05:12 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** ILLNESS DETAILS - eCRF Audit Trail History
on Nov/27/2020

Form Version: 06-Jul-2020 21:52

Form Status: Data Complete, Frozen, Verified

Site No: 1241

Site Name: (1241) Hospital Irma Dulce

Subject No: 12411279

Subject Initials: ---

Generated By: (b) (4)

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

			Nov/27/2020	
Dec-22-2020 11:54:46 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

3. Toxicity Grade:

Date	Location	User	Value	Reason
Dec-22-2020 11:54:46 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 1	Initial Entry

Header Text: c4591001

Visit: POT_COVID_CONVA 1 - Unscheduled
Visit on Dec/28/2020

Form Version: 22-Apr-2020 21:04

Site No: 1241

Subject No: 12411279

Generated By: (b) (4)

Form: DATE OF VISIT - ILLNESS CONVALESCENT - 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
Dec-28-2020 11:05:14 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Dec/28/2020	Initial Entry

3. COVID-19 Illness Visit:

Date	Location	User	Value	Reason
Dec-28-2020 11:05:14 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: COVID_A1	Initial Entry

090177e196ae3f38\Final\Final On: 01-Apr-2021 05:12 (GMT)

Header Text: c4591001

Visit: POT_COVID_CONVA 1 - Unscheduled
Visit on Dec/28/2020

Form Version: 22-Apr-2020 21:03

Site No: 1241

Subject No: 12411279

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY -
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. Data Origin

Date	Location	User	Value	Reason
Dec-28-2020 11:12:56 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Dec-28-2020 11:12:56 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SERUM	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Dec-28-2020 11:13:11 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Dec-28-2020 11:12:56 (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.
Dec-28-2020 11:12:56 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Date of Collection: Dec/28/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Dec-28-2020 11:13:11 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BR797H	Initial Entry

5.a Sample ID

090177e196ae3f38\Final\Final On: 01-Apr-2021 05:12 (GMT)

Header Text: c4591001

Visit: POT_COVID_CONVA 1 - Unscheduled
Visit on Dec/28/2020

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: 12411279

Subject Initials: ---

Generated By: (b) (4)

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

Date	Location	User	Value	Reason
Dec-28-2020 11:13:11 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> BR797H	Initial Entry

5.b

Date	Location	User	Value	Reason
Dec-28-2020 11:13:21 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Sample ID: BS2JVC	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Dec-28-2020 11:13:21 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> BS2JVC	Initial Entry

5.c

Date	Location	User	Value	Reason
Dec-28-2020 11:13:28 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Sample ID: BS2JVD	Initial Entry

5.c Sample ID

Date	Location	User	Value	Reason
Dec-28-2020 11:13:28 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> BS2JVD	Initial Entry

090177e196ae3f38\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: 22-Apr-2020 21:05

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1241

Site Name: (1241) Hospital Irma Dulce

Subject No: 12411279

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
Sep-10-2020 13:02:29 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sep/10/2020	Initial Entry

2. Phase of Disposition:

Date	Location	User	Value	Reason
Sep-10-2020 13:02:29 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: VACCINATION	Initial Entry

3. Status:

Date	Location	User	Value	Reason
Oct-23-2020 08:01:11 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Deleted	Pregnancy updated as AE.
Oct-16-2020 09:32:55 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Candidate	Status needs to be updated as AE.
Oct-11-2020 05:22:07 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Closed	Response satisfies query
Oct-09-2020 14:42:37 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Answered	data updated
Oct-08-2020 12:36:42 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Opened	DM: The Adverse Event Action Taken is DRUG WITHDRAWN but reason for treatment discontinuation is not reported as ADVERSE EVENT or DEATH. Please review and clarify.

090177e196ae3f38\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: 22-Apr-2020 21:05

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1241

Site Name: (1241) Hospital Irma Dulce

Subject No: 12411279

Subject Initials: ---

Generated By: (b) (4)

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

Sep-10-2020 13:05:04 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Sep-10-2020 13:02:29 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	Response to "Status" is PREGNANCY but "Specify Status" is Provided.
Sep-10-2020 13:02:29 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: PREGNANCY	Initial Entry

4. Specify Status:

Date	Location	User	Value	Reason
Sep-10-2020 13:05:04 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Transcription Error
Sep-10-2020 13:02:29 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Discontinued	Initial Entry

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Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1241

Subject No: 12411279

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
Sep-14-2020 08:13:11 (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: 12411279

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-09-2020 14:43:51 (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: 12411279

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-30-2020 16:07:41 (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: 12411279

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 09:22:13 (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: 12411279

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 09:23:01 (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: 12411279

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - Audit Trail

Form Status:

Site Name: (1241) Hospital Irma Dulce

Subject Initials: ---

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Date	Location	User	Value	Reason
Mar-09-2021 09:23:52 (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: 12411279

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Not Complete

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
Sep-14-2020 08:13:11 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: ADVERSE EVENT	Initial Entry

2. AE ID:

Date	Location	User	Value	Reason
Sep-14-2020 08:13:11 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 1	Initial Entry

3. Adverse Event:

(If possible specify diagnosis, not individual symptoms)

Date	Location	User	Value	Reason
Nov-04-2020 06:56:41 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Nov-03-2020 14:09:03 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	A follow up AEM form was sent to SDB on 30-Oct-2020.
Nov-03-2020 10:50:44 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	SAE RECON:AER#2020352761, the term in safety database was recorded as pregnancy. Based on the latest EDP guidance,the term should be reported as 'EXPOSURE DURING PREGNANCY'. Please submit a follow up AEM form to update SDB term.
Oct-30-2020 18:38:39 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Exposure during pregnancy	Transcription Error
Oct-30-2020 18:38:23 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Expose during pregnancy	Transcription Error

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Header Text: c4591001

Visit: Logs - Unscheduled

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Site No: 1241

Subject No: 12411279

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Not Complete

Site Name: (1241) Hospital Irma Dulce

Subject Initials: ---

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

Sep-14-2020 08:13:11 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Pregnancy	Initial Entry
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4. Start Date Time:

Date	Location	User	Value	Reason
Oct-06-2020 14:12:54 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	Giselle Castillo (b) (4)	Query 1: Closed	Response satisfies query
Oct-06-2020 12:12:05 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Subject did not take ultrasound
Oct-02-2020 19:21:04 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	Giselle Castillo (b) (4)	Query 1: Opened	Per case narrative in ultrasound gestational age was 6 weeks 2 days by 22Sep2020, and probable date of conception is 09Aug2020. The ultrasound is the more accurate way to date a pregnancy, Please update start date and send a FU SAE form.
Sep-14-2020 08:13:11 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sep/10/2020 UNK:UNK	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Oct-16-2020 17:48:08 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO End Date Time: Oct/14/2020 UNK:UNK	New Information
Sep-14-2020 08:13:11 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

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Header Text: c4591001

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Site No: 1241

Subject No: 12411279

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Not Complete

Site Name: (1241) Hospital Irma Dulce

Subject Initials: ---

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

6. Toxicity Grade:

Date	Location	User	Value	Reason
Sep-14-2020 08:13:24 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	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
Nov-14-2020 12:42:34 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 7: Closed	issue considered resolved
Nov-06-2020 01:14:04 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 7: Reissued:Candidate	SAE RECON: For Clinical review
Nov-05-2020 14:20:36 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 7: Answered	According with the monitor guidance the event is not considered as serious criteria. SAE form was updated 30Oct2020.
Nov-05-2020 01:49:43 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 7: Opened	SAE RECON: AER#2020352761, Exposure during pregnancy was reported as serious in Safety database while recorded as non serious in AE CRF. Since the participant had a retained abortion. Please confirm seriousness and update accordingly.
Nov-04-2020 07:00:13 (UTC-03:00) City of	ACV0PFEINFP6000	auto query (autoquery)	Query 6: Deleted	Close Auto Query

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Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1241

Subject No: 12411279

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Not Complete

Site Name: (1241) Hospital Irma Dulce

Subject Initials: ---

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

Buenos Aires				
Nov-04-2020 06:56:51 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 6: Candidate	For AE Exposure during pregnancy: Response to "Is the adverse event serious?" is 'No' but "Serious Adverse Event Number" is present.
Nov-02-2020 18:42:38 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	Hayley Wyper (b) (4)	Query 5: Closed	safety following up for SAE of 'retained abortion'
Nov-02-2020 11:45:11 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 5: Answered	According to the monitor instructions, the exposure of pregnancy is not consider a SAE.
Nov-02-2020 11:06:30 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 4: Deleted	Close Auto Query
Nov-02-2020 08:54:42 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	Hayley Wyper (b) (4)	Query 5: Opened	CLINQUERY: Please review if this event should be updated to reflect Serious criteria met if an abnormal outcome has occurred (eg spontaneous abortion)
Oct-31-2020 11:55:52 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Closed	Response satisfies query
Oct-30-2020 18:38:39 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 4: Candidate	For AE Exposure during pregnancy: Response to "Is the adverse event serious?" is 'No' but "Serious Adverse Event Number" is present.
Oct-30-2020 18:38:23 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 4: Candidate	For AE Expose during pregnancy: Response to "Is the adverse event

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Header Text: c4591001**Visit:** Logs - Unscheduled**Form Version:** 22-Apr-2020 21:02**Site No:** 1241**Subject No:** 12411279**Generated By:** (b) (4)**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History**Form Status:** Data Complete, Locked, Frozen, Not Complete**Site Name:** (1241) Hospital Irma Dulce**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 19:09

				serious?" is 'No' but "Serious Adverse Event Number" is present.
Oct-30-2020 18:29:20 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 4: Candidate	For AE Pregnancy: Response to "Is the adverse event serious?" is 'No' but "Serious Adverse Event Number" is present.
Oct-30-2020 18:29:20 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Transcription Error
Oct-30-2020 16:00:42 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Answered	PI considered the pregnancy as medically important serious event. SAE form was updated and sent to pharmacovigilance on 16Oct2020 with abortion information.
Oct-30-2020 09:11:08 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Opened	SAE RECON: AER#2020352761.Per Clinical,per protocol section 8.3.5, incomplete abortion meets seriousness criteria. Please retain "exposure during pregnancy" as the non-serious AE and add Incomplete abortion event to the AE log and submit an SAE form.
Oct-27-2020 10:15:18 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Closed	Response satisfies query
Oct-26-2020 14:16:21 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Answered	Transcription Error

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<p>Oct-26-2020 14:16:21 (UTC-03:00) City of Buenos Aires</p>	<p>ACV0PFEINFP6000</p>	<p>(b) (4), (b) (6)</p>	<p>Data Entry: YES Is this serious event associated with congenital anomaly or birth defect? YES Did this serious event result in death? NO Did this serious event require or prolong hospitalization? YES Did this serious event result in persistent or significant disability/incapacity? NO Is this serious event life threatening? NO Other medically important serious event YES</p>	<p>Transcription Error</p>
<p>Oct-24-2020 14:50:15 (UTC-03:00) City of Buenos Aires</p>	<p>ACV0PFEINFP6000</p>	<p>(b) (4), (b) (6)</p>	<p>Query 2: Reissued:Opened</p>	<p>"Is this serious event associated with congenital anomaly or birth defect?" is answered as no. Per previous query, source reported that criteria as yes. Please review and update as appropriate.</p>
<p>Oct-23-2020 20:11:56 (UTC-03:00) City of Buenos Aires</p>	<p>ACV0PFEINFP6000</p>	<p>auto query (autoquery)</p>	<p>Query 2: Answered</p>	<p>New Information</p>

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Oct-23-2020 20:11:56 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Is this serious event associated with congenital anomaly or birth defect? NO Did this serious event result in death? NO Did this serious event require or prolong hospitalization? YES Did this serious event result in persistent or significant disability/incapacity? NO Is this serious event life threatening? NO Other medically important serious event YES	New Information
Oct-22-2020 14:37:09 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Opened	According to source document, reporter considered 3 seriousness criteria: medically important serious event, hospitalization and congenital anomaly or birth defect. Please verify and update, if applicable. Thank you.
Sep-15-2020 06:57:27 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query

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Sep-14-2020 08:13:11 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	For AE Pregnancy: Response to "Is the adverse event serious?" is 'Yes' but "Serious Adverse Event Number" is blank.
Sep-14-2020 08:13:11 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Is this serious event associated with congenital anomaly or bir th defect? NO Did this serious event result in death? NO Did this serious event require or prolong hospitalization? NO Did this serious event result in persistent or significant disabil ity/incapacity? NO Is this serious event life threat ening? NO Other medically important seri ous event YES	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
Sep-14-2020 08:13:11 (UTC-03:00) City of	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

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Buenos Aires		(b) (4), (b) (6)	
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9. Is this event related to study treatment:

Date	Location	User	Value	Reason
Sep-14-2020 08:13:11 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NOT RELATED If Not Related to study treatment(s), this event is due to: OTHER If Other, specify: Pregnancy	Initial Entry

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Oct-16-2020 08:48:39 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	Hayley Wyper (b) (4)	Query 2: Closed	Response satisfies query
Oct-15-2020 17:11:06 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Answered	Transcription Error
Oct-15-2020 17:11:06 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: DRUG WITHDRAWN	Transcription Error
Oct-13-2020 08:20:19 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	Hayley Wyper (b) (4)	Query 2: Opened	CLINQUERY: Please review entry: EOT tab reports end of treatment due to pregnancy; no Vaccination 2 administered
Oct-09-2020 14:42:22 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NOT APPLICABLE	Transcription Error
Sep-16-2020 05:59:18 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query

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10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Sep-15-2020 11:20:02 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Original value is correct
Sep-15-2020 02:33:24 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (b) (4)	Query 1: Opened	DMW4691768;The Latest Action to Study Treatment is DRUG WITHDRAWN, but the Disposition-Treatment Form Status is not DEATH OR ADVERSE EVENT. Please review and update as appropriate.
Sep-14-2020 08:13:11 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: DRUG WITHDRAWN	Initial Entry

11. Was a Concomitant Medication given?

Date	Location	User	Value	Reason
Oct-30-2020 18:29:43 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Transcription Error
Oct-24-2020 14:47:43 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Oct-23-2020 20:12:27 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	New Information
Oct-23-2020 20:12:27 (UTC-03:00) City of	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	New Information

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Buenos Aires		(b) (4), (b) (6)		
Oct-22-2020 14:40:25 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	According to source document, patient received dipyrone and ferrous sulfate as well as IV anesthesia. Please verify and update, if applicable. Tks.
Sep-14-2020 08:13:11 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Sep-14-2020 08:13:11 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

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

Date	Location	User	Value	Reason
Oct-21-2020 07:14:41 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Closed	SDB data updated
Oct-21-2020 02:29:26 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Reissued:Candid ate	SAE recon: pending SDB update
Oct-20-2020 13:20:19 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Answered	Outcome is resolved. SAE FUP form was sent to safety on 16Oct2020.
Oct-17-2020 10:35:52 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Opened	SAE RECON:AER#2020352761 ,outcome was updated to RECOVERED/RESOLVED in AE CRF however, retained as NOT RECOVERED/NOT RESOLVED on SDB. Please confirm correct outcome. If safety update is required, please submit a follow-up

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				form.
Oct-16-2020 17:48:49 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Closed	Close Auto Query
Oct-16-2020 17:48:49 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: RECOVERED/RESOLVE D	New Information
Oct-16-2020 17:48:08 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Opened	For AE Pregnancy: Response to "What was the outcome of this adverse event?" is 'Not Recovered/Not Resolved' but AE End Date/Time is present.
Sep-16-2020 10:00:14 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Issue resolved
Sep-15-2020 11:20:26 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Transcription Error
Sep-15-2020 11:20:26 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NOT RECOVERED/NOT RESOLVED	Transcription Error
Sep-15-2020 07:00:57 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	SAE RECON:AER#2020352761 ,outcome was reported as NOT RECOVERED/NOT RESOLVED to Safety DB however, recorded as RECOVERING/RESOLVING on AE CRF. Please confirm correct outcome. If safety update is required, please submit a follow-up form.
Sep-14-2020 08:13:11 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: RECOVERING/RESOLV ING	Initial Entry

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

Date	Location	User	Value	Reason
Sep-14-2020 08:13:11 (UTC-03:00) City of	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

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Buenos Aires	(b) (4), (b) (6)
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15. Serious Adverse Event Number: For Pfizer Use Only

Date	Location	User	Value	Reason
Nov-04-2020 07:00:13 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	event not serious
Nov-04-2020 06:56:51 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 2020352761	Initial Entry
Nov-02-2020 11:06:30 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	downgraded to non serious
Sep-15-2020 06:57:27 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 2020352761	Initial Entry

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1. Category:

Date	Location	User	Value	Reason
Oct-09-2020 14:43:51 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: ADVERSE EVENT	Initial Entry

2. AE ID:

Date	Location	User	Value	Reason
Oct-09-2020 14:43:51 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 2	Initial Entry

3. Adverse Event:

(If possible specify diagnosis, not individual symptoms)

Date	Location	User	Value	Reason
Oct-09-2020 14:43:51 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Vaginal bleeding	Initial Entry

4. Start Date Time:

Date	Location	User	Value	Reason
Oct-09-2020 14:43:51 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Oct/5/2020 UNK:UNK	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Nov-04-2020 05:43:37 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Nov-03-2020 14:06:33 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Transcription Error
Nov-03-2020 14:06:33 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO End Date Time:	Transcription Error

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			Oct/14/2020 UNK:UNK	
Nov-03-2020 12:28:43 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	CLINQUERY: AE "vaginal bleeding" was reported on Oct 05 : Please review if event remains ongoing. Else, report end date and update event outcome status. Thank you
Oct-09-2020 14:43:51 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

6. Toxicity Grade:

Date	Location	User	Value	Reason
Oct-09-2020 14:43:51 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 1	Initial Entry

7. Is the adverse event serious?

If Yes, NOTIFY PFIZER IMMEDIATELY.

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

Date	Location	User	Value	Reason
Oct-09-2020 14:43:51 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 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-09-2020 14:43:51 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

9. Is this event related to study treatment:

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Date	Location	User	Value	Reason
Nov-03-2020 15:11:17 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NOT RELATED If Not Related to study treatment(s), this event is due to: OTHER <i>If Other, specify:</i> threat of abortion	Transcription Error
Oct-09-2020 14:43:51 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NOT RELATED If Not Related to study treatment(s), this event is due to: OTHER <i>If Other, specify:</i> Pregnacy	Initial Entry

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Oct-09-2020 14:43:51 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NOT APPLICABLE	Initial Entry

11. Was a Concomitant Medication given?

Date	Location	User	Value	Reason
Oct-09-2020 14:43:51 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Oct-09-2020 14:43:51 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

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

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Date	Location	User	Value	Reason
Nov-03-2020 14:07:52 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Nov-03-2020 14:07:52 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: RECOVERED/RESOLVED	Transcription Error
Nov-03-2020 14:06:33 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	For AE Vaginal bleeding: Response to "What was the outcome of this adverse event?" is 'Recovering/Resolving' but AE End Date/Time is present.
Oct-09-2020 14:43:51 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: RECOVERING/RESOLVING	Initial Entry

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

Date	Location	User	Value	Reason
Oct-09-2020 14:43:51 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

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1. Category:

Date	Location	User	Value	Reason
Oct-30-2020 16:07:41 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: ADVERSE EVENT	Initial Entry

2. AE ID:

Date	Location	User	Value	Reason
Oct-30-2020 16:07:41 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 3	Initial Entry

3. Adverse Event:

(If possible specify diagnosis, not individual symptoms)

Date	Location	User	Value	Reason
Nov-07-2020 13:36:30 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Closed	SDB term updated
Nov-06-2020 08:21:12 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Reissued: Candidate	Pending SDB update
Nov-05-2020 14:21:25 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Answered	I confirm that a follow up AEM form was submitted to update term in SDB.
Nov-05-2020 04:37:54 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Opened	SAE RECON: AER#2020362930, the term was updated to 'RETAINED PRODUCTS 'Retained abortion' while retained as 'Retained abortion' in Safety database.

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				Please confirm if a follow up AEM form was submitted to update term in SDB.
Nov-04-2020 20:35:19 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000.InFormAdapter.Discrepancy	PFETMS Oracle (b) (4)	Query 1: Closed	Discrepancy has been closed.
Nov-04-2020 15:54:53 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Transcription Error
Nov-04-2020 15:54:53 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry : RETAINED PRODUCTS OF CONCEPTION	Transcription Error
Nov-04-2020 15:28:40 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reissued: Opened	Please update the term to specify the adverse event being reported. Are you reporting ABORTION INCOMPLETE? ABORTION COMPLICATED? ABORTION INCOMPLETE COMPLICATED? RETAINED PRODUCTS OF CONCEPTION? Other? Please update the verbatim term to clarify.
Nov-03-2020	ACV0PFEINFP6000	(b) (4), (b) (6)	Query	Original value is

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14:58:29 (UTC-03:00) City of Buenos Aires		(b) (4), (b) (6)	1: An swere d	correct
Oct-31-2020 08:55:21 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000.InFormAdapter.Discrepancy	PFETMS Oracle (b) (4)	Query 1: Op ened	Clarify RETAINED ABORTION as follows...Are you reporting ABORTION INCOMPLETE? ABORTION COMPLICATED? ABORTION INCOMPLETE COMPLICATED? RETAINED PRODUCTS OF CONCEPTION? Other? Please update the verbatim term to clarify. Thank you.
Oct-30-2020 16:07:41 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry : RETA INED ABO RTIO N	Initial Entry

4. Start Date Time:

Date	Location	User	Value	Reason
Nov-11-2020 08:55:48 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	onset date updated in SDB
Nov-05-2020 04:33:45 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reissued:Candidate	For PSSR review
Nov-04-2020 11:08:21 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	10sep2020 was reported the pregnancy. the retained abortion occurred in

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				14oct2020.
Nov-04-2020 07:02:05 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	SAE RECON: AER#2020352761 ,onset date was reported as 10Sep2020 in Safety database however, recorded as 14Oct2020 on AE CRF. Please confirm correct Onset Date. If safety update is required, please submit a follow-up SAE form.
Oct-30-2020 16:07:41 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Oct/14/2020 UNK:UNK	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Oct-30-2020 16:07:41 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO End Date Time: Oct/14/2020 UNK:UNK	Initial Entry

6. Toxicity Grade:

Date	Location	User	Value	Reason
Oct-30-2020 16:07:41 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 3	Initial Entry

7. Is the adverse event serious?

If Yes, NOTIFY PFIZER IMMEDIATELY.

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

Date	Location	User	Value	Reason
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Header Text: c4591001**Visit:** Logs - Unscheduled**Form Version:** 22-Apr-2020 21:02**Site No:** 1241**Subject No:** 12411279**Generated By:** (b) (4)**Form:** ADVERSE EVENT REPORT - 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

Nov-04-2020 07:00:59 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Closed	Response satisfies query
Nov-03-2020 13:50:51 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Answered	The follow up form was sent on 30-Oct-2020.
Nov-02-2020 12:14:17 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Opened	SAE RECON: AER#2020352761 Pregnancy was recorded in SDB however, RETAINED ABORTION was not recorded in Safety database. A follow up AEM form is required to add RETAINED ABORTION as the SAE. Please confirm and submit the ffup form as appropriate.
Nov-02-2020 12:04:23 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Deleted	Query can be addressed internally
Oct-30-2020 16:08:20 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Closed	Close Auto Query
Oct-30-2020 16:08:20 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Is this serious event associated with congenital anomaly or birth defect? NO Did this serious event result in death? NO Did this serious event require or prolong hospitalization? YES	Transcription Error

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			<p>Did this serious event result in persistent or significant disability/incapacity?</p> <p>NO</p> <p>Is this serious event life threatening?</p> <p>NO</p> <p>Other medically important serious event</p> <p>YES</p>	
Oct-30-2020 16:07:41 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Opened	Is this adverse event serious?' is reported 'Yes', but at least one seriousness criteria is missing. Please review and update as appropriate.
Oct-30-2020 16:07:41 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	For AE RETAINED ABORTION: Response to "Is the adverse event serious?" is 'Yes' but "Serious Adverse Event Number" is blank.
Oct-30-2020 16:07:41 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<p>Data Entry:</p> <p>YES</p> <p>Is this serious event associated with congenital anomaly or birth defect?</p> <p>NO</p> <p>Did this serious event result in death?</p> <p>NO</p> <p>Did this serious event require or prolong hospitalization?</p>	Initial Entry

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			YES	
			Other medically important serious event	
			YES	

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-30-2020 16:07:41 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

9. Is this event related to study treatment:

Date	Location	User	Value	Reason
Nov-04-2020 15:16:09 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Closed	Response satisfies query
Nov-04-2020 11:07:15 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Answered	Transcription Error
Nov-04-2020 11:07:15 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NOT RELATED If Not Related to study treatment(s), this event is due to: OTHER If Other, specify: Vaginal bleeding	Transcription Error
Nov-03-2020 16:41:09 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Opened	According to the patient chart, etiology of this event needs to be clarified, please review patient chart and correct, if necessary.
Nov-03-2020 14:57:43 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	Hayley Wyper (b) (4)	Query 1: Closed	Response satisfies query

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Nov-03-2020 13:49:05 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Transcription Error
Nov-03-2020 13:49:05 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NOT RELATED If Not Related to study treatment(s), this event is due to: OTHER <i>If Other, specify:</i> pregnancy	Transcription Error
Nov-02-2020 08:48:49 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	Hayley Wyper (b) (4)	Query 1: Opened	CLINQUERY: Please review this entry for the etiology of 'Retained Abortion' - should pregnancy not be captured?
Oct-30-2020 16:07:41 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NOT RELATED If Not Related to study treatment(s), this event is due to: OTHER <i>If Other, specify:</i> vaginal bleeding	Initial Entry

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Nov-10-2020 10:07:43 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Closed	Acceptable discrepancy per Clinical review
Nov-07-2020 13:15:51 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Reissued:Candidate	SAE RECON: For Clinical review
Nov-06-2020 15:48:39 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Answered	no action taken. please consider data as inserted.

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Nov-06-2020 01:16:05 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Reissued:Opened	SAE RECON 1: The action taken in AE CRF was recorded as not Applicable. Please confirm if this should be updated to DRUG WITHDRAWN per previous query response.
Nov-05-2020 14:24:28 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Answered	the study treatment was permanently withdrawn due to AE exposure to pregnancy.
Nov-05-2020 04:32:22 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Opened	SAE RECON:AER#2020352761 ,action taken was reported as NOT APPLICABLE in AE CRF while PERMANENTLY WITHDRAWN in Safety database. Please confirm. If safety update is required, please submit a follow up form
Nov-05-2020 04:30:16 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Closed	new query issued. to indicate correct AER and term
Nov-04-2020 11:00:11 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Answered	AER is not for this patient and it is no pulmonary embolism. please verify.
Nov-04-2020 07:03:33 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Opened	SAE RECON:AER#2020373624 ,action taken was reported as NOT APPLICABLE in AE CRF while PERMANENTLY WITHDRAWN in Safety database.Please confirm. If safety update is required, please submit a follow up form
Nov-02-2020 12:08:08 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	Hayley Wyper (b) (4)	Query 1: Closed	Response satisfies query
Nov-02-2020 11:46:55	ACV0PFEINFP6000	auto query	Query 1: Answered	Transcription Error

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(UTC-03:00) City of Buenos Aires		(autoquery)		
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10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Nov-02-2020 11:46:55 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NOT APPLICABLE	Transcription Error
Nov-02-2020 08:56:27 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	Hayley Wyper (b) (4)	Query 1: Opened	CLINQUERY: Please review entry - Drug Withdrawn was already reported due to the pregnancy
Oct-30-2020 16:07:41 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: DRUG WITHDRAWN	Initial Entry

11. Was a Concomitant Medication given?

Date	Location	User	Value	Reason
Oct-30-2020 16:07:41 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Oct-30-2020 16:07:41 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

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

Date	Location	User	Value	Reason
Oct-30-2020 16:07:41 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: RECOVERED/RESOLVED	Initial Entry

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

Date	Location	User	Value	Reason
Oct-30-2020 16:07:41 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

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Buenos Aires	(b) (4), (b) (6)
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15. Serious Adverse Event Number: For Pfizer Use Only

Date	Location	User	Value	Reason
Nov-04-2020 07:00:32 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 2020352761	Initial Entry

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1. Category:

Date	Location	User	Value	Reason
Mar-09-2021 09:22:13 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: ADVERSE EVENT	Initial Entry

2. AE ID:

Date	Location	User	Value	Reason
Mar-09-2021 09:22:13 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 4	Initial Entry

3. Adverse Event:

(If possible specify diagnosis, not individual symptoms)

Date	Location	User	Value	Reason
Mar-09-2021 09:22:13 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Myalgia	Initial Entry

4. Start Date Time:

Date	Location	User	Value	Reason
Mar-09-2021 09:22:13 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Feb/16/2021 20:00	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Mar-09-2021 09:22:13 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO End Date Time: Feb/19/2021 UNK:UNK	Initial Entry

6. Toxicity Grade:

Date	Location	User	Value	Reason
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Mar-09-2021 09:22:13 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 1	Initial Entry
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7. Is the adverse event serious?

If Yes, NOTIFY PFIZER IMMEDIATELY.

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

Date	Location	User	Value	Reason
Mar-09-2021 09:22:13 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 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
Mar-09-2021 09:22:13 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

9. Is this event related to study treatment:

Date	Location	User	Value	Reason
Mar-09-2021 09:22:13 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: RELATED	Initial Entry

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Mar-09-2021 09:22:13 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NOT APPLICABLE	Initial Entry

11. Was a Concomitant Medication given?

Date	Location	User	Value	Reason
Mar-09-2021 09:22:13 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

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12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Mar-09-2021 09:22:13 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

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

Date	Location	User	Value	Reason
Mar-09-2021 09:22:13 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: RECOVERED/RESOLVED	Initial Entry

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

Date	Location	User	Value	Reason
Mar-09-2021 09:22:13 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

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1. Category:

Date	Location	User	Value	Reason
Mar-09-2021 09:23:01 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: ADVERSE EVENT	Initial Entry

2. AE ID:

Date	Location	User	Value	Reason
Mar-09-2021 09:23:01 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 5	Initial Entry

3. Adverse Event:

(If possible specify diagnosis, not individual symptoms)

Date	Location	User	Value	Reason
Mar-09-2021 09:23:01 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Chills	Initial Entry

4. Start Date Time:

Date	Location	User	Value	Reason
Mar-09-2021 09:23:01 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Feb/16/2021 20:00	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Mar-09-2021 09:23:01 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO End Date Time: Feb/19/2021 UNK:UNK	Initial Entry

6. Toxicity Grade:

Date	Location	User	Value	Reason
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Mar-09-2021 09:23:01 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 1	Initial Entry
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7. Is the adverse event serious?

If Yes, NOTIFY PFIZER IMMEDIATELY.

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

Date	Location	User	Value	Reason
Mar-09-2021 09:23:01 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 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
Mar-09-2021 09:23:01 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

9. Is this event related to study treatment:

Date	Location	User	Value	Reason
Mar-09-2021 09:23:01 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: RELATED	Initial Entry

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Mar-09-2021 09:23:01 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NOT APPLICABLE	Initial Entry

11. Was a Concomitant Medication given?

Date	Location	User	Value	Reason
Mar-09-2021 09:23:01 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

090177e196ae3f38\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: 12411279

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - 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

12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Mar-09-2021 09:23:01 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

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

Date	Location	User	Value	Reason
Mar-09-2021 09:23:01 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: RECOVERED/RESOLVED	Initial Entry

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

Date	Location	User	Value	Reason
Mar-09-2021 09:23:01 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

090177e196ae3f38\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: 12411279

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - 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. Category:

Date	Location	User	Value	Reason
Mar-09-2021 09:23:52 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: ADVERSE EVENT	Initial Entry

2. AE ID:

Date	Location	User	Value	Reason
Mar-09-2021 09:23:52 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 6	Initial Entry

3. Adverse Event:

(If possible specify diagnosis, not individual symptoms)

Date	Location	User	Value	Reason
Mar-09-2021 09:23:52 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Injection site pain	Initial Entry

4. Start Date Time:

Date	Location	User	Value	Reason
Mar-09-2021 09:23:52 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Feb/16/2021 20:00	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Mar-09-2021 09:23:52 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO End Date Time: Feb/19/2021 UNK:UNK	Initial Entry

6. Toxicity Grade:

Date	Location	User	Value	Reason
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090177e196ae3f38\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, Frozen

Site No: 1241

Site Name: (1241) Hospital Irma Dulce

Subject No: 12411279

Subject Initials: ---

Generated By: (b) (4)

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

Mar-09-2021 09:23:52 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 1	Initial Entry
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7. Is the adverse event serious?

If Yes, NOTIFY PFIZER IMMEDIATELY.

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

Date	Location	User	Value	Reason
Mar-09-2021 09:23:52 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 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
Mar-09-2021 09:23:52 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

9. Is this event related to study treatment:

Date	Location	User	Value	Reason
Mar-09-2021 09:23:52 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: RELATED	Initial Entry

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Mar-09-2021 09:23:52 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NOT APPLICABLE	Initial Entry

11. Was a Concomitant Medication given?

Date	Location	User	Value	Reason
Mar-09-2021 09:23:52 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

090177e196ae3f38\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: 12411279

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - 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

12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Mar-09-2021 09:23:52 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

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

Date	Location	User	Value	Reason
Mar-09-2021 09:23:52 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: RECOVERED/RESOLVED	Initial Entry

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

Date	Location	User	Value	Reason
Mar-09-2021 09:23:52 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

090177e196ae3f38\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: 12411279

Subject Initials: ---

Generated By: (b) (4)

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

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I. Date of Visit

Date	Location	User	Value	Reason
Feb-16-2021 12:42:17 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Jan/29/2021	Initial Entry

Header Text: c4591001

Visit: Potential ReVax Initial Contact -
Unscheduled

Form Version: 10-Dec-2020 02:25

Site No: 1241

Subject No: 12411279

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
Feb-16-2021 12:42:26 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Participant is willing to return for V accination 3 Participant is: eligible per local/national recom mendations and confirmed to ha ve received only placebo at Vacc ination 1/2	Initial Entry

Header Text: c4591001

Visit: Disposition - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1241

Subject No: 12411279

Generated By: (b) (4)

Form: TREATMENT UNBLINDED - 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 Treatment Unblinded :

Date	Location	User	Value	Reason
Feb-16-2021 12:41:58 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Jan/29/2021	Initial Entry

2. Primary Reason for Unblinding:

Date	Location	User	Value	Reason
Feb-16-2021 12:41:58 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: ASSESS ELIGIBILITY FOR ADD ITIONAL VACCINATION	Initial Entry

Header Text: c4591001

Visit: V101_VAX3

Form Version: 22-Apr-2020 21:02

Site No: 1241

Subject No: 12411279

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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I. Date of Visit

Date	Location	User	Value	Reason
Feb-16-2021 12:42:45 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Feb/16/2021	Initial Entry

Header Text: c4591001

Visit: V101_VAX3

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

Form Version: 10-Dec-2020 02:31

Form Status: Data Complete, Frozen, Verified

Site No: 1241

Site Name: (1241) Hospital Irma Dulce

Subject No: 12411279

Subject Initials: ---

Generated By: (b) (4)

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

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I. Consent Was:

Date	Location	User	Value	Reason
Feb-16-2021 20:10:01 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Feb-16-2021 12:48:16 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Original value is correct
Feb-16-2021 12:43:08 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	Date Informed Consent Obtained is not the same as the Date of Visit. Please correct as necessary.
Feb-16-2021 12:43:08 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: OBTAINED Date Written Consent Obtained Feb/11/2021	Initial Entry

090177e196ae3f38\Final\Final On: 01-Apr-2021 05:12 (GMT)

Header Text: c4591001

Visit: V101_VAX3

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

Form Version: 10-Dec-2020 02:31

Form Status: Data Complete, Frozen, Verified

Site No: 1241

Site Name: (1241) Hospital Irma Dulce

Subject No: 12411279

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
Feb-16-2021 12:43:45 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Feb/16/2021	Initial Entry

2. Phase of Disposition:

Date	Location	User	Value	Reason
Feb-16-2021 12:43:45 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: REPEAT SCREENING 1	Initial Entry

3. Status:

Date	Location	User	Value	Reason
Feb-16-2021 12:43:45 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: COMPLETED	Initial Entry

090177e196ae3f38\Final\Final On: 01-Apr-2021 05:12 (GMT)

Header Text: c4591001

Visit: V101_VAX3

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

Form Version: 14-Jan-2021 02:21

Form Status: Data Complete, Frozen, Verified

Site No: 1241

Site Name: (1241) Hospital Irma Dulce

Subject No: 12411279

Subject Initials: ---

Generated By: (b) (4)

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

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1. Lab Panel:

Date	Location	User	Value	Reason
Feb-16-2021 12:44:01 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: URINALYSIS	Initial Entry

2. Lab Sub-Panel:

Date	Location	User	Value	Reason
Feb-16-2021 12:44:01 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: PREGNANCY	Initial Entry

3. Collection Date:

Date	Location	User	Value	Reason
Feb-16-2021 12:44:01 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Feb/16/2021	Initial Entry

4. Laboratory Name and Address (Derived)

Date	Location	User	Value	Reason
Feb-16-2021 12:44:01 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: STUDY SITE	Initial Entry

5. Specimen Type:

Date	Location	User	Value	Reason
Feb-16-2021 12:44:01 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: URINE	Initial Entry

6.a

Date	Location	User	Value	Reason
Feb-16-2021 12:44:01 (UTC-03:00) City of	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sponsor-Define 113	Initial Entry

090177e196ae3f38\Final\Final On: 01-Apr-2021 05:12 (GMT)

Header Text: c4591001

Visit: V101_VAX3

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

Form Version: 14-Jan-2021 02:21

Form Status: Data Complete, Frozen, Verified

Site No: 1241

Site Name: (1241) Hospital Irma Dulce

Subject No: 12411279

Subject Initials: ---

Generated By: (b) (4)

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

Buenos Aires			d Identifier:	
			Test::	Choriogonadotrop in Beta_PX113
			Result::	NEGATIVE
			Not Done::	

6.a Sponsor ID:

Date	Location	User	Value	Reason
Feb-16-2021 12:44:01 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 113	Initial Entry

6.a Test:

Date	Location	User	Value	Reason
Feb-16-2021 12:44:01 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Choriogonadotropin Beta_PX113	Initial Entry

6.a Result:

Date	Location	User	Value	Reason
Feb-16-2021 12:44:01 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NEGATIVE	Initial Entry

090177e196ae3f38\Final\Final On: 01-Apr-2021 05:12 (GMT)

Header Text: c4591001

Visit: V101_VAX3

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1241

Site Name: (1241) Hospital Irma Dulce

Subject No: 12411279

Subject Initials: ---

Generated By: (b) (4)

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

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1. Data Origin

Date	Location	User	Value	Reason
Feb-16-2021 12:46:08 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Feb-16-2021 12:46:08 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SERUM	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Feb-16-2021 12:46:24 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Feb-16-2021 12:46:08 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Feb-16-2021 12:46:08 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Date of Collection: Feb/16/2021	Initial Entry

5.a

Date	Location	User	Value	Reason
Feb-16-2021 12:46:24 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BRKF3D	Initial Entry

5.a Sample ID

090177e196ae3f38\Final\Final On: 01-Apr-2021 05:12 (GMT)

Header Text: c4591001

Visit: V101_VAX3

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1241

Site Name: (1241) Hospital Irma Dulce

Subject No: 12411279

Subject Initials: ---

Generated By: (b) (4)

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

Date	Location	User	Value	Reason
Feb-16-2021 12:46:24 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> BRKF3D	Initial Entry

5.b

Date	Location	User	Value	Reason
Feb-16-2021 12:46:36 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Sample ID: BS2Y73	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Feb-16-2021 12:46:36 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> BS2Y73	Initial Entry

5.c

Date	Location	User	Value	Reason
Feb-16-2021 12:46:45 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Sample ID: BS2Y74	Initial Entry

5.c Sample ID

Date	Location	User	Value	Reason
Feb-16-2021 12:46:45 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> BS2Y74	Initial Entry

090177e196ae3f38\Final\Final On: 01-Apr-2021 05:12 (GMT)

Header Text: c4591001

Visit: V101_VAX3

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1241

Site Name: (1241) Hospital Irma Dulce

Subject No: 12411279

Subject Initials: ---

Generated By: (b) (4)

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

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1. Data Origin

Date	Location	User	Value	Reason
Feb-16-2021 12:45:39 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Feb-16-2021 12:45:39 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: NASAL_SWAB	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Feb-16-2021 12:45:52 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Feb-16-2021 12:45:39 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Feb-16-2021 12:45:39 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Date of Collection: Feb/16/2021	Initial Entry

5.a

Date	Location	User	Value	Reason
Feb-16-2021 12:45:52 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BRKF65	Initial Entry

5.a Sample ID

090177e196ae3f38\Final\Final On: 01-Apr-2021 05:12 (GMT)

Header Text: c4591001

Visit: V101_VAX3

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1241

Site Name: (1241) Hospital Irma Dulce

Subject No: 12411279

Subject Initials: ---

Generated By: (b) (4)

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

Date	Location	User	Value	Reason
Feb-16-2021 12:45:52 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BRKF65	Initial Entry

Header Text: c4591001

Visit: V101_VAX3

Form Version: 10-Dec-2020 02:26

Site No: 1241

Subject No: 12411279

Generated By: (b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1241) Hospital Irma Dulce

Subject Initials: ---

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

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1. Was there a temporary delay of vaccination?

Date	Location	User	Value	Reason
Feb-16-2021 12:45:17 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2. Treatment Name

Date	Location	User	Value	Reason
Feb-16-2021 12:45:17 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: BNT162b2	Initial Entry

3. Formulation:

Date	Location	User	Value	Reason
Feb-16-2021 12:45:17 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: INJECTION	Initial Entry

4. Dose Date Time:

Date	Location	User	Value	Reason
Feb-16-2021 12:45:17 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Feb/16/2021 11:46	Initial Entry

5. Anatomical Location:

Date	Location	User	Value	Reason
Feb-16-2021 12:45:17 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: DELTOID MUSCLE	Initial Entry

6. Body Side:

Date	Location	User	Value	Reason
Feb-16-2021 12:45:17 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: LEFT	Initial Entry

090177e196ae3f38\Final\Final On: 01-Apr-2021 05:12 (GMT)

Header Text: c4591001

Visit: V101_VAX3

Form: VACCINATION - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:26

Form Status: Data Complete, Frozen, Verified

Site No: 1241

Site Name: (1241) Hospital Irma Dulce

Subject No: 12411279

Subject Initials: ---

Generated By: (b) (4)

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

7. Route:

Date	Location	User	Value	Reason
Feb-16-2021 12:45:17 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: INTRAMUSCULAR	Initial Entry

8. Actual Dose:

Date	Location	User	Value	Reason
Feb-16-2021 12:45:17 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 30.0	Initial Entry

9. Unit:

Date	Location	User	Value	Reason
Feb-16-2021 12:45:17 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: ug	Initial Entry

10. Timeframe Subject Was Observed

Date	Location	User	Value	Reason
Feb-16-2021 12:45:17 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 30 MINUTES	Initial Entry

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

Date	Location	User	Value	Reason
Feb-16-2021 12:45:17 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

090177e196ae3f38\Final\Final On: 01-Apr-2021 05:12 (GMT)

Header Text: c4591001

Visit: V102_VAX4

Form Version: 22-Apr-2020 21:02

Site No: 1241

Subject No: 12411279

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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I. Date of Visit

Date	Location	User	Value	Reason
Mar-09-2021 09:20:23 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Mar/9/2021	Initial Entry

Header Text: c4591001

Visit: V102_VAX4

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

Form Version: 14-Jan-2021 02:21

Form Status: Data Complete, Frozen, Verified

Site No: 1241

Site Name: (1241) Hospital Irma Dulce

Subject No: 12411279

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
Mar-09-2021 09:20:34 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: URINALYSIS	Initial Entry

2. Lab Sub-Panel:

Date	Location	User	Value	Reason
Mar-09-2021 09:20:34 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: PREGNANCY	Initial Entry

3. Collection Date:

Date	Location	User	Value	Reason
Mar-09-2021 09:20:34 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Mar/9/2021	Initial Entry

4. Laboratory Name and Address (Derived)

Date	Location	User	Value	Reason
Mar-09-2021 09:20:34 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: STUDY SITE	Initial Entry

5. Specimen Type:

Date	Location	User	Value	Reason
Mar-09-2021 09:20:34 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: URINE	Initial Entry

6.a

Date	Location	User	Value	Reason
Mar-09-2021 09:20:34 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sponsor-Define 113	Initial Entry

090177e196ae3f38\Final\Final On: 01-Apr-2021 05:12 (GMT)

Header Text: c4591001

Visit: V102_VAX4

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

Form Version: 14-Jan-2021 02:21

Form Status: Data Complete, Frozen, Verified

Site No: 1241

Site Name: (1241) Hospital Irma Dulce

Subject No: 12411279

Subject Initials: ---

Generated By: (b) (4)

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

Buenos Aires			d Identifier:	
			Test::	Choriogonadotrop in Beta_PX113
			Result::	NEGATIVE
			Not Done::	

6.a Sponsor ID:

Date	Location	User	Value	Reason
Mar-09-2021 09:20:34 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 113	Initial Entry

6.a Test:

Date	Location	User	Value	Reason
Mar-09-2021 09:20:34 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Choriogonadotropin Beta_PX113	Initial Entry

6.a Result:

Date	Location	User	Value	Reason
Mar-09-2021 09:20:34 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NEGATIVE	Initial Entry

090177e196ae3f38\Final\Final On: 01-Apr-2021 05:12 (GMT)

Header Text: c4591001

Visit: V102_VAX4

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1241

Site Name: (1241) Hospital Irma Dulce

Subject No: 12411279

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 10:31:58 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Mar-09-2021 10:31:58 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: NASAL_SWAB	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Mar-09-2021 10:32:11 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Mar-09-2021 10:31:58 (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 10:31:58 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Date of Collection: Mar/9/2021	Initial Entry

5.a

Date	Location	User	Value	Reason
Mar-09-2021 10:32:11 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BRCFLC	Initial Entry

5.a Sample ID

090177e196ae3f38\Final\Final On: 01-Apr-2021 05:12 (GMT)

Header Text: c4591001

Visit: V102_VAX4

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1241

Site Name: (1241) Hospital Irma Dulce

Subject No: 12411279

Subject Initials: ---

Generated By: (b) (4)

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

Date	Location	User	Value	Reason
Mar-09-2021 10:32:11 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BRCFLC	Initial Entry

Header Text: c4591001

Visit: V102_VAX4

Form Version: 10-Dec-2020 02:26

Site No: 1241

Subject No: 12411279

Generated By: (b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1241) Hospital Irma Dulce

Subject Initials: ---

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

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1. Was there a temporary delay of vaccination?

Date	Location	User	Value	Reason
Mar-09-2021 09:21:02 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2. Treatment Name

Date	Location	User	Value	Reason
Mar-09-2021 09:21:02 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: BNT162b2	Initial Entry

3. Formulation:

Date	Location	User	Value	Reason
Mar-09-2021 09:21:02 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: INJECTION	Initial Entry

4. Dose Date Time:

Date	Location	User	Value	Reason
Mar-09-2021 09:21:02 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Mar/9/2021 08:33	Initial Entry

5. Anatomical Location:

Date	Location	User	Value	Reason
Mar-09-2021 09:21:02 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: DELTOID MUSCLE	Initial Entry

6. Body Side:

Date	Location	User	Value	Reason
Mar-09-2021 09:21:02 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: LEFT	Initial Entry

090177e196ae3f38\Final\Final On: 01-Apr-2021 05:12 (GMT)

Header Text: c4591001

Visit: V102_VAX4

Form: VACCINATION - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:26

Form Status: Data Complete, Frozen, Verified

Site No: 1241

Site Name: (1241) Hospital Irma Dulce

Subject No: 12411279

Subject Initials: ---

Generated By: (b) (4)

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

7. Route:

Date	Location	User	Value	Reason
Mar-09-2021 09:21:02 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: INTRAMUSCULAR	Initial Entry

8. Actual Dose:

Date	Location	User	Value	Reason
Mar-09-2021 09:21:02 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 30.0	Initial Entry

9. Unit:

Date	Location	User	Value	Reason
Mar-09-2021 09:21:02 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: ug	Initial Entry

10. Timeframe Subject Was Observed

Date	Location	User	Value	Reason
Mar-09-2021 09:21:02 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 30 MINUTES	Initial Entry

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

Date	Location	User	Value	Reason
Mar-09-2021 09:21:02 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

090177e196ae3f38\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: 12411279

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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I. Subject Status

Date	Location	User	Value	Reason
Sep-10-2020 13:02:29 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: DISCONTINUED	Initial Entry
Aug-19-2020 13:45:27 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: ENROLLED/RANDOMIZED	Initial Entry
Aug-19-2020 13:41:19 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SCREENED	Initial Entry

2. Subject Status Date

Date	Location	User	Value	Reason
Sep-10-2020 13:02:29 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sep/10/2020	Initial Entry
Aug-19-2020 13:45:27 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Aug/19/2020	Initial Entry
Aug-19-2020 13:41:19 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Aug/19/2020	Initial Entry

090177e196ae3f38\Final\Final On: 01-Apr-2021 05:12 (GMT)

Header Text: c4591001

Visit: Investigator Signature - Unscheduled

Form Version: 22-Apr-2020 21:04

Site No: 1241

Subject No: 12411279

Generated By: (b) (4)

Form: CASEBOOK SIGNATURE FORM - eCRF Audit Trail History

Form Status: Data Complete, Signed, Verified

Site Name: (1241) Hospital Irma Dulce

Subject Initials: ---

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

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I. Casebook Signature

Date	Location	User	Value	Reason
Oct-22-2020 23:32:43 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	Edson Moreira (b) (4)	Data Entry: Click Here to Enable	Initial Entry