

Header Text: c4591001

Visit: COHORT_SELECTION

Form: COHORT_SELECTION

Form Version: 30-Jul-2020 21:29

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1241

Site Name: (1241) Hospital Irma Dulce

Subject No: 12411206

Subject Initials: ---

Generated By: (b) (4)

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

[eCRF Audit Trail History](#)

Cohort Selection

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

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

Header Text: c4591001

Visit: COHORT_SELECTION

Form: MAIN INFORMED CONSENT

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1241

Site Name: (1241) Hospital Irma Dulce

Subject No: 12411206

Subject Initials: ---

Generated By: (b) (4)

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

[eCRF Audit Trail History](#)

Informed Consent

1.	Consent Was:	OBTAINED Date Written Consent Obtained Aug/18/2020
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Header Text: c4591001

Visit: COHORT_SELECTION

Form: DEMOGRAPHY

Form Version: 06-Jul-2020 21:55

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1241

Site Name: (1241) Hospital Irma Dulce

Subject No: 12411206

Subject Initials: ---

Generated By: (b) (4)

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

[eCRF Audit Trail History](#)

Demography

1.	Subject ID	[12411206]
2.	Birth Date:	(b) (6) 1982
3.	Sex:	FEMALE
4.	Ethnicity:	NOT HISPANIC OR LATINO(A) OR OF SPANISH ORIGIN
5.	Race: (Check X all that apply):	BLACK OR AFRICAN AMERICAN WHITE
6.	Racial Designation:	

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:02

Site No: 1241

Subject No: 12411206

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/18/2020
2.	Erroneous Visit	

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 30-Jul-2020 21:27

Site No: 1241

Subject No: 12411206

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

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Visit: V1_DAY1_VAX1_L

Form Version: 30-Jul-2020 21:27

Site No: 1241

Subject No: 12411206

Generated By: (b) (4)

Form: INCLUSION/EXCLUSION CRITERIA

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1241) Hospital Irma Dulce

Subject Initials: ---

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

Exclusion Criteria

2.a	Exclusion Number:	1
	Criterion Description:	Other medical or psychiatric condition incl. recent (within past year) or active suicidal ideation/behavior/lab abnormality that may increase the risk of study participation
	Criterion met?	NO
	Criterion ID: (For Pfizer use only)	EX01A00
2.b	Exclusion Number:	2
	Criterion Description:	Known infection with human immunodeficiency virus (HIV), hepatitis C virus (HCV), or hepatitis B virus (HBV)
	Criterion met?	NO
	Criterion ID: (For Pfizer use only)	EX02A00
2.c	Exclusion Number:	3
	Criterion Description:	History of severe adverse reaction associated with a vaccine and/or severe allergic reaction (eg, anaphylaxis) to any component of the study intervention(s)
	Criterion met?	NO
	Criterion ID: (For Pfizer use only)	EX03A00
2.d	Exclusion Number:	4
	Criterion Description:	Receipt of medications intended to prevent COVID-19
	Criterion met?	NO
	Criterion ID: (For Pfizer use only)	EX04A00

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Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 30-Jul-2020 21:27

Site No: 1241

Subject No: 12411206

Generated By: (b) (4)

Form: INCLUSION/EXCLUSION CRITERIA

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1241) Hospital Irma Dulce

Subject Initials: ---

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

2.e	Exclusion Number:	8
	Criterion Description:	Immunocompromised individuals with known or suspected immunodeficiency, as determined by history and/or laboratory/physical examination
	Criterion met?	NO
	Criterion ID: (For Pfizer use only)	EX08A00
2.f	Exclusion Number:	10
	Criterion Description:	Bleeding diathesis or condition associated with prolonged bleeding that would, in the opinion of the investigator, contraindicate intramuscular injection
	Criterion met?	NO
	Criterion ID: (For Pfizer use only)	EX10A00
2.g	Exclusion Number:	11
	Criterion Description:	Women who are pregnant or breastfeeding
	Criterion met?	NO
	Criterion ID: (For Pfizer use only)	EX11A00
2.h	Exclusion Number:	12
	Criterion Description:	Previous vaccination with any coronavirus vaccine
	Criterion met?	NO
	Criterion ID: (For Pfizer use only)	EX12A00
2.i	Exclusion Number:	13
	Criterion Description:	Subjects who receive immunosuppressive therapy, such as cytotoxic agents or systemic corticosteroids
	Criterion met?	NO
	Criterion ID: (For Pfizer use only)	EX13A01

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Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 30-Jul-2020 21:27

Site No: 1241

Subject No: 12411206

Generated By: (b) (4)

Form: INCLUSION/EXCLUSION CRITERIA

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1241) Hospital Irma Dulce

Subject Initials: ---

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

2.j	Exclusion Number:	15
	Criterion Description:	Receipt of blood/plasma products or immunoglobulin, from 60 days before study intervention administration or planned receipt throughout the study
	Criterion met?	NO
	Criterion ID: (For Pfizer use only)	EX14A01
2.k	Exclusion Number:	16
	Criterion Description:	Participation in other studies involving study intervention within 28 days prior to study entry and/or during study participation
	Criterion met?	NO
	Criterion ID: (For Pfizer use only)	EX15A01
2.l	Exclusion Number:	17
	Criterion Description:	Previous participation in other studies involving study intervention containing lipid nanoparticles
	Criterion met?	NO
	Criterion ID: (For Pfizer use only)	EX16A01
2.m	Exclusion Number:	22
	Criterion Description:	Investigator site staff or Pfizer employees directly involved in the conduct of the study, site staff otherwise supervised by the investigator, and their respective family members
	Criterion met?	NO
	Criterion ID: (For Pfizer use only)	EX21A01

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Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1241

Subject No: 12411206

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/18/2020
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: 12411206

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1241) Hospital Irma Dulce

Subject Initials: ---

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

[Form Comments](#)

[eCRF Audit Trail History](#)

Medical History Details

1.a	Line/MH Number:	[1]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Breast lump]
	Start Date:	UNK/UNK/2018
	Ongoing:	YES

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 30-Jul-2020 21:28

Site No: 1241

Subject No: 12411206

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/18/2020
2.	Weight:	[55.5]
3.	Unit:	kg
4.	Height:	[152.5]
5.	Unit:	cm
6.	Body Mass Index:	[23.9]

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: 12411206

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/18/2020
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: 12411206

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/18/2020
2.	Randomization Number:	[53756]
3.	Randomization Group:	[]

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1241

Site Name: (1241) Hospital Irma Dulce

Subject No: 12411206

Subject Initials: ---

Generated By: (b) (4)

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

[eCRF Audit Trail History](#)

Electronic Sample Tracking

1.	Data Origin	SITE
2.	Sample Type	SERUM
3.	Sample Collected?	YES Date of Collection: Aug/18/2020
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[]

Aliquot

Please enter barcode for each aliquot.

5.a	Sample ID	[BP5RZW]
5.b	Sample ID	[BP5RZX]
5.c	Sample ID	[BP5RZY]
5.d	Sample ID	[BLCH8T]
5.e	Sample ID	[BLCH8V]

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Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1241

Subject No: 12411206

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/18/2020
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[]

Aliquot

Please enter barcode for each aliquot.

5.a	Sample ID	[BP5RZ6]
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090177e196ae3f78\Final\Final On: 01-Apr-2021 05:17 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:04

Site No: 1241

Subject No: 12411206

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/18/2020 09:26
5.	Anatomical Location:	DELTOID MUSCLE
6.	Body Side:	LEFT
7.	Route:	INTRAMUSCULAR
8.	Actual Dose:	[]
9.	Unit:	
10.	Timeframe Subject Was Observed	THE PROTOCOL SPECIFIED OBSERVATION PERIOD
11.	Was the subject observed for at least the protocol specified observation period after investigational product administration?	YES

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Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 06-Jul-2020 21:53

Site No: 1241

Subject No: 12411206

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	YES - REACTOGENICITY E-DIARY COLLECTED FOR THIS SUBJECT
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090177e196ae3f78\Final\Final On: 01-Apr-2021 05:17 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:02

Site No: 1241

Subject No: 12411206

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/9/2020
2.	Erroneous Visit	

Header Text: c4591001

Visit: V2_VAX2_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES

Form Version: 30-Jul-2020 21:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1241

Site Name: (1241) Hospital Irma Dulce

Subject No: 12411206

Subject Initials: ---

Generated By: (b) (4)

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

[eCRF Audit Trail History](#)

Vaccination Symptoms Diary - Symptom Resolved Dates

1.	Were medications to treat fever/pain given on the last day the Subject Diary was completed?	NO
2.a	Symptom:	FEVER
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO
2.b	Symptom:	FATIGUE
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO
2.c	Symptom:	HEADACHE
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO
2.d	Symptom:	CHILLS
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO
2.e	Symptom:	VOMITING
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO

090177e196ae3f78\Final\Final On: 01-Apr-2021 05:17 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES

Form Version: 30-Jul-2020 21:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1241

Site Name: (1241) Hospital Irma Dulce

Subject No: 12411206

Subject Initials: ---

Generated By: (b) (4)

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

2 f	Symptom:	DIARRHEA
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO
2.g	Symptom:	NEW OR WORSENERD MUSCLE PAIN
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO
2 h	Symptom:	NEW OR WORSENERD JOINT PAIN
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO
3.	Injection Site Location:	DELTOID MUSCLE
4.	Injection Site Body Side:	LEFT
5.a	Injection Site Reaction:	REDNESS
	Were injection site reactions present on the last day the Subject Diary was completed?	NO
5.b	Injection Site Reaction:	SWELLING
	Were injection site reactions present on the last day the Subject Diary was completed?	NO
5.c	Injection Site Reaction:	PAIN AT INJECTION SITE
	Were injection site reactions present on the last day the Subject Diary was completed?	NO

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Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 21-Aug-2020 02:51

Site No: 1241

Subject No: 12411206

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/9/2020
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Vital Signs Details

2.a	Record Identifier:	1
	Temperature:	[36.5]
	Unit:	C
	Temperature Location:	ORAL CAVITY

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 30-Jul-2020 21:27

Site No: 1241

Subject No: 12411206

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/9/2020
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:	

090177e196ae3f78\Final\Final On: 01-Apr-2021 05:17 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:03

Site No: 1241

Subject No: 12411206

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/9/2020
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	[BPX0RL]
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090177e196ae3f78\Final\Final On: 01-Apr-2021 05:17 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:04

Site No: 1241

Subject No: 12411206

Generated By: (b) (4)

Form: VACCINATION

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1241) Hospital Irma Dulce

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Vaccination

1.	Was there a temporary delay of vaccination?	NO
2.	Treatment Name	[BLINDED THERAPY]
3.	Formulation:	INJECTION
4.	Dose Date Time:	Sep/9/2020 10:33
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

090177e196ae3f78\Final\Final On: 01-Apr-2021 05:17 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form Version: 22-Apr-2020 21:02

Site No: 1241

Subject No: 12411206

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/7/2020
2.	Erroneous Visit	

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES

Form Version: 30-Jul-2020 21:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1241

Site Name: (1241) Hospital Irma Dulce

Subject No: 12411206

Subject Initials: ---

Generated By: (b) (4)

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

[eCRF Audit Trail History](#)

Vaccination Symptoms Diary - Symptom Resolved Dates

1.	Were medications to treat fever/pain given on the last day the Subject Diary was completed?	NO
2.a	Symptom:	FEVER
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO
2.b	Symptom:	FATIGUE
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO
2.c	Symptom:	HEADACHE
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO
2.d	Symptom:	CHILLS
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO
2.e	Symptom:	VOMITING
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO

090177e196ae3f78\Final\Final On: 01-Apr-2021 05:17 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES

Form Version: 30-Jul-2020 21:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1241

Site Name: (1241) Hospital Irma Dulce

Subject No: 12411206

Subject Initials: ---

Generated By: (b) (4)

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

2 f	Symptom:	DIARRHEA
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO
2.g	Symptom:	NEW OR WORSENERD MUSCLE PAIN
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO
2 h	Symptom:	NEW OR WORSENERD JOINT PAIN
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO
3.	Injection Site Location:	DELTOID MUSCLE
4.	Injection Site Body Side:	LEFT
5.a	Injection Site Reaction:	REDNESS
	Were injection site reactions present on the last day the Subject Diary was completed?	NO
5.b	Injection Site Reaction:	SWELLING
	Were injection site reactions present on the last day the Subject Diary was completed?	NO
5.c	Injection Site Reaction:	PAIN AT INJECTION SITE
	Were injection site reactions present on the last day the Subject Diary was completed?	NO

090177e196ae3f78\Final\Final On: 01-Apr-2021 05:17 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1241

Site Name: (1241) Hospital Irma Dulce

Subject No: 12411206

Subject Initials: ---

Generated By: (b) (4)

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

[eCRF Audit Trail History](#)

Electronic Sample Tracking

1.	Data Origin	SITE
2.	Sample Type	SERUM
3.	Sample Collected?	YES Date of Collection: Oct/7/2020
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	[BPWXP2]
5.b	Sample ID	[BHHZSK]
5.c	Sample ID	[BHHZSL]

090177e196ae3f78\Final\Final On: 01-Apr-2021 05:17 (GMT)

Header Text: c4591001

Visit: V4_MONTH6_L

Form Version: 22-Apr-2020 21:02

Site No: 1241

Subject No: 12411206

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/3/2021
2.	Erroneous Visit	

Header Text: c4591001

Visit: V4_MONTH6_L

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: 12411206

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: Mar/3/2021
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[]

Aliquot

Please enter barcode for each aliquot.

5.a	Sample ID	[BRC1HP]
5.b	Sample ID	[BSCYKV]
5.c	Sample ID	[BSCYKW]

090177e196ae3f78\Final\Final On: 01-Apr-2021 05:17 (GMT)

Header Text: c4591001

Visit: V5_MONTH12_L

Form Version: 22-Apr-2020 21:02

Site No: 1241

Subject No: 12411206

Generated By: (b) (4)

Form: DATE OF VISIT

Form Status: Not Started

Site Name: (1241) Hospital Irma Dulce

Subject Initials: ---

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

Date of Visit

1.	Date of Visit	//
2.	Erroneous Visit	

Header Text: c4591001

Visit: V5_MONTH12_L

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1241

Site Name: (1241) Hospital Irma Dulce

Subject No: 12411206

Subject Initials: ---

Generated By: (b) (4)

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

Electronic Sample Tracking

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

Aliquot

Please enter barcode for each aliquot.

5.	Sample ID	[]
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090177e196ae3f78\Final\Final On: 01-Apr-2021 05:17 (GMT)

Header Text: c4591001

Visit: V6_MONTH24_L

Form Version: 22-Apr-2020 21:02

Site No: 1241

Subject No: 12411206

Generated By: (b) (4)

Form: DATE OF VISIT

Form Status: Not Started

Site Name: (1241) Hospital Irma Dulce

Subject Initials: ---

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

Date of Visit

1.	Date of Visit	//
2.	Erroneous Visit	

Header Text: c4591001

Visit: V6_MONTH24_L

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1241

Site Name: (1241) Hospital Irma Dulce

Subject No: 12411206

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	[]
----	-----------	-----

090177e196ae3f78\Final\Final On: 01-Apr-2021 05:17 (GMT)

Header Text: c4591001

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

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1241

Site Name: (1241) Hospital Irma Dulce

Subject No: 12411206

Subject Initials: ---

Generated By: (b) (4)

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

Date of Visit

1.	Date of Visit	//
2.	Erroneous Visit	

COVID-19 Illness Visit

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

Header Text: c4591001

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

Form Version: 20-Feb-2021 02:17

Form Status: Not Started

Site No: 1241

Site Name: (1241) Hospital Irma Dulce

Subject No: 12411206

Subject Initials: ---

Generated By: (b) (4)

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

Signs and Symptoms

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

Symptoms

4.	Symptoms:	
	Was symptom present?	

Symptoms - Other

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

Header Text: c4591001

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

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1241

Site Name: (1241) Hospital Irma Dulce

Subject No: 12411206

Subject Initials: ---

Generated By: (b) (4)

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

Electronic Sample Tracking

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

Aliquot

Please enter barcode for each aliquot.

5.	Sample ID	[]
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090177e196ae3f78\Final\Final On: 01-Apr-2021 05:17 (GMT)

Header Text: c4591001

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

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1241

Site Name: (1241) Hospital Irma Dulce

Subject No: 12411206

Subject Initials: ---

Generated By: (b) (4)

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

Electronic Sample Tracking

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

Aliquot

Please enter barcode for each aliquot.

5.	Sample ID	[]
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090177e196ae3f78\Final\Final On: 01-Apr-2021 05:17 (GMT)

Header Text: c4591001

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

Form Version: 20-Feb-2021 02:19

Form Status: Not Started

Site No: 1241

Site Name: (1241) Hospital Irma Dulce

Subject No: 12411206

Subject Initials: ---

Generated By: (b) (4)

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

Health Care Utilization

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

Health Care Utilization Other

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

Health Care Utilization

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

090177e196ae3f78\Final\Final On: 01-Apr-2021 05:17 (GMT)

Header Text: c4591001

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

Form Version: 06-Jul-2020 21:52

Form Status: Not Started

Site No: 1241

Site Name: (1241) Hospital Irma Dulce

Subject No: 12411206

Subject Initials: ---

Generated By: (b) (4)

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

Illness Details

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

Header Text: c4591001

Visit: POT_COVID_CONVA - New
Unscheduled Visit

Form: DATE OF VISIT - ILLNESS CONVALESCENT

Form Version: 22-Apr-2020 21:04

Form Status: Not Started

Site No: 1241

Site Name: (1241) Hospital Irma Dulce

Subject No: 12411206

Subject Initials: ---

Generated By: (b) (4)

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

Date of Visit

1.	Date of Visit	//
2.	Erroneous Visit	

COVID-19 Illness Visit

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

090177e196ae3f78\Final\Final On: 01-Apr-2021 05:17 (GMT)

Header Text: c4591001

Visit: POT_COVID_CONVA - New
Unscheduled Visit

Form Version: 22-Apr-2020 21:03

Site No: 1241

Subject No: 12411206

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING -
IMMUNOGENICITY

Form Status: Not Started

Site Name: (1241) Hospital Irma Dulce

Subject Initials: ---

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

Electronic Sample Tracking

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

Aliquot

Please enter barcode for each aliquot.

5.	Sample ID	[]
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090177e196ae3f78\Final\Final On: 01-Apr-2021 05:17 (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: 12411206

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: 12411206

Subject Initials: ---

Generated By: (b) (4)

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

Unplanned Assessments

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

Header Text: c4591001

Visit: End of Treatment - Unscheduled

Form: DISPOSITION - TREATMENT

Form Version: 15-Sep-2020 21:55

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1241

Site Name: (1241) Hospital Irma Dulce

Subject No: 12411206

Subject Initials: ---

Generated By: (b) (4)

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

[eCRF Audit Trail History](#)

Disposition - Treatment

1.	Date of Completion/Discontinuation /Death :	Oct/7/2020
2.	Phase of Disposition:	VACCINATION
3.	Status:	COMPLETED
4.	Specify Status:	[]

Header Text: c4591001

Visit: Follow-Up - Unscheduled

Form: DISPOSITION - FOLLOW-UP

Form Version: 15-Sep-2020 21:53

Form Status: Not Started

Site No: 1241

Site Name: (1241) Hospital Irma Dulce

Subject No: 12411206

Subject Initials: ---

Generated By: (b) (4)

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

Disposition - Follow-Up

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

Header Text: c4591001

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

Form Version: 10-Oct-2020 15:57

Form Status: Not Started

Site No: 1241

Site Name: (1241) Hospital Irma Dulce

Subject No: 12411206

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

Form Version: 10-Oct-2020 15:57

Form Status: Not Started

Site No: 1241

Site Name: (1241) Hospital Irma Dulce

Subject No: 12411206

Subject Initials: ---

Generated By: (b) (4)

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

Electronic Sample Tracking

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

Aliquot

Please enter barcode for each aliquot.

5.	Sample ID	[]
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090177e196ae3f78\Final\Final On: 01-Apr-2021 05:17 (GMT)

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: 12411206

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	Atypical intraductal hyperplasia in left breast	Sep/29/2020 UNK:UNK	NO End Date Time: Sep/30/2020 UNK:UNK	Repeating Pages

090177e196ae3f78\Final\Final On: 01-Apr-2021 05:17 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1241

Subject No: 12411206

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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[Form Audit Trail](#)

Adverse Event Report

1.	Category:	ADVERSE EVENT
2.	AE ID:	[1]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[Atypical intraductal hyperplasia in left breast]
4.	Start Date Time:	Sep/29/2020 UNK:UNK
5.	Is the adverse event still ongoing?	NO End Date Time: Sep/30/2020 UNK:UNK
6.	Toxicity Grade:	2
7.	Is the adverse event serious? If Yes, NOTIFY PFIZER IMMEDIATELY. Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).	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 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

090177e196ae3f78\Final\Final On: 01-Apr-2021 05:17 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1241

Subject No: 12411206

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

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: [Breast nodule]
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	[2020390848]

090177e196ae3f78\Final\Final On: 01-Apr-2021 05:17 (GMT)

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: 12411206

Subject Initials: ---

Generated By: (b) (4)

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

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

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 17-Jul-2020 21:54

Site No: 1241

Subject No: 12411206

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	[]

090177e196ae3f78\Final\Final On: 01-Apr-2021 05:17 (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: 12411206

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: 12411206

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:	//

090177e196ae3f78\Final\Final On: 01-Apr-2021 05:17 (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: 12411206

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

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1241

Subject No: 12411206

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?	

090177e196ae3f78\Final\Final On: 01-Apr-2021 05:17 (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: 12411206

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: 12411206

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: 12411206

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: 12411206

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: 12411206

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: 12411206

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: 12411206

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:	

090177e196ae3f78\Final\Final On: 01-Apr-2021 05:17 (GMT)

Header Text: c4591001

Visit: Unplanned Vaccination - Unscheduled

Form: VACCINATION

Form Version: 10-Dec-2020 02:26

Form Status: Not Started

Site No: 1241

Site Name: (1241) Hospital Irma Dulce

Subject No: 12411206

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?	

090177e196ae3f78\Final\Final On: 01-Apr-2021 05:17 (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: 12411206

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: 12411206

Subject Initials: ---

Generated By: (b) (4)

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

Contact Outcome

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

Header Text: c4591001

Visit: V201_SURVEIL_CONSENT -
Unscheduled

Form: DATE OF VISIT

Form Version: 22-Apr-2020 21:02

Form Status: Not Started

Site No: 1241

Site Name: (1241) Hospital Irma Dulce

Subject No: 12411206

Subject Initials: ---

Generated By: (b) (4)

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

Date of Visit

1.	Date of Visit	//
2.	Erroneous Visit	

Header Text: c4591001

Visit: V201_SURVEIL_CONSENT -
Unscheduled

Form: INFORMED CONSENT - ASYMPTOMATIC
SURVEILLANCE

Form Version: 14-Jan-2021 02:29

Form Status: Not Started

Site No: 1241

Site Name: (1241) Hospital Irma Dulce

Subject No: 12411206

Subject Initials: ---

Generated By: (b) (4)

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

Informed Consent - Asymptomatic Surveillance

1.	Consent Was:	
----	--------------	--

Header Text: c4591001

Visit: V201_SURVEIL_CONSENT -
Unscheduled

Form: ELECTRONIC SAMPLE TRACKING -
IMMUNOGENICITY

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1241

Site Name: (1241) Hospital Irma Dulce

Subject No: 12411206

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	[]
----	-----------	-----

090177e196ae3f78\Final\Final On: 01-Apr-2021 05:17 (GMT)

Header Text: c4591001

Visit: V201_SURVEIL_CONSENT -
Unscheduled

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1241

Site Name: (1241) Hospital Irma Dulce

Subject No: 12411206

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	[]
----	-----------	-----

090177e196ae3f78\Final\Final On: 01-Apr-2021 05:17 (GMT)

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: 12411206

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: 12411206

Subject Initials: ---

Generated By: (b) (4)

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

[eCRF Audit Trail History](#)

Further Vaccination Confirmation

1.	Select appropriate response - Is participant willing to return for Vaccination 3?	Participant is willing to return for Vaccination 3 Participant is: eligible and NOT confirmed to have received only placebo at Vaccination 1/2
----	---	--

Header Text: c4591001

Visit: Disposition - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1241

Subject No: 12411206

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: 12411206

Subject Initials: ---

Generated By: (b) (4)

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

Withdrawal Of Consent

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

Header Text: c4591001

Visit: Disposition - Unscheduled

Form: DEATH DETAILS CODED

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1241

Site Name: (1241) Hospital Irma Dulce

Subject No: 12411206

Subject Initials: ---

Generated By: (b) (4)

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

Death Details

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

Cause of Death

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

Header Text: c4591001

Visit: Subject Status - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1241

Subject No: 12411206

Generated By: (b) (4)

Form: SUBJECT STATUS

Form Status: Data Complete, Verified

Site Name: (1241) Hospital Irma Dulce

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Subject Status

1.	Subject Status	FOLLOW-UP
2.	Subject Status Date	Oct/7/2020

Header Text: c4591001

Visit: Investigator Signature - Unscheduled

Form: CASEBOOK SIGNATURE FORM

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Signed, Verified

Site No: 1241

Site Name: (1241) Hospital Irma Dulce

Subject No: 12411206

Subject Initials: ---

Generated By: (b) (4)

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

[eCRF Audit Trail History](#)

Casebook Signature Form

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

Visit: Investigator Signature - Unscheduled

Form: CASEBOOK SIGNATURE FORM

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Signed, Verified

Site No: 1241

Site Name: (1241) Hospital Irma Dulce

Subject No: 12411206

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
Edson Moreira	Approved	Mar-08-2021 10:15:06 (UTC-03:00) City of Buenos Aires	BOOK	Signed

Affidavit:

By my dated signature below, I, Edson Moreira, 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.

090177e196ae3f78\Final\Final On: 01-Apr-2021 05:17 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1241

Subject No: 12411206

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - Comments

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1241) Hospital Irma Dulce

Subject Initials: ---

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

[Back to Form](#)

Item	Date	User	Comment
Form	Oct-07-2020 11:53:22 (UTC-03:00) City of Buenos Aires	(b) (4), (b) (6)	
Form	Aug-18-2020 11:38:31 (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: 12411206

Subject Initials: ---

Generated By: (b) (4)

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

[Back to Form](#)

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

- CRF_Sign

Name	Signature Meaning	Date	Type	Action
Edson Moreira	Approved	Mar-08-2021 10:15:06 (UTC-03:00) City of Buenos Aires	BOOK	Signed

Affidavit:

By my dated signature below, I, Edson Moreira, 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-03-2021 10:45:46 (UTC-03:00) City of Buenos Aires		Edit - All signatures invalidated
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Affidavit:

N/A

(b) (6)	Approved	Feb-04-2021 17:07:02 (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-01-2021 16:53:28 (UTC-03:00) City of Buenos Aires		Edit - All signatures invalidated
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090177e196ae3f78\Final\Final On: 01-Apr-2021 05:17 (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:** 12411206**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 19:09**Affidavit:**

N/A

Edson Moreira	Approved	Oct-27-2020 17:53:53 (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-27-2020 17:13:27 (UTC-03:00) City of Buenos Aires		Edit - All signatures invalidated
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Affidavit:

N/A

Edson Moreira	Approved	Oct-27-2020 14:58:36 (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-27-2020 03:27:39 (UTC-03:00) City of Buenos Aires		Edit - All signatures invalidated
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Affidavit:

N/A

Edson Moreira	Approved	Oct-26-2020 21:01:44 (UTC-03:00) City of Buenos Aires	BOOK	Signed
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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: 12411206

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	Oct-26-2020 16:19:44 (UTC-03:00) City of Buenos Aires		Edit - All signatures invalidated
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Affidavit:

N/A

Edson Moreira	Approved	Oct-22-2020 22:58:10 (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.

090177e196ae3f78\Final\Final On: 01-Apr-2021 05:17 (GMT)

Header Text: c4591001

Visit: COHORT_SELECTION

Form: COHORT SELECTION - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:29

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1241

Site Name: (1241) Hospital Irma Dulce

Subject No: 12411206

Subject Initials: ---

Generated By: (b) (4)

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

[Back to Form](#)

1. Select appropriate response - Protocol version

Date	Location	User	Value	Reason
Aug-18-2020 11:36:18 (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-18-2020 11:36:18 (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: MAIN INFORMED CONSENT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1241

Site Name: (1241) Hospital Irma Dulce

Subject No: 12411206

Subject Initials: ---

Generated By: (b) (4)

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

[Back to Form](#)

I. Consent Was:

Date	Location	User	Value	Reason
Aug-18-2020 11:36:24 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> OBTAINED Date Written Consent Obtained Aug/18/2020	Initial Entry

090177e196ae3f78\Final\Final On: 01-Apr-2021 05:17 (GMT)

Header Text: c4591001

Visit: COHORT_SELECTION

Form Version: 06-Jul-2020 21:55

Site No: 1241

Subject No: 12411206

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

[Back to Form](#)

1. Subject ID

Date	Location	User	Value	Reason
Aug-18-2020 11:36:08 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 12411206	Item copied from previous form

2. Birth Date:

Date	Location	User	Value	Reason
Aug-18-2020 11:36:04 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: (b) (6) 1982	Enrollment Entry

3. Sex:

Date	Location	User	Value	Reason
Aug-18-2020 11:36:42 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: FEMALE	Initial Entry

4. Ethnicity:

Date	Location	User	Value	Reason
Aug-18-2020 11:36:42 (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

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

Date	Location	User	Value	Reason
Aug-18-2020 11:36:42 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BLACK OR AFRICAN AMERICAN WHITE	Initial Entry

090177e196ae3f78\Final\Final On: 01-Apr-2021 05:17 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:02

Site No: 1241

Subject No: 12411206

Generated By: (b) (4)

Form: DATE OF VISIT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1241) Hospital Irma Dulce

Subject Initials: ---

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

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1. Date of Visit

Date	Location	User	Value	Reason
Aug-18-2020 11:37:02 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Aug/18/2020	Initial Entry

090177e196ae3f78\Final\Final On: 01-Apr-2021 05:17 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: INCLUSION/EXCLUSION CRITERIA - 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: 12411206

Subject Initials: ---

Generated By: (b) (4)

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

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I.a

Date	Location	User	Value	Reason
Aug-18-2020 11:37:52 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Inclusion Number: Criterion 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?: Criterion ID: (For Pfizer use only):	Initial Entry

I.a Inclusion Number:

Date	Location	User	Value	Reason
Aug-18-2020 11:37:52 (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
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Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: INCLUSION/EXCLUSION CRITERIA - 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: 12411206

Subject Initials: ---

Generated By: (b) (4)

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

Aug-18-2020 11:37:52 (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
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I.a Criterion met?

Date	Location	User	Value	Reason
Aug-18-2020 11:37:52 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

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

Date	Location	User	Value	Reason
Aug-18-2020 11:37:52 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: IN01A00	Initial Entry

I.b

Date	Location	User	Value	Reason
Aug-18-2020 11:37:52 (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	Initial Entry

090177e196ae3f78\Final\Final On: 01-Apr-2021 05:17 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: INCLUSION/EXCLUSION CRITERIA - 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: 12411206

Subject Initials: ---

Generated By: (b) (4)

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

			Criterion ID : (For Pfizer use only): IN02A00	
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1.b Inclusion Number:

Date	Location	User	Value	Reason
Aug-18-2020 11:37:52 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 2	Initial Entry

1.b Criterion Description:

Date	Location	User	Value	Reason
Aug-18-2020 11:37:52 (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

1.b Criterion met?

Date	Location	User	Value	Reason
Aug-18-2020 11:37:52 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

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

Date	Location	User	Value	Reason
Aug-18-2020 11:37:52 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: IN02A00	Initial Entry

1.c

090177e196ae3f78\Final\Final On: 01-Apr-2021 05:17 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: INCLUSION/EXCLUSION CRITERIA - 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: 12411206

Subject Initials: ---

Generated By: (b) (4)

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

Date	Location	User	Value	Reason
Aug-18-2020 11:37:52 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Inclusion Number: Criterion: 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: IN03A00 Use only: (For Pfizer only)	Initial Entry

090177e196ae3f78\Final\Final On: 01-Apr-2021 05:17 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: INCLUSION/EXCLUSION CRITERIA - 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: 12411206

Subject Initials: ---

Generated By: (b) (4)

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

I.c Inclusion Number:

Date	Location	User	Value	Reason
Aug-18-2020 11:37:52 (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-18-2020 11:37:52 (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-18-2020 11:37:52 (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-18-2020 11:37:52 (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-18-2020 11:37:52 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Inclusion Number:	Initial Entry

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Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: INCLUSION/EXCLUSION CRITERIA - 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: 12411206

Subject Initials: ---

Generated By: (b) (4)

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

			<p>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</p> <p>Criterion Met?: YES</p> <p>Criterion ID: IN04A00</p> <p>Use only: (For Pfizer use only):</p>	
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090177e196ae3f78\Final\Final On: 01-Apr-2021 05:17 (GMT)

Header Text: c4591001**Visit:** V1_DAY1_VAX1_L**Form:** INCLUSION/EXCLUSION CRITERIA - 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:** 12411206**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 19:09***1.d Inclusion Number:***

Date	Location	User	Value	Reason
Aug-18-2020 11:37:52 (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-18-2020 11:37:52 (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-18-2020 11:37:52 (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-18-2020 11:37:52 (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-18-2020 11:37:52 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Exclu 1 sion N umbe r:	Initial Entry

Header Text: c4591001**Visit:** V1_DAY1_VAX1_L**Form:** INCLUSION/EXCLUSION CRITERIA - 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:** 12411206**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 19:09

			<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</p> <p>Use only: (For Pfizer use only)</p>	
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2.a Exclusion Number:

Date	Location	User	Value	Reason
Aug-18-2020 11:37:52 (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-18-2020 11:37:52 (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-18-2020 11:37:52 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: INCLUSION/EXCLUSION CRITERIA - 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: 12411206

Subject Initials: ---

Generated By: (b) (4)

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

Buenos Aires	(b) (4), (b) (6)
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2.a Criterion ID: (For Pfizer use only)

Date	Location	User	Value	Reason
Aug-18-2020 11:37:52 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: EX01A00	Initial Entry

2.b

Date	Location	User	Value	Reason
Aug-18-2020 11:37:52 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Exclusi 2 on Nu mber: Criteria Known infection with on Desc human immunodefici ription: ency virus (HIV), hep atitis C virus (HCV), or hepatitis B virus (HBV) Criteria NO on met ?: Criteria EX02A00 on ID: (For Pfi zer use only):	Initial Entry

090177e196ae3f78\Final\Final On: 01-Apr-2021 05:17 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: INCLUSION/EXCLUSION CRITERIA - 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: 12411206

Subject Initials: ---

Generated By: (b) (4)

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

2.b Exclusion Number:

Date	Location	User	Value	Reason
Aug-18-2020 11:37:52 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> 2	Initial Entry

2.b Criterion Description:

Date	Location	User	Value	Reason
Aug-18-2020 11:37:52 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> 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-18-2020 11:37:52 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NO	Initial Entry

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

Date	Location	User	Value	Reason
Aug-18-2020 11:37:52 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> EX02A00	Initial Entry

2.c

Date	Location	User	Value	Reason
Aug-18-2020 11:37:52 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Exclus 3 ion N umber :	Initial Entry

090177e196ae3f78\Final\Final On: 01-Apr-2021 05:17 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: INCLUSION/EXCLUSION CRITERIA - 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: 12411206

Subject Initials: ---

Generated By: (b) (4)

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

			<p>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)</p> <p>Criterion ID: EX03A00</p> <p>Criterion Name: (For Pfizer use only):</p>	
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Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: INCLUSION/EXCLUSION CRITERIA - 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: 12411206

Subject Initials: ---

Generated By: (b) (4)

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

2.c Exclusion Number:

Date	Location	User	Value	Reason
Aug-18-2020 11:37:52 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> 3	Initial Entry

2.c Criterion Description:

Date	Location	User	Value	Reason
Aug-18-2020 11:37:52 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> 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-18-2020 11:37:52 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NO	Initial Entry

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

Date	Location	User	Value	Reason
Aug-18-2020 11:37:52 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> EX03A00	Initial Entry

2.d

Date	Location	User	Value	Reason
Aug-18-2020 11:37:52 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Exclusion Number: 4	Initial Entry

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Header Text: c4591001

Visit: V1_DAY1_VAX1_L

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Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1241

Site Name: (1241) Hospital Irma Dulce

Subject No: 12411206

Subject Initials: ---

Generated By: (b) (4)

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

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

Date	Location	User	Value	Reason
Aug-18-2020 11:37:52 (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-18-2020 11:37:52 (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-18-2020 11:37:52 (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-18-2020 11:37:52 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: EX04A00	Initial Entry

2.e

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Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: INCLUSION/EXCLUSION CRITERIA - eCRF Audit Trail History

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Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1241

Site Name: (1241) Hospital Irma Dulce

Subject No: 12411206

Subject Initials: ---

Generated By: (b) (4)

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

Date	Location	User	Value	Reason
Aug-18-2020 11:37:52 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Exclusion Number: Criterion: Immunocompromised individuals with known or suspected immunodeficiency, as determined by history and/or laboratory/physical examination Criterion met?: Criterion ID: EX08A00 (For Pfizer use only):	Initial Entry

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Header Text: c4591001

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Form: INCLUSION/EXCLUSION CRITERIA - 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: 12411206

Subject Initials: ---

Generated By: (b) (4)

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

2.e Exclusion Number:

Date	Location	User	Value	Reason
Aug-18-2020 11:37:52 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> 8	Initial Entry

2.e Criterion Description:

Date	Location	User	Value	Reason
Aug-18-2020 11:37:52 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Immunocompromised individuals with known or suspected immunodeficiency, as determined by history and/or laboratory/physical examination	Initial Entry

2.e Criterion met?

Date	Location	User	Value	Reason
Aug-18-2020 11:37:52 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NO	Initial Entry

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

Date	Location	User	Value	Reason
Aug-18-2020 11:37:52 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> EX08A00	Initial Entry

2.f

Date	Location	User	Value	Reason
Aug-18-2020 11:37:52 (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

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Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1241

Site Name: (1241) Hospital Irma Dulce

Subject No: 12411206

Subject Initials: ---

Generated By: (b) (4)

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

			<p>Criterion Description: Bleeding diathesis or condition associated with prolonged bleeding that would, in the opinion of the investigator, contraindicate intramuscular injection</p> <p>Criterion Met? NO</p> <p>Criterion ID: EX10A00</p> <p>Use Only: (For Pfizer use only)</p>	
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Header Text: c4591001**Visit:** V1_DAY1_VAX1_L**Form:** INCLUSION/EXCLUSION CRITERIA - 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:** 12411206**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 19:09**2.f Exclusion Number:**

Date	Location	User	Value	Reason
Aug-18-2020 11:37:52 (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-18-2020 11:37:52 (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-18-2020 11:37:52 (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-18-2020 11:37:52 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: EX10A00	Initial Entry

2.g

Date	Location	User	Value	Reason
Aug-18-2020 11:37:52 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Exclusion Number: Criterion Description: Women who are pregnant or breastfeeding	Initial Entry

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: INCLUSION/EXCLUSION CRITERIA - 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: 12411206

Subject Initials: ---

Generated By: (b) (4)

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

2.g Exclusion Number:

Date	Location	User	Value	Reason
Aug-18-2020 11:37:52 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> 11	Initial Entry

2.g Criterion Description:

Date	Location	User	Value	Reason
Aug-18-2020 11:37:52 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Women who are pregnant or breastfeeding	Initial Entry

2.g Criterion met?

Date	Location	User	Value	Reason
Aug-18-2020 11:37:52 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NO	Initial Entry

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

Date	Location	User	Value	Reason
Aug-18-2020 11:37:52 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> EX11A00	Initial Entry

2.h

Date	Location	User	Value	Reason
Aug-18-2020 11:37:52 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Exclusion N 12	Initial Entry

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Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1241

Site Name: (1241) Hospital Irma Dulce

Subject No: 12411206

Subject Initials: ---

Generated By: (b) (4)

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

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

Date	Location	User	Value	Reason
Aug-18-2020 11:37:52 (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-18-2020 11:37:52 (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-18-2020 11:37:52 (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-18-2020 11:37:52 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: EX12A00	Initial Entry

2.i

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Subject Initials: ---

Generated By: (b) (4)

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

Date	Location	User	Value	Reason
Aug-18-2020 11:37:52 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 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	Initial Entry

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Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1241

Site Name: (1241) Hospital Irma Dulce

Subject No: 12411206

Subject Initials: ---

Generated By: (b) (4)

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

2.i Exclusion Number:

Date	Location	User	Value	Reason
Aug-18-2020 11:37:52 (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-18-2020 11:37:52 (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-18-2020 11:37:52 (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-18-2020 11:37:52 (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-18-2020 11:37:52 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Exclusion Number: 15	Initial Entry

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Header Text: c4591001

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Site No: 1241

Site Name: (1241) Hospital Irma Dulce

Subject No: 12411206

Subject Initials: ---

Generated By: (b) (4)

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

			<p>Criterion Description: Receipt of blood/plasma products or immunoglobulin, from 60 days before study intervention on administration or planned receipt throughout the study</p> <p>Criterion Met?: NO</p> <p>Criterion ID: EX14A01</p> <p>Use Only: (For Pfizer use only)</p>	
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Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1241

Site Name: (1241) Hospital Irma Dulce

Subject No: 12411206

Subject Initials: ---

Generated By: (b) (4)

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

2.j Exclusion Number:

Date	Location	User	Value	Reason
Aug-18-2020 11:37:52 (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-18-2020 11:37:52 (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-18-2020 11:37:52 (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-18-2020 11:37:52 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: EX14A01	Initial Entry

090177e196ae3f78\Final\Final On: 01-Apr-2021 05:17 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: INCLUSION/EXCLUSION CRITERIA - 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: 12411206

Subject Initials: ---

Generated By: (b) (4)

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

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2.k

Date	Location	User	Value	Reason
Aug-18-2020 11:37:52 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<p>Data Entry:</p> <p>Exclusion Number: 16</p> <p>Criteria on Description: Participation in other studies involving study intervention within 28 days prior to study entry and/or during study participation</p> <p>Criteria on ID: NO</p> <p>Criteria on ID: EX15A01</p> <p>(For Pfizer use only):</p>	Initial Entry

090177e196ae3f78\Final\Final On: 01-Apr-2021 05:17 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: INCLUSION/EXCLUSION CRITERIA - 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: 12411206

Subject Initials: ---

Generated By: (b) (4)

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

2.k Exclusion Number:

Date	Location	User	Value	Reason
Aug-18-2020 11:37:52 (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-18-2020 11:37:52 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Participation in other studies in involving study intervention with in 28 days prior to study entry and/or during study participation	Initial Entry

2.k Criterion met?

Date	Location	User	Value	Reason
Aug-18-2020 11:37:52 (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-18-2020 11:37:52 (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-18-2020 11:37:52 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Exclusio 17 n Num ber:	Initial Entry

090177e196ae3f78\Final\Final On: 01-Apr-2021 05:17 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: INCLUSION/EXCLUSION CRITERIA - 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: 12411206

Subject Initials: ---

Generated By: (b) (4)

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

			<p>Criterion Description: Previous participation in other studies involving study intervention containing lipid nanoparticles</p> <p>Criterion met?: NO</p> <p>Criterion ID: (Former Pfizer use only): EX16A01</p>	
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090177e196ae3f78\Final\Final On: 01-Apr-2021 05:17 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: INCLUSION/EXCLUSION CRITERIA - 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: 12411206

Subject Initials: ---

Generated By: (b) (4)

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

2.1 Exclusion Number:

Date	Location	User	Value	Reason
Aug-18-2020 11:37:52 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 17	Initial Entry

2.1 Criterion Description:

Date	Location	User	Value	Reason
Aug-18-2020 11:37:52 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Previous participation in other studies involving study intervention containing lipid nanoparticles	Initial Entry

2.1 Criterion met?

Date	Location	User	Value	Reason
Aug-18-2020 11:37:52 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2.1 Criterion ID: (For Pfizer use only)

Date	Location	User	Value	Reason
Aug-18-2020 11:37:52 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: EX16A01	Initial Entry

2.m

Date	Location	User	Value	Reason
Aug-18-2020 11:37:52 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Exclu 22 sion Num ber:	Initial Entry

090177e196ae3f78\Final\Final On: 01-Apr-2021 05:17 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: INCLUSION/EXCLUSION CRITERIA - 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: 12411206

Subject Initials: ---

Generated By: (b) (4)

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

			<p>Crite Investigator site staff o rion r Pfizer employees dire Descr ctly involved in the con ption duct of the study, site st : aff otherwise supervise d by the investigator, a nd their respective fami ly members</p> <p>Crite NO rion met?:</p> <p>Crite EX21A01 rion I D: (F or Pfi zer us e only):</p>	
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090177e196ae3f78\Final\Final On: 01-Apr-2021 05:17 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: INCLUSION/EXCLUSION CRITERIA - 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: 12411206

Subject Initials: ---

Generated By: (b) (4)

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

2.m Exclusion Number:

Date	Location	User	Value	Reason
Aug-18-2020 11:37:52 (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-18-2020 11:37:52 (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-18-2020 11:37:52 (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-18-2020 11:37:52 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: EX21A01	Initial Entry

090177e196ae3f78\Final\Final On: 01-Apr-2021 05:17 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1241

Subject No: 12411206

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-18-2020 11:38:03 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Aug/18/2020	Initial Entry

2. Phase of Disposition:

Date	Location	User	Value	Reason
Aug-18-2020 11:38:03 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SCREENING	Initial Entry

3. Status:

Date	Location	User	Value	Reason
Aug-18-2020 11:38:03 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: COMPLETED	Initial Entry

090177e196ae3f78\Final\Final On: 01-Apr-2021 05:17 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1241

Subject No: 12411206

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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1.a

Date	Location	User	Value	Reason
Oct-07-2020 11:54:06 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 1 Medical History Term: Breast lump Start Date: UNK/UNK/2018 Ongoing: YES	Initial Entry

1.a Line/MH Number:

Date	Location	User	Value	Reason
Oct-07-2020 11:54:06 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 1	Initial Entry

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

Date	Location	User	Value	Reason
Oct-07-2020 11:54:06 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Breast lump	Initial Entry

1.a Start Date:

Date	Location	User	Value	Reason
Oct-07-2020 11:54:06 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: UNK/UNK/2018	Initial Entry

1.a Ongoing:

Date	Location	User	Value	Reason
Oct-07-2020 11:54:06 (UTC-03:00) City of	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

090177e196ae3f78\Final\Final On: 01-Apr-2021 05:17 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1241

Subject No: 12411206

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)

090177e196ae3f78\Final\Final On: 01-Apr-2021 05:17 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 30-Jul-2020 21:28

Site No: 1241

Subject No: 12411206

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-18-2020 11:39:23 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Aug/18/2020	Initial Entry

2. Weight:

Date	Location	User	Value	Reason
Aug-18-2020 11:39:23 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> 55.5	Initial Entry

3. Unit:

Date	Location	User	Value	Reason
Aug-18-2020 11:39:23 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> kg	Initial Entry

4. Height:

Date	Location	User	Value	Reason
Aug-18-2020 11:39:23 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> 152.5	Initial Entry

5. Unit:

Date	Location	User	Value	Reason
Aug-18-2020 11:39:23 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> cm	Initial Entry

6. Body Mass Index:

Date	Location	User	Value	Reason
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090177e196ae3f78\Final\Final On: 01-Apr-2021 05:17 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 30-Jul-2020 21:28

Site No: 1241

Subject No: 12411206

Generated By: (b) (4)

Form: VITAL SIGNS - BASELINE - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1241) Hospital Irma Dulce

Subject Initials: ---

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

Aug-18-2020 11:39:23 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 23.9	Initial Entry
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7.a

Date	Location	User	Value	Reason
Aug-18-2020 11:39:23 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Record Identifier: Temperature: 36.4 Temperature Unit: Temperature Location: ORAL CAVITY	Initial Entry

7.a Record Identifier:

Date	Location	User	Value	Reason
Aug-18-2020 11:39:23 (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-18-2020 11:39:23 (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-18-2020 11:39:23 (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
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090177e196ae3f78\Final\Final On: 01-Apr-2021 05:17 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 30-Jul-2020 21:28

Site No: 1241

Subject No: 12411206

Generated By: (b) (4)

Form: VITAL SIGNS - BASELINE - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1241) Hospital Irma Dulce

Subject Initials: ---

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

Aug-18-2020 11:39:23 (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: 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: 12411206

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-18-2020 11:39:34 (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
Aug-18-2020 11:39:34 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: PREGNANCY	Initial Entry

3. Collection Date:

Date	Location	User	Value	Reason
Aug-18-2020 11:39:34 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Aug/18/2020	Initial Entry

4. Laboratory Name and Address (Derived)

Date	Location	User	Value	Reason
Aug-18-2020 11:39:34 (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
Aug-18-2020 11:39:34 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: URINE	Initial Entry

6.a

Date	Location	User	Value	Reason
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090177e196ae3f78\Final\Final On: 01-Apr-2021 05:17 (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: 12411206

Subject Initials: ---

Generated By: (b) (4)

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

Aug-18-2020 11:39:34 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sponsor-Defined Identifier: 113 Test:: Choriogonadotropin Beta_PX13 Result:: NEGATIVE Not Done::	Initial Entry
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6.a Sponsor ID:

Date	Location	User	Value	Reason
Aug-18-2020 11:39:34 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 113	Initial Entry

6.a Test:

Date	Location	User	Value	Reason
Aug-18-2020 11:39:34 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Choriogonadotropin Beta_PX13	Initial Entry

6.a Result:

Date	Location	User	Value	Reason
Aug-18-2020 11:39:34 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NEGATIVE	Initial Entry

090177e196ae3f78\Final\Final On: 01-Apr-2021 05:17 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1241

Subject No: 12411206

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-18-2020 11:40:40 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Aug/18/2020	Initial Entry

2. Randomization Number:

Date	Location	User	Value	Reason
Aug-18-2020 11:40:40 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 53756	Initial Entry

090177e196ae3f78\Final\Final On: 01-Apr-2021 05:17 (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: 12411206

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-18-2020 16:17:33 (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-18-2020 16:17:33 (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-18-2020 16:17:40 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Aug-18-2020 16:17:33 (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-18-2020 16:17:33 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Date of Collection: Aug/18/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
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090177e196ae3f78\Final\Final On: 01-Apr-2021 05:17 (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: 12411206

Subject Initials: ---

Generated By: (b) (4)

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

Aug-18-2020 16:17:40 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BP5RZW	Initial Entry
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5.a Sample ID

Date	Location	User	Value	Reason
Aug-18-2020 16:17:40 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BP5RZW	Initial Entry

5.b

Date	Location	User	Value	Reason
Aug-18-2020 16:17:49 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BP5RZX	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Aug-18-2020 16:17:49 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BP5RZX	Initial Entry

5.c

Date	Location	User	Value	Reason
Aug-18-2020 16:17:56 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BP5RZY	Initial Entry

5.c Sample ID

Date	Location	User	Value	Reason
Aug-18-2020 16:17:56 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BP5RZY	Initial Entry

5.d

090177e196ae3f78\Final\Final On: 01-Apr-2021 05:17 (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: 12411206

Subject Initials: ---

Generated By: (b) (4)

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

Date	Location	User	Value	Reason
Aug-18-2020 16:18:07 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BLCH8T	Initial Entry

5.d Sample ID

Date	Location	User	Value	Reason
Aug-18-2020 16:18:07 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BLCH8T	Initial Entry

5.e

Date	Location	User	Value	Reason
Aug-18-2020 16:18:13 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BLCH8V	Initial Entry

5.e Sample ID

Date	Location	User	Value	Reason
Aug-18-2020 16:18:13 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BLCH8V	Initial Entry

090177e196ae3f78\Final\Final On: 01-Apr-2021 05:17 (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:** 12411206**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 19:09[Back to Form](#)**1. Data Origin**

Date	Location	User	Value	Reason
Aug-18-2020 16:14:00 (UTC-03:00) City of Buenos Aires	ACVOPFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Aug-18-2020 16:14:00 (UTC-03:00) City of Buenos Aires	ACVOPFEINFP6000	auto calc (autocalc)	Data Entry: NASAL_SWAB	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Aug-18-2020 16:14:08 (UTC-03:00) City of Buenos Aires	ACVOPFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Aug-18-2020 16:14:00 (UTC-03:00) City of Buenos Aires	ACVOPFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Aug-18-2020 16:14:00 (UTC-03:00) City of Buenos Aires	ACVOPFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Date of Collection: Aug/18/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
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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: 12411206

Subject Initials: ---

Generated By: (b) (4)

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

Aug-18-2020 16:14:08 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BP5RZ6	Initial Entry
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5.a Sample ID

Date	Location	User	Value	Reason
Aug-18-2020 16:14:08 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BP5RZ6	Initial Entry

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:04

Site No: 1241

Subject No: 12411206

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-18-2020 11:41:06 (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-18-2020 11:41:06 (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-18-2020 11:41:06 (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-18-2020 11:41:06 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Aug/18/2020 09:26	Initial Entry

5. Anatomical Location:

Date	Location	User	Value	Reason
Aug-18-2020 11:41:06 (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
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090177e196ae3f78\Final\Final On: 01-Apr-2021 05:17 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:04

Site No: 1241

Subject No: 12411206

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

Aug-18-2020 11:41:06 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: LEFT	Initial Entry
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7. Route:

Date	Location	User	Value	Reason
Aug-18-2020 11:41:06 (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-18-2020 11:41:06 (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-18-2020 11:41:06 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

090177e196ae3f78\Final\Final On: 01-Apr-2021 05:17 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 06-Jul-2020 21:53

Site No: 1241

Subject No: 12411206

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-18-2020 11:41:11 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES - REACTOGENICITY E- DIARY COLLECTED FOR T HIS SUBJECT	Initial Entry

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:02

Site No: 1241

Subject No: 12411206

Generated By: (b) (4)

Form: DATE OF VISIT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1241) Hospital Irma Dulce

Subject Initials: ---

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

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1. Date of Visit

Date	Location	User	Value	Reason
Sep-09-2020 11:40:33 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sep/9/2020	Initial Entry

Header Text: c4591001

Visit: V2_VAX2_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1241

Site Name: (1241) Hospital Irma Dulce

Subject No: 12411206

Subject Initials: ---

Generated By: (b) (4)

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

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1. Were medications to treat fever/pain given on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Sep-09-2020 11:41:48 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NO	Initial Entry

2.a

Date	Location	User	Value	Reason
Sep-09-2020 11:41:48 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Symptom:: FE VE R Were fever or systemic symptoms present on the last day the Subject Diary was completed?: N O	Initial Entry

2.a Symptom:

Date	Location	User	Value	Reason
Sep-09-2020 11:41:48 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> FEVER	Initial Entry

2.a Were fever or systemic symptoms present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Sep-09-2020 11:41:48 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NO	Initial Entry

2.b

Date	Location	User	Value	Reason
Sep-09-2020 11:41:48	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u>	Initial Entry

090177e196ae3f78\Final\Final On: 01-Apr-2021 05:17 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1241

Site Name: (1241) Hospital Irma Dulce

Subject No: 12411206

Subject Initials: ---

Generated By: (b) (4)

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

(UTC-03:00) City of Buenos Aires	(b) (4), (b) (6)	Symptom::	FA TI GU E
		Were fever or systemic symptoms present on the last day the Subject Diary was completed?:	NO

2.b Symptom:

Date	Location	User	Value	Reason
Sep-09-2020 11:41:48 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: FATIGUE	Initial Entry

2.b Were fever or systemic symptoms present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Sep-09-2020 11:41:48 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2.c

Date	Location	User	Value	Reason
Sep-09-2020 11:41:48 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom:: HE AD AC HE	Initial Entry
		Were fever or systemic symptoms present on the last day the Subject Diary was completed?:	NO	

090177e196ae3f78\Final\Final On: 01-Apr-2021 05:17 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1241

Site Name: (1241) Hospital Irma Dulce

Subject No: 12411206

Subject Initials: ---

Generated By: (b) (4)

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

2.c Symptom:

Date	Location	User	Value	Reason
Sep-09-2020 11:41:48 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> HEADACHE	Initial Entry

2.c Were fever or systemic symptoms present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Sep-09-2020 11:41:48 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NO	Initial Entry

2.d

Date	Location	User	Value	Reason
Sep-09-2020 11:41:48 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Symptom:: CH IL LS Were fever or systemic s N ymptoms present on the l O ast day the Subject Diary was completed?:	Initial Entry

2.d Symptom:

Date	Location	User	Value	Reason
Sep-09-2020 11:41:48 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> CHILLS	Initial Entry

2.d Were fever or systemic symptoms present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Sep-09-2020 11:41:48 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NO	Initial Entry

090177e196ae3f78\Final\Final On: 01-Apr-2021 05:17 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1241

Site Name: (1241) Hospital Irma Dulce

Subject No: 12411206

Subject Initials: ---

Generated By: (b) (4)

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

2.e

Date	Location	User	Value	Reason
Sep-09-2020 11:41:28 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom:: VO MIT ING Were fever or systemic symptoms present on the last day the Subject Diary was completed?: NO	Initial Entry

2.e Symptom:

Date	Location	User	Value	Reason
Sep-09-2020 11:41:48 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: VOMITING	Initial Entry

2.e Were fever or systemic symptoms present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Sep-09-2020 11:41:48 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2.f

Date	Location	User	Value	Reason
Sep-09-2020 11:41:28 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom:: DIA RR HE A Were fever or systemic symptoms present on the last day the Subject Diary was completed?: NO	Initial Entry

090177e196ae3f78\Final\Final On: 01-Apr-2021 05:17 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1241

Site Name: (1241) Hospital Irma Dulce

Subject No: 12411206

Subject Initials: ---

Generated By: (b) (4)

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

2.f Symptom:

Date	Location	User	Value	Reason
Sep-09-2020 11:41:48 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: DIARRHEA	Initial Entry

2.f Were fever or systemic symptoms present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Sep-09-2020 11:41:48 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2.g

Date	Location	User	Value	Reason
Sep-09-2020 11:41:48 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom:: NEW OR WORSE NED MU SCLE PA IN Were fever or systemic symptoms present on the last day the Subject Diary was completed?: NO	Initial Entry

090177e196ae3f78\Final\Final On: 01-Apr-2021 05:17 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1241

Site Name: (1241) Hospital Irma Dulce

Subject No: 12411206

Subject Initials: ---

Generated By: (b) (4)

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

2.g Symptom:

Date	Location	User	Value	Reason
Sep-09-2020 11:41:48 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NEW OR WORSENER MUSC LE PAIN	Initial Entry

2.g Were fever or systemic symptoms present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Sep-09-2020 11:41:48 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2.h

Date	Location	User	Value	Reason
Sep-09-2020 11:41:48 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom:: NEW O R WOR SENER JOINT P AIN Were fever or syste mic symptoms pres ent on the last day t he Subject Diary w as completed?: NO	Initial Entry

090177e196ae3f78\Final\Final On: 01-Apr-2021 05:17 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1241

Site Name: (1241) Hospital Irma Dulce

Subject No: 12411206

Subject Initials: ---

Generated By: (b) (4)

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

2.h Symptom:

Date	Location	User	Value	Reason
Sep-09-2020 11:41:48 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NEW OR WORSENERD JOINT PAIN	Initial Entry

2.h Were fever or systemic symptoms present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Sep-09-2020 11:41:48 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

3. Injection Site Location:

Date	Location	User	Value	Reason
Sep-09-2020 11:41:48 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: DELTOID MUSCLE	Initial Entry

4. Injection Site Body Side:

Date	Location	User	Value	Reason
Sep-09-2020 11:41:48 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: LEFT	Initial Entry

5.a

Date	Location	User	Value	Reason
Sep-09-2020 11:41:48 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Injection Site Reaction: RE DN ES S Were injection site react NO ions present on the last day the Subject Diary w as completed?:	Initial Entry

090177e196ae3f78\Final\Final On: 01-Apr-2021 05:17 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1241

Site Name: (1241) Hospital Irma Dulce

Subject No: 12411206

Subject Initials: ---

Generated By: (b) (4)

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

5.a Injection Site Reaction:

Date	Location	User	Value	Reason
Sep-09-2020 11:41:48 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> REDNESS	Initial Entry

5.a Were injection site reactions present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Sep-09-2020 11:41:48 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NO	Initial Entry

5.b

Date	Location	User	Value	Reason
Sep-09-2020 11:41:48 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Injection Site Reaction: SW : ELL ING Were injection site reac NO tions present on the last day the Subject Diary was completed?:	Initial Entry

5.b Injection Site Reaction:

Date	Location	User	Value	Reason
Sep-09-2020 11:41:48 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> SWELLING	Initial Entry

5.b Were injection site reactions present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Sep-09-2020 11:41:48 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NO	Initial Entry

090177e196ae3f78\Final\Final On: 01-Apr-2021 05:17 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1241

Site Name: (1241) Hospital Irma Dulce

Subject No: 12411206

Subject Initials: ---

Generated By: (b) (4)

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

5.c

Date	Location	User	Value	Reason
Sep-09-2020 11:41:48 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Injection Site Reaction: PAIN AT INJECTION SITE Were injection site reactions present on the last day the Subject Diary was completed?: NO	Initial Entry

5.c Injection Site Reaction:

Date	Location	User	Value	Reason
Sep-09-2020 11:41:48 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: PAIN AT INJECTION SITE	Initial Entry

5.c Were injection site reactions present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Sep-09-2020 11:41:48 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

090177e196ae3f78\Final\Final On: 01-Apr-2021 05:17 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 21-Aug-2020 02:51

Site No: 1241

Subject No: 12411206

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-09-2020 11:42:05 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Sep/9/2020	Initial Entry

2.a

Date	Location	User	Value	Reason
Sep-09-2020 11:42:05 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Record Identifier 1 :: Temperature: 36.5 Temperature Unit: Temperature Location: ORAL CAVITY	Initial Entry

2.a Record Identifier:

Date	Location	User	Value	Reason
Sep-09-2020 11:42:05 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> 1	Initial Entry

2.a Temperature:

Date	Location	User	Value	Reason
Sep-09-2020 11:42:05 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> 36.5	Initial Entry

2.a Unit:

Date	Location	User	Value	Reason
Sep-09-2020 11:42:05 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> C	Initial Entry

090177e196ae3f78\Final\Final On: 01-Apr-2021 05:17 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 21-Aug-2020 02:51

Site No: 1241

Subject No: 12411206

Generated By: (b) (4)

Form: VITAL SIGNS - TEMP - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1241) Hospital Irma Dulce

Subject Initials: ---

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

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

Date	Location	User	Value	Reason
Sep-09-2020 11:42:05 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: ORAL CAVITY	Initial Entry

Header Text: c4591001

Visit: V2_VAX2_L

Form: 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: 12411206

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-09-2020 11:42:13 (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-09-2020 11:42:13 (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-09-2020 11:42:13 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sep/9/2020	Initial Entry

4. Laboratory Name and Address (Derived)

Date	Location	User	Value	Reason
Sep-09-2020 11:42:13 (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-09-2020 11:42:13 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: URINE	Initial Entry

6.a

Date	Location	User	Value	Reason
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090177e196ae3f78\Final\Final On: 01-Apr-2021 05:17 (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: 12411206

Subject Initials: ---

Generated By: (b) (4)

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

Sep-09-2020 11:42:13 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sponsor-Defined Identifier: 113 Test:: Choriogonadotropin Beta_PX113 Result:: NEGATIVE Not Done::	Initial Entry
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6.a Sponsor ID:

Date	Location	User	Value	Reason
Sep-09-2020 11:42:13 (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-09-2020 11:42:13 (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-09-2020 11:42:13 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NEGATIVE	Initial Entry

090177e196ae3f78\Final\Final On: 01-Apr-2021 05:17 (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: 12411206

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-09-2020 13:21:34 (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-09-2020 13:21:34 (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-09-2020 13:21:42 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Sep-09-2020 13:21:34 (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-09-2020 13:21:34 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Date of Collection: Sep/9/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
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090177e196ae3f78\Final\Final On: 01-Apr-2021 05:17 (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: 12411206

Subject Initials: ---

Generated By: (b) (4)

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

Sep-09-2020 13:21:42 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BPX0RL	Initial Entry
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5.a Sample ID

Date	Location	User	Value	Reason
Sep-09-2020 13:21:42 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BPX0RL	Initial Entry

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:04

Site No: 1241

Subject No: 12411206

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-09-2020 11:42:39 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2. Treatment Name

Date	Location	User	Value	Reason
Sep-09-2020 11:42:39 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: BLINDED THERAPY	Initial Entry

3. Formulation:

Date	Location	User	Value	Reason
Sep-09-2020 11:42:39 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: INJECTION	Initial Entry

4. Dose Date Time:

Date	Location	User	Value	Reason
Sep-23-2020 08:57:49 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Sep-23-2020 08:04:07 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	The date of vaccination is 09Sep2020
Sep-22-2020 10:43:54 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	eDiary: Per eDiary records, vaccination date is 10-Sep-2020. Please reconcile and update or confirm in the query response as

090177e196ae3f78\Final\Final On: 01-Apr-2021 05:17 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:04

Site No: 1241

Subject No: 12411206

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

				appropriate. Thanks
Sep-09-2020 11:42:39 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sep/9/2020 10:33	Initial Entry

5. Anatomical Location:

Date	Location	User	Value	Reason
Sep-09-2020 11:42:39 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: DELTOID MUSCLE	Initial Entry

6. Body Side:

Date	Location	User	Value	Reason
Sep-09-2020 11:42:39 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: LEFT	Initial Entry

7. Route:

Date	Location	User	Value	Reason
Sep-09-2020 11:42:39 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: INTRAMUSCULAR	Initial Entry

10. Timeframe Subject Was Observed

Date	Location	User	Value	Reason
Sep-09-2020 11:42:39 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: THE PROTOCOL SPECIFIED OBSERVATION PERIOD	Initial Entry

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

Date	Location	User	Value	Reason
Sep-09-2020 11:42:39 (UTC-03:00) City of	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

090177e196ae3f78\Final\Final On: 01-Apr-2021 05:17 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:04

Site No: 1241

Subject No: 12411206

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

Buenos Aires

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

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form Version: 22-Apr-2020 21:02

Site No: 1241

Subject No: 12411206

Generated By: (b) (4)

Form: DATE OF VISIT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1241) Hospital Irma Dulce

Subject Initials: ---

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

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1. Date of Visit

Date	Location	User	Value	Reason
Oct-07-2020 11:48:43 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Oct/7/2020	Initial Entry

090177e196ae3f78\Final\Final On: 01-Apr-2021 05:17 (GMT)

Header Text: c4591001**Visit:** V3_MONTH1_POSTVAX2_L**Form:** VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History**Form Version:** 30-Jul-2020 21:30**Form Status:** Data Complete, Locked, Frozen, Verified**Site No:** 1241**Site Name:** (1241) Hospital Irma Dulce**Subject No:** 12411206**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 19:09[Back to Form](#)**1. Were medications to treat fever/pain given on the last day the Subject Diary was completed?**

Date	Location	User	Value	Reason
Oct-07-2020 11:50:01 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2.a

Date	Location	User	Value	Reason
Oct-07-2020 11:50:01 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom:: FE VE R Were fever or systemic symptoms present on the last day the Subject Diary was completed?: N O	Initial Entry

2.a Symptom:

Date	Location	User	Value	Reason
Oct-07-2020 11:50:01 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: FEVER	Initial Entry

2.a Were fever or systemic symptoms present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Oct-07-2020 11:50:01 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2.b

Date	Location	User	Value	Reason
Oct-07-2020 11:50:01	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Initial Entry

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1241

Site Name: (1241) Hospital Irma Dulce

Subject No: 12411206

Subject Initials: ---

Generated By: (b) (4)

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

(UTC-03:00) City of Buenos Aires	(b) (4), (b) (6)	Symptom::	FA TI GU E
		Were fever or systemic symptoms present on the last day the Subject Diary was completed?:	NO

2.b Symptom:

Date	Location	User	Value	Reason
Oct-07-2020 11:50:01 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: FATIGUE	Initial Entry

2.b Were fever or systemic symptoms present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Oct-07-2020 11:50:01 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2.c

Date	Location	User	Value	Reason
Oct-07-2020 11:50:01 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom:: HE AD AC HE	Initial Entry
			Were fever or systemic symptoms present on the last day the Subject Diary was completed?:	NO

090177e196ae3f78\Final\Final On: 01-Apr-2021 05:17 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1241

Site Name: (1241) Hospital Irma Dulce

Subject No: 12411206

Subject Initials: ---

Generated By: (b) (4)

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

2.c Symptom:

Date	Location	User	Value	Reason
Oct-07-2020 11:50:01 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> HEADACHE	Initial Entry

2.c Were fever or systemic symptoms present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Oct-07-2020 11:50:01 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NO	Initial Entry

2.d

Date	Location	User	Value	Reason
Oct-07-2020 11:50:01 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Symptom:: CH IL LS Were fever or systemic s N ymptoms present on the l O ast day the Subject Diary was completed?:	Initial Entry

2.d Symptom:

Date	Location	User	Value	Reason
Oct-07-2020 11:50:01 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> CHILLS	Initial Entry

2.d Were fever or systemic symptoms present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Oct-07-2020 11:50:01 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NO	Initial Entry

090177e196ae3f78\Final\Final On: 01-Apr-2021 05:17 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1241

Site Name: (1241) Hospital Irma Dulce

Subject No: 12411206

Subject Initials: ---

Generated By: (b) (4)

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

2.e

Date	Location	User	Value	Reason
Oct-07-2020 11:50:01 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom:: VO MIT ING Were fever or systemic symptoms present on the last day the Subject Diary was completed?: NO	Initial Entry

2.e Symptom:

Date	Location	User	Value	Reason
Oct-07-2020 11:50:01 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: VOMITING	Initial Entry

2.e Were fever or systemic symptoms present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Oct-07-2020 11:50:01 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2.f

Date	Location	User	Value	Reason
Oct-07-2020 11:50:01 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom:: DIA RR HE A Were fever or systemic symptoms present on the last day the Subject Diary was completed?: NO	Initial Entry

090177e196ae3f78\Final\Final On: 01-Apr-2021 05:17 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1241

Site Name: (1241) Hospital Irma Dulce

Subject No: 12411206

Subject Initials: ---

Generated By: (b) (4)

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

2.f Symptom:

Date	Location	User	Value	Reason
Oct-07-2020 11:50:01 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: DIARRHEA	Initial Entry

2.f Were fever or systemic symptoms present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Oct-07-2020 11:50:01 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2.g

Date	Location	User	Value	Reason
Oct-07-2020 11:50:01 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom:: NEW OR WORSE NED MU SCLE PA IN Were fever or systemic symptoms present on the last day the Subject Diary was completed?: NO	Initial Entry

090177e196ae3f78\Final\Final On: 01-Apr-2021 05:17 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1241

Site Name: (1241) Hospital Irma Dulce

Subject No: 12411206

Subject Initials: ---

Generated By: (b) (4)

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

2.g Symptom:

Date	Location	User	Value	Reason
Oct-07-2020 11:50:01 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NEW OR WORSENE MUSC LE PAIN	Initial Entry

2.g Were fever or systemic symptoms present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Oct-07-2020 11:50:01 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2.h

Date	Location	User	Value	Reason
Oct-07-2020 11:50:01 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom:: NEW O R WOR SENE D JOINT P AIN Were fever or syste mic symptoms pres ent on the last day t he Subject Diary w as completed?: NO	Initial Entry

090177e196ae3f78\Final\Final On: 01-Apr-2021 05:17 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1241

Site Name: (1241) Hospital Irma Dulce

Subject No: 12411206

Subject Initials: ---

Generated By: (b) (4)

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

2.h Symptom:

Date	Location	User	Value	Reason
Oct-07-2020 11:50:01 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NEW OR WORSENERD JOINT PAIN	Initial Entry

2.h Were fever or systemic symptoms present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Oct-07-2020 11:50:01 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

3. Injection Site Location:

Date	Location	User	Value	Reason
Oct-07-2020 11:50:01 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: DELTOID MUSCLE	Initial Entry

4. Injection Site Body Side:

Date	Location	User	Value	Reason
Oct-07-2020 11:50:01 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: LEFT	Initial Entry

5.a

Date	Location	User	Value	Reason
Oct-07-2020 11:50:01 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Injection Site Reaction: RE DN ES S Were injection site react ions present on the last day the Subject Diary w as completed?: NO	Initial Entry

090177e196ae3f78\Final\Final On: 01-Apr-2021 05:17 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1241

Site Name: (1241) Hospital Irma Dulce

Subject No: 12411206

Subject Initials: ---

Generated By: (b) (4)

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

5.a Injection Site Reaction:

Date	Location	User	Value	Reason
Oct-07-2020 11:50:01 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> REDNESS	Initial Entry

5.a Were injection site reactions present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Oct-07-2020 11:50:01 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NO	Initial Entry

5.b

Date	Location	User	Value	Reason
Oct-07-2020 11:50:01 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Injection Site Reaction: SW : ELL ING Were injection site reac NO tions present on the last day the Subject Diary was completed?:	Initial Entry

5.b Injection Site Reaction:

Date	Location	User	Value	Reason
Oct-07-2020 11:50:01 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> SWELLING	Initial Entry

5.b Were injection site reactions present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Oct-07-2020 11:50:01 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NO	Initial Entry

090177e196ae3f78\Final\Final On: 01-Apr-2021 05:17 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1241

Site Name: (1241) Hospital Irma Dulce

Subject No: 12411206

Subject Initials: ---

Generated By: (b) (4)

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

5.c

Date	Location	User	Value	Reason
Oct-07-2020 11:50:01 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Injection Site Reaction: PAIN AT INJECTION SITE Were injection site reactions present on the last day the Subject Diary was completed?: NO	Initial Entry

5.c Injection Site Reaction:

Date	Location	User	Value	Reason
Oct-07-2020 11:50:01 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: PAIN AT INJECTION SITE	Initial Entry

5.c Were injection site reactions present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Oct-07-2020 11:50:01 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

090177e196ae3f78\Final\Final On: 01-Apr-2021 05:17 (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: 12411206

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-08-2020 09:51:00 (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-08-2020 09:51:00 (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-08-2020 09:51:08 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Oct-08-2020 09:51:00 (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-08-2020 09:51:00 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Date of Collection: Oct/7/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
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090177e196ae3f78\Final\Final On: 01-Apr-2021 05:17 (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: 12411206

Subject Initials: ---

Generated By: (b) (4)

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

Oct-08-2020 09:51:08 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Sample ID: BPWXP2	Initial Entry
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5.a Sample ID

Date	Location	User	Value	Reason
Oct-08-2020 09:51:08 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> BPWXP2	Initial Entry

5.b

Date	Location	User	Value	Reason
Oct-08-2020 09:51:18 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Sample ID: BHHZSK	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Oct-08-2020 09:51:18 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> BHHZSK	Initial Entry

5.c

Date	Location	User	Value	Reason
Oct-08-2020 09:51:26 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Sample ID: BHHZSL	Initial Entry

5.c Sample ID

Date	Location	User	Value	Reason
Oct-08-2020 09:51:26 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> BHHZSL	Initial Entry

090177e196ae3f78\Final\Final On: 01-Apr-2021 05:17 (GMT)

Header Text: c4591001

Visit: V4_MONTH6_L

Form Version: 22-Apr-2020 21:02

Site No: 1241

Subject No: 12411206

Generated By: (b) (4)

Form: DATE OF VISIT - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1241) Hospital Irma Dulce

Subject Initials: ---

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

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1. Date of Visit

Date	Location	User	Value	Reason
Mar-03-2021 10:45:46 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Mar/3/2021	Initial Entry

Header Text: c4591001

Visit: V4_MONTH6_L

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1241

Site Name: (1241) Hospital Irma Dulce

Subject No: 12411206

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-03-2021 11:09:15 (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-03-2021 11:09:15 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SERUM	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Mar-03-2021 11:09:25 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Mar-03-2021 11:09:15 (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-03-2021 11:09:15 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Date of Collection: Mar/3/2021	Initial Entry

5.a

Date	Location	User	Value	Reason
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090177e196ae3f78\Final\Final On: 01-Apr-2021 05:17 (GMT)

Header Text: c4591001

Visit: V4_MONTH6_L

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1241

Site Name: (1241) Hospital Irma Dulce

Subject No: 12411206

Subject Initials: ---

Generated By: (b) (4)

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

Mar-03-2021 11:09:25 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BRC1HP	Initial Entry
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5.a Sample ID

Date	Location	User	Value	Reason
Mar-03-2021 11:09:25 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BRC1HP	Initial Entry

5.b

Date	Location	User	Value	Reason
Mar-03-2021 11:09:36 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BSCYKV	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Mar-03-2021 11:09:36 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BSCYKV	Initial Entry

5.c

Date	Location	User	Value	Reason
Mar-03-2021 11:09:44 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BSCYKW	Initial Entry

5.c Sample ID

Date	Location	User	Value	Reason
Mar-03-2021 11:09:44 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BSCYKW	Initial Entry

090177e196ae3f78\Final\Final On: 01-Apr-2021 05:17 (GMT)

Header Text: c4591001

Visit: End of Treatment - Unscheduled

Form: DISPOSITION - TREATMENT - eCRF Audit Trail History

Form Version: 15-Sep-2020 21:55

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1241

Site Name: (1241) Hospital Irma Dulce

Subject No: 12411206

Subject Initials: ---

Generated By: (b) (4)

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

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1. Date of Completion/Discontinuation/Death :

Date	Location	User	Value	Reason
Oct-07-2020 11:50:18 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Oct/7/2020	Initial Entry

2. Phase of Disposition:

Date	Location	User	Value	Reason
Oct-07-2020 11:50:18 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: VACCINATION	Initial Entry

3. Status:

Date	Location	User	Value	Reason
Oct-07-2020 11:50:18 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: COMPLETED	Initial Entry

090177e196ae3f78\Final\Final On: 01-Apr-2021 05:17 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1241

Subject No: 12411206

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-07-2020 11:57:53 (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: 12411206

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
Oct-07-2020 11:57:53 (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-07-2020 11:57:53 (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
Oct-29-2020 06:30:28 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	event term updated in SDB. Issue resolved
Oct-28-2020 11:56:07 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	The AEM will be submitted
Oct-28-2020 00:09:46 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reissued:Opened	SAE RECON 2:Thankk you for the update. Please confirm if a follow up AEM form was submitted to update the event term in Safety database.
Oct-27-2020 17:13:27 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Transcription Error
Oct-27-2020 17:13:27 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Atypical intraductal hyperplasia in left breast	Transcription Error

090177e196ae3f78\Final\Final On: 01-Apr-2021 05:17 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1241

Subject No: 12411206

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: ---

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Oct-27-2020 07:21:44 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reissued:Opened	SAE RECON 1: The event term in Inform was recorded as 'BREAST NODULE REMOVAL'. Per Clinical review event term cannot be a surgical procedure but the underlying diagnosis. Please review the AE term and update to a term for which the procedure was perform
Oct-27-2020 03:27:28 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reissued:Candidate	SAE RECON 1: The event term in Inform was recorded as 'BREAST NODULE REMOVAL'. Per Clinical review event term cannot be a surgical procedure but the underlying diagnosis. Please review the AE term and update to a term for which the procedure was perform
Oct-26-2020 16:23:08 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	A SAE FORM will be sent to update the diagnosis
Oct-25-2020 10:28:41 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	SAE RECON: AER#2020390848 Per Clinical, event term cannot be a surgical procedure but the underlying diagnosis. Please review and enter the AE term for which

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Header Text: c4591001

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Subject No: 12411206

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

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

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				the procedure was performed.
Oct-07-2020 11:57:53 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Breast nodule removal	Initial Entry

4. Start Date Time:

Date	Location	User	Value	Reason
Oct-26-2020 16:19:44 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sep/29/2020 UNK:UNK	Transcription Error
Oct-20-2020 09:30:57 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Oct-15-2020 17:01:52 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Transcription Error
Oct-15-2020 17:01:52 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sep/30/2020 UNK:UNK	Transcription Error
Oct-15-2020 11:31:38 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	As per source, start date is 30Sep2020. Please verify and update, if applicable. Thank you.
Oct-07-2020 11:57:53 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sep/29/2020 UNK:UNK	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Oct-07-2020 11:57:53 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO End Date Time: Sep/30/2020 UNK:UNK	Initial Entry

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Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

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

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6. Toxicity Grade:

Date	Location	User	Value	Reason
Oct-07-2020 11:57:53 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> 2	Initial Entry

7. Is the adverse event serious?

If Yes, NOTIFY PFIZER IMMEDIATELY.

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

Date	Location	User	Value	Reason
Oct-27-2020 03:29:38 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Closed	Response satisfies query
Oct-27-2020 03:27:39 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 3: Deleted	Close Auto Query
Oct-26-2020 16:20:40 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 3: Candidate	For AE Breast nodule removal: Response to "Is the adverse event serious?" is 'Yes' but "Serious Adverse Event Number" is blank.
Oct-26-2020 16:20:40 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Answered	Transcription Error
Oct-26-2020 16:20:40 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> YES Is this serious event associated with congenital anomaly or birth defect? NO	Transcription Error

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			<p>Did this serious event result in death?</p> <p>NO</p> <p>Did this serious event require or prolong hospitalization?</p> <p>YES</p> <p>Did this serious event result in persistent or significant disability/incapacity?</p> <p>NO</p> <p>Is this serious event life threatening?</p> <p>NO</p> <p>Other medically important serious event</p> <p>NO</p>	
Oct-25-2020 10:27:01 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Opened	SAE RECON:Breast nodule removal(Onset date:29Sep2020) was reported as serious to Safety database but non serious on AE CRF. Confirm seriousness. If this event is not serious, please submit a follow up AEM form to downgrade event in Safety

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Subject No: 12411206

Generated By: (b) (4)

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Oct-16-2020 06:52:36 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	seriousness downgraded to NO
Oct-15-2020 10:03:50 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Answer Auto Query
Oct-15-2020 10:03:50 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	MH reported elective procedure
Oct-12-2020 07:52:06 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reissued:Opened	SAE RECON 1: The term appears to be a procedure. Please confirm if the event being reported is breast nodule.
Oct-09-2020 08:56:26 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reissued:Candidate	SAE RECON: For Clinical review
Oct-08-2020 11:59:24 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	It will be reported
Oct-08-2020 08:20:21 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	SAE RECON:Breast nodule removal(Onset date:29Sep2020) is not reported to Safety database but marked serious on AE CRF. Confirm seriousness and report to Pfizer immediately. If this event is not serious, downgrade the event on AE CRF
Oct-07-2020 11:57:53 (UTC-03:00) City of	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	For AE Breast nodule removal:

090177e196ae3f78\Final\Final On: 01-Apr-2021 05:17 (GMT)

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

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Subject Initials: ---

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

Buenos Aires				Response to "Is the adverse event serious?" is 'Yes' but "Serious Adverse Event Number" is blank.
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Oct-07-2020 11:57:53 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<p>Data Entry: 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> <p>YES</p> <p>Did this serious event result in persistent or significant disability/incapacity?</p> <p>NO</p> <p>Is this serious event life threatening?</p> <p>NO</p> <p>Other medically important serious event</p> <p>NO</p>	Initial Entry
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8. Is this adverse event the result of a study Medication Error?
If Yes, record the type of medication error on the Medication Error Log.

Date	Location	User	Value	Reason
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Subject No: 12411206

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

Oct-07-2020 11:57:53 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NO	Initial Entry
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9. Is this event related to study treatment:

Date	Location	User	Value	Reason
Oct-28-2020 05:02:35 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2 : Closed	Response satisfies query
Oct-27-2020 17:14:27 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 2 : Answered	Transcription Error
Oct-27-2020 17:14:27 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NOT RELATED If Not Related to study treatment(s), this event is due to: OTHER If Other, sp	Transcription Error

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Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1241

Subject No: 12411206

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

			<i>ecif</i> y:	
Oct-27-2020 09:16:19 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000.InFormAdapter.Discrepancy	PFE SDQ PROD (b) (4)	Query 2 : Opened	Please review "If not related to study treatment other" field, the following text was indicated in the comment field [Benign nodule]. Any symptoms, AEs or other key data should be collected on the appropriate page. Please review and update as necessary. (b) (4)
Oct-08-2020 19:06:28 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	Hayley Wyper (b) (4)	Query 1 : Closed	Response satisfies query

090177e196ae3f78\Final\Final On: 01-Apr-2021 05:17 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1241

Subject No: 12411206

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

<p>Oct-08-2020 12:00:18 (UTC-03:00) City of Buenos Aires</p>	<p>ACV0PFEINFP6000</p>	<p>auto query (autoquery)</p>	<p>Query 1 : Answered</p>	<p>Transcription Error</p>
<p>Oct-08-2020 12:00:18 (UTC-03:00) City of Buenos Aires</p>	<p>ACV0PFEINFP6000</p>	<p>(b) (4), (b) (6)</p>	<p>Data Entry: NOT RELATED If Not Related to study treatment(s), this event is due to: OTHER <i>If Other, specify:</i> Benign nodules</p>	<p>Transcription Error</p>

090177e196ae3f78\Final\Final On: 01-Apr-2021 05:17 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1241

Subject No: 12411206

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

Oct-08-2020 07:29:21 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	Hayley Wyper (b) (4)	Query 1 : Opened	CLINQUERY: The indication for the procedure should be captured here. The MH reports the Breast Lump.
Oct-07-2020 11:57:53 (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> Surgery	Initial Entry

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
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090177e196ae3f78\Final\Final On: 01-Apr-2021 05:17 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1241

Subject No: 12411206

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

Oct-07-2020 11:57:53 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NOT APPLICABLE	Initial Entry
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11. Was a Concomitant Medication given?

Date	Location	User	Value	Reason
Oct-07-2020 11:57:53 (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-07-2020 11:57:53 (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-07-2020 11:57:53 (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-07-2020 11:57:53 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

090177e196ae3f78\Final\Final On: 01-Apr-2021 05:17 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1241

Subject No: 12411206

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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15. Serious Adverse Event Number: For Pfizer Use Only

Date	Location	User	Value	Reason
Oct-27-2020 03:27:39 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 2020390848	Initial Entry

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: 12411206

Subject Initials: ---

Generated By: (b) (4)

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

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1. Date of Visit

Date	Location	User	Value	Reason
Feb-01-2021 16:53:40 (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: 12411206

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-01-2021 16:53:45 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Participant is willing to return for Vaccination 3 Participant is: eligible and NOT confirme d to have received only pla cebo at Vaccination 1/2	Initial Entry

Header Text: c4591001

Visit: Disposition - Unscheduled

Form: TREATMENT UNBLINDED - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1241

Site Name: (1241) Hospital Irma Dulce

Subject No: 12411206

Subject Initials: ---

Generated By: (b) (4)

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

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1. Date Treatment Unblinded :

Date	Location	User	Value	Reason
Feb-01-2021 16:53:28 (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-01-2021 16:53:28 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: ASSESS ELIGIBILITY FOR ADDITIONAL VACCINATI ON	Initial Entry

090177e196ae3f78\Final\Final On: 01-Apr-2021 05:17 (GMT)

Header Text: c4591001

Visit: Subject Status - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1241

Subject No: 12411206

Generated By: (b) (4)

Form: SUBJECT STATUS - eCRF Audit Trail History

Form Status: Data Complete, Verified

Site Name: (1241) Hospital Irma Dulce

Subject Initials: ---

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

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1. Subject Status

Date	Location	User	Value	Reason
Oct-07-2020 11:50:18 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: FOLLOW-UP	Initial Entry
Aug-18-2020 11:40:40 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: ENROLLED/RANDOMIZED	Initial Entry
Aug-18-2020 11:38:03 (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
Oct-07-2020 11:50:18 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Oct/7/2020	Initial Entry
Aug-18-2020 11:40:40 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Aug/18/2020	Initial Entry
Aug-18-2020 11:38:03 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Aug/18/2020	Initial Entry

090177e196ae3f78\Final\Final On: 01-Apr-2021 05:17 (GMT)

Header Text: c4591001

Visit: Investigator Signature - Unscheduled

Form: CASEBOOK SIGNATURE FORM - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Signed, Verified

Site No: 1241

Site Name: (1241) Hospital Irma Dulce

Subject No: 12411206

Subject Initials: ---

Generated By: (b) (4)

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

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1. Casebook Signature

Date	Location	User	Value	Reason
Oct-22-2020 22:58:03 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	Edson Moreira (b) (4)	Data Entry: Click Here to Enable	Initial Entry