

Header Text: C4591001

Visit: COHORT_SELECTION

Form: COHORT_SELECTION

Form Version: 10-Oct-2020 16:01

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1210

Site Name: (1210) Medipol University Medical Faculty

Subject No: 12101029

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:11

[eCRF Audit Trail History](#)

Cohort Selection

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

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

Header Text: C4591001

Visit: COHORT_SELECTION

Form Version: 22-Apr-2020 21:02

Site No: 1210

Subject No: 12101029

Generated By: (b) (4)

Form: MAIN INFORMED CONSENT

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1210) Medipol University Medical Faculty

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:11

[eCRF Audit Trail History](#)

Informed Consent

1.	Consent Was:	OBTAINED Date Written Consent Obtained Oct/30/2020
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Header Text: C4591001

Visit: COHORT_SELECTION

Form: DEMOGRAPHY

Form Version: 15-Sep-2020 21:54

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1210

Site Name: (1210) Medipol University Medical Faculty

Subject No: 12101029

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:11

[eCRF Audit Trail History](#)

Demography

1.	Subject ID	[12101029]
2.	Birth Date:	(b) (6)/1983
3.	Sex:	MALE
4.	Ethnicity:	NOT HISPANIC OR LATINO(A) OR OF SPANISH ORIGIN
5.	Race: (Check X all that apply):	WHITE
6.	Racial Designation:	

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:02

Site No: 1210

Subject No: 12101029

Generated By: (b) (4)

Form: DATE OF VISIT

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1210) Medipol University Medical Faculty

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:11

[eCRF Audit Trail History](#)

Date of Visit

1.	Date of Visit	Oct/30/2020
2.	Erroneous Visit	

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 10-Oct-2020 16:00

Site No: 1210

Subject No: 12101029

Generated By: (b) (4)

Form: INCLUSION/EXCLUSION CRITERIA

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1210) Medipol University Medical Faculty

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:11

Form Comments

Inclusion Criteria Not Met

1.	Description of Inclusion Criterion Not Met	Not Applicable
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Exclusion Criteria Met

2.	Description of Exclusion Criterion Met	Not Applicable
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090177e196ae2fe0\Final\Final On: 01-Apr-2021 03:54 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 15-Sep-2020 21:52

Site No: 1210

Subject No: 12101029

Generated By: (b) (4)

Form: DISPOSITION - SCREENING

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1210) Medipol University Medical Faculty

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:11

[eCRF Audit Trail History](#)

Disposition - Screening

1.	Date of Completion/Discontinuation/Death	Oct/30/2020
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: 1210

Subject No: 12101029

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1210) Medipol University Medical Faculty

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:11

Form Comments

Medical History Details

1.	Line/MH Number:	Not Applicable _____
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	Not Applicable _____
	Start Date:	Not Applicable _____ //
	Ongoing:	Not Applicable _____

090177e196ae2fe0\Final\Final On: 01-Apr-2021 03:54 (GMT)

Header Text: C4591001	Form: HIV STATUS
Visit: V1_DAY1_VAX1_L	Form Status: Data Complete, Locked, Frozen, Verified
Form Version: 15-Sep-2020 21:57	Site Name: (1210) Medipol University Medical Faculty
Site No: 1210	Subject Initials: ---
Subject No: 12101029	Generated Time (GMT): 29-Mar-2021 13:11
Generated By: (b) (4)	

[eCRF Audit Trail History](#)

HIV Status

1.	Select appropriate response - What is the subject HIV status?	The subject is NOT known to be HIV POSITIVE
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Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 10-Oct-2020 16:04

Site No: 1210

Subject No: 12101029

Generated By: (b) (4)

Form: VITAL SIGNS - BASELINE

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1210) Medipol University Medical Faculty

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:11

[eCRF Audit Trail History](#)

Vital Signs

1.	Date:	Oct/30/2020
2.	Weight:	[105.0]
3.	Unit:	kg
4.	Height:	[173.0]
5.	Unit:	cm
6.	Body Mass Index:	[35.1]

Vital Signs Details

7.a	Record Identifier:	1
	Temperature:	[36.1]
	Unit:	C
	Temperature Location:	FOREHEAD

090177e196ae2fe0\Final\Final On: 01-Apr-2021 03:54 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1210

Subject No: 12101029

Generated By: (b) (4)

Form: RANDOMIZATION

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1210) Medipol University Medical Faculty

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:11

[eCRF Audit Trail History](#)

Disposition

1.	Randomization Date :	Oct/30/2020
2.	Randomization Number:	[114945]
3.	Randomization Group:	[]

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1210

Subject No: 12101029

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1210) Medipol University Medical Faculty

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:11

[eCRF Audit Trail History](#)

Electronic Sample Tracking

1.	Data Origin	SITE
2.	Sample Type	SERUM
3.	Sample Collected?	YES Date of Collection: Oct/30/2020
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	[BSHB2Z]
5.b	Sample ID	[BSHB30]
5.c	Sample ID	[BRCXNM]
5.d	Sample ID	[BRCXNN]

090177e196ae2fe0\Final\Final On: 01-Apr-2021 03:54 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1210

Subject No: 12101029

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1210) Medipol University Medical Faculty

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:11

[eCRF Audit Trail History](#)

Electronic Sample Tracking

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB
3.	Sample Collected?	YES Date of Collection: Oct/30/2020
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	[BSHB2Z]
5.b	Sample ID	[BSHB30]
5.c	Sample ID	[BRCXP3]

090177e196ae2fe0\Final\Final On: 01-Apr-2021 03:54 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:04

Site No: 1210

Subject No: 12101029

Generated By: (b) (4)

Form: VACCINATION

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1210) Medipol University Medical Faculty

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:11

[eCRF Audit Trail History](#)

Vaccination

1.	Was there a temporary delay of vaccination?	NO
2.	Treatment Name	[BLINDED THERAPY]
3.	Formulation:	INJECTION
4.	Dose Date Time:	Oct/30/2020 15:57
5.	Anatomical Location:	DELTOID MUSCLE
6.	Body Side:	LEFT
7.	Route:	INTRAMUSCULAR
8.	Actual Dose:	[]
9.	Unit:	
10.	Timeframe Subject Was Observed	THE PROTOCOL SPECIFIED OBSERVATION PERIOD
11.	Was the subject observed for at least the protocol specified observation period after investigational product administration?	YES

090177e196ae2fe0\Final\Final On: 01-Apr-2021 03:54 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 06-Jul-2020 21:53

Site No: 1210

Subject No: 12101029

Generated By: (b) (4)

Form: REACTOGENICITY DIARY

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1210) Medipol University Medical Faculty

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:11

[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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Header Text: C4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:02

Site No: 1210

Subject No: 12101029

Generated By: (b) (4)

Form: DATE OF VISIT

Form Status: Data Complete, Frozen, Verified

Site Name: (1210) Medipol University Medical Faculty

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:11

[eCRF Audit Trail History](#)

Date of Visit

1.	Date of Visit	Nov/20/2020
2.	Erroneous Visit	

Header Text: C4591001

Visit: V2_VAX2_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES

Form Version: 10-Oct-2020 16:03

Form Status: Data Complete, Frozen, Verified

Site No: 1210

Site Name: (1210) Medipol University Medical Faculty

Subject No: 12101029

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:11

[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
2.f	Symptom:	DIARRHEA
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO

090177e196ae2fe0\Final\Final On: 01-Apr-2021 03:54 (GMT)

Header Text: C4591001

Visit: V2_VAX2_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES

Form Version: 10-Oct-2020 16:03

Form Status: Data Complete, Frozen, Verified

Site No: 1210

Site Name: (1210) Medipol University Medical Faculty

Subject No: 12101029

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:11

2.g	Symptom:	NEW OR WORSENERED MUSCLE PAIN
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO
2.h	Symptom:	NEW OR WORSENERED 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

090177e196ae2fe0\Final\Final On: 01-Apr-2021 03:54 (GMT)

Header Text: C4591001

Visit: V2_VAX2_L

Form Version: 10-Oct-2020 16:01

Site No: 1210

Subject No: 12101029

Generated By: (b) (4)

Form: VITAL SIGNS - TEMP

Form Status: Data Complete, Frozen, Verified

Site Name: (1210) Medipol University Medical Faculty

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:11

[eCRF Audit Trail History](#)

Vital Signs

1.	Date:	Nov/20/2020
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Vital Signs Details

2.a	Record Identifier:	1
	Temperature:	[36.1]
	Unit:	C
	Temperature Location:	FOREHEAD

Header Text: C4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:03

Site No: 1210

Subject No: 12101029

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB

Form Status: Data Complete, Frozen, Verified

Site Name: (1210) Medipol University Medical Faculty

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:11

[eCRF Audit Trail History](#)

Electronic Sample Tracking

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB
3.	Sample Collected?	YES Date of Collection: Nov/20/2020
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	[BR5DKX]
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090177e196ae2fe0\Final\Final On: 01-Apr-2021 03:54 (GMT)

Header Text: C4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:04

Site No: 1210

Subject No: 12101029

Generated By: (b) (4)

Form: VACCINATION

Form Status: Data Complete, Frozen, Verified

Site Name: (1210) Medipol University Medical Faculty

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:11

[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:	Nov/20/2020 10:07
5.	Anatomical Location:	DELTOID MUSCLE
6.	Body Side:	LEFT
7.	Route:	INTRAMUSCULAR
8.	Actual Dose:	[]
9.	Unit:	
10.	Timeframe Subject Was Observed	THE PROTOCOL SPECIFIED OBSERVATION PERIOD
11.	Was the subject observed for at least the protocol specified observation period after investigational product administration?	YES

090177e196ae2fe0\Final\Final On: 01-Apr-2021 03:54 (GMT)

Header Text: C4591001

Visit: V3_MONTH1_POSTVAX2_L

Form Version: 22-Apr-2020 21:02

Site No: 1210

Subject No: 12101029

Generated By: (b) (4)

Form: DATE OF VISIT

Form Status: Data Complete, Frozen, Verified

Site Name: (1210) Medipol University Medical Faculty

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:11

[eCRF Audit Trail History](#)

Date of Visit

1.	Date of Visit	Dec/18/2020
2.	Erroneous Visit	

Header Text: C4591001

Visit: V3_MONTH1_POSTVAX2_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES

Form Version: 10-Oct-2020 16:03

Form Status: Data Complete, Frozen, Verified

Site No: 1210

Site Name: (1210) Medipol University Medical Faculty

Subject No: 12101029

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:11

[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
2.f	Symptom:	DIARRHEA
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO

090177e196ae2fe0\Final\Final On: 01-Apr-2021 03:54 (GMT)

Header Text: C4591001

Visit: V3_MONTH1_POSTVAX2_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES

Form Version: 10-Oct-2020 16:03

Form Status: Data Complete, Frozen, Verified

Site No: 1210

Site Name: (1210) Medipol University Medical Faculty

Subject No: 12101029

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:11

2.g	Symptom:	NEW OR WORSENERED MUSCLE PAIN
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO
2.h	Symptom:	NEW OR WORSENERED 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

090177e196ae2fe0\Final\Final On: 01-Apr-2021 03:54 (GMT)

Header Text: C4591001

Visit: V3_MONTH1_POSTVAX2_L

Form Version: 22-Apr-2020 21:03

Site No: 1210

Subject No: 12101029

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Status: Data Complete, Frozen, Verified

Site Name: (1210) Medipol University Medical Faculty

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:11

[eCRF Audit Trail History](#)

Electronic Sample Tracking

1.	Data Origin	SITE
2.	Sample Type	SERUM
3.	Sample Collected?	YES Date of Collection: Dec/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	[BRCXWC]
5.b	Sample ID	[BRCXWD]
5.c	Sample ID	[BSHB6R]
5.d	Sample ID	[BSHB6S]

090177e196ae2fe0\Final\Final On: 01-Apr-2021 03:54 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL - New Unscheduled Visit

Form: DATE OF VISIT - ILLNESS ONSET

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1210

Site Name: (1210) Medipol University Medical Faculty

Subject No: 12101029

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:11

Date of Visit

1.	Date of Visit	//
2.	Erroneous Visit	

COVID-19 Illness Visit

3.	COVID-19 Illness Visit:	
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090177e196ae2fe0\Final\Final On: 01-Apr-2021 03:54 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL - New Unscheduled Visit

Form: SIGNS AND SYMPTOMS OF POTENTIAL COVID-19

Form Version: 20-Feb-2021 02:17

Form Status: Not Started

Site No: 1210

Site Name: (1210) Medipol University Medical Faculty

Subject No: 12101029

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:11

Signs and Symptoms

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

Symptoms

4.	Symptoms:	
	Was symptom present?	

Symptoms - Other

5.	Symptoms - Other Text:	[]
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Header Text: C4591001

Visit: POT_COVID_ILL - New Unscheduled Visit

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB SELF

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1210

Site Name: (1210) Medipol University Medical Faculty

Subject No: 12101029

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:11

Electronic Sample Tracking

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

Aliquot

Please enter barcode for each aliquot.

5.	Sample ID	[]
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Header Text: C4591001

Visit: POT_COVID_ILL - New Unscheduled Visit

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1210

Site Name: (1210) Medipol University Medical Faculty

Subject No: 12101029

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:11

Electronic Sample Tracking

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

Aliquot

Please enter barcode for each aliquot.

5.	Sample ID	[]
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Header Text: C4591001

Visit: POT_COVID_ILL - New Unscheduled Visit

Form: HEALTH CARE UTILIZATION

Form Version: 20-Feb-2021 02:19

Form Status: Not Started

Site No: 1210

Site Name: (1210) Medipol University Medical Faculty

Subject No: 12101029

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:11

Health Care Utilization

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

Health Care Utilization Other

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

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

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: 1210

Site Name: (1210) Medipol University Medical Faculty

Subject No: 12101029

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:11

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: 1210

Site Name: (1210) Medipol University Medical Faculty

Subject No: 12101029

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:11

Date of Visit

1.	Date of Visit	//
2.	Erroneous Visit	

COVID-19 Illness Visit

3.	COVID-19 Illness Visit:	
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Header Text: C4591001

Visit: POT_COVID_CONVA - New
Unscheduled Visit

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1210

Site Name: (1210) Medipol University Medical Faculty

Subject No: 12101029

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:11

Electronic Sample Tracking

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

Aliquot

Please enter barcode for each aliquot.

5.	Sample ID	[]
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Header Text: C4591001

Visit: POT_COVID_REPEAT_SWAB - New
Unscheduled Visit

Form: DATE OF VISIT - REPEAT SWAB

Form Version: 10-Oct-2020 15:57

Form Status: Not Started

Site No: 1210

Site Name: (1210) Medipol University Medical Faculty

Subject No: 12101029

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:11

Date of Visit

1.	Date of Visit	//
2.	Erroneous Visit	

COVID-19 Repeat Swab

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

Header Text: C4591001

Visit: POT_COVID_REPEAT_SWAB - New
Unscheduled Visit

Form: ELECTRONIC SAMPLE TRACKING - REPEAT SWAB

Form Version: 10-Oct-2020 15:57

Form Status: Not Started

Site No: 1210

Site Name: (1210) Medipol University Medical Faculty

Subject No: 12101029

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:11

Electronic Sample Tracking

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

Aliquot

Please enter barcode for each aliquot.

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

Header Text: C4591001

Visit: Logs

Form: ADVERSE EVENT REPORT

Form Version: 22-Apr-2020 21:02

Site No: 1210

Site Name: (1210) Medipol University Medical Faculty

Subject No: 12101029

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:11

#	Category	AE Identifier	Adverse Event	Start Date	Is the Adverse Event Still Ongoing	Form Instance
1.	ADVERSE EVENT	1	joint pain	Nov/4/2020 20:00	NO End Date Time: Nov/5/2020 08:00	Repeating Pages
2.	ADVERSE EVENT	2	Axillary lymphadenopathy on the left.	Jan/20/2021 UNK:UNK	NO End Date Time: Jan/23/2021 UNK:UNK	Repeating Pages

090177e196ae2fe0\Final\Final On: 01-Apr-2021 03:54 (GMT)

Header Text: C4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1210

Subject No: 12101029

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1210) Medipol University Medical Faculty

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:11

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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)	[joint pain]
4.	Start Date Time:	Nov/4/2020 20:00
5.	Is the adverse event still ongoing?	NO End Date Time: Nov/5/2020 08:00
6.	Toxicity Grade:	3
7.	Is the adverse event serious? If Yes, NOTIFY PFIZER IMMEDIATELY. Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).	NO
8.	Is this adverse event the result of a study Medication Error? If Yes, record the type of medication error on the Medication Error Log.	NO
9.	Is this event related to study treatment:	NOT RELATED If Not Related to study treatment(s), this event is due to: OTHER If Other, specify: [ride motorcycle]
10.	Latest Action Taken with Study Treatment:	NOT APPLICABLE

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Header Text: C4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1210

Subject No: 12101029

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1210) Medipol University Medical Faculty

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:11

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	[]

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Header Text: C4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1210

Subject No: 12101029

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Frozen, Verified

Site Name: (1210) Medipol University Medical Faculty

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:11

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Adverse Event Report

1.	Category:	ADVERSE EVENT
2.	AE ID:	[2]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[Axillary lymphadenopathy on the left.]
4.	Start Date Time:	Jan/20/2021 UNK:UNK
5.	Is the adverse event still ongoing?	NO End Date Time: Jan/23/2021 UNK:UNK
6.	Toxicity Grade:	2
7.	Is the adverse event serious? If Yes, NOTIFY PFIZER IMMEDIATELY. Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).	NO
8.	Is this adverse event the result of a study Medication Error? If Yes, record the type of medication error on the Medication Error Log.	NO
9.	Is this event related to study treatment:	RELATED
10.	Latest Action Taken with Study Treatment:	NOT APPLICABLE
11.	Was a Concomitant Medication given?	NO

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Header Text: C4591001
Visit: Logs - Unscheduled
Form Version: 22-Apr-2020 21:02
Site No: 1210
Subject No: 12101029
Generated By: (b) (4)

Form: ADVERSE EVENT REPORT
Form Status: Data Complete, Frozen, Verified
Site Name: (1210) Medipol University Medical Faculty
Subject Initials: ---
Generated Time (GMT): 29-Mar-2021 13:11

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	[]

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Header Text: C4591001

Visit: Logs

Form: MEDICATION ERROR

Form Version: 17-Jul-2020 21:54

Site No: 1210

Site Name: (1210) Medipol University Medical Faculty

Subject No: 12101029

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:11

#	Category	Medication Error	Start Date	Is the medication error Still Ongoing	Study Medication Errors Action	Form Instance
1.	Not Applicable	Not Applicable	Not Applicable	Not Applicable	Not Applicable	Repeating Pages

Header Text: C4591001

Visit: Logs - Unscheduled

Form Version: 17-Jul-2020 21:54

Site No: 1210

Subject No: 12101029

Generated By: (b) (4)

Form: MEDICATION ERROR

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1210) Medipol University Medical Faculty

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:11

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Medication Error

1.	Category:	Not Applicable _____	Comments
2.	Medication Error (Type of Medication Error):	Not Applicable _____ []	Comments
3.	Start Date:	Not Applicable _____ //	Comments
4.	Is the medication error still ongoing?	Not Applicable _____	Comments
5.	Latest Action Taken with Study Treatment:	Not Applicable _____	Comments
6.	Was a Concomitant Medication given?	Not Applicable _____	Comments
7.	Was a Non-Drug Treatment given?	Not Applicable _____	Comments
8.	Did the Medication Error cause the subject to be discontinued from the study?	Not Applicable _____	Comments
9.	Was this medication error associated with any adverse events?	Not Applicable _____	Comments
10.	Serious Adverse Event Number: For Pfizer Use Only	Not Applicable _____ []	Comments

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Header Text: C4591001

Visit: Logs

Form: CONCOMITANT MEDICATIONS - NON STUDY
VACCINATIONS

Form Version: 22-Apr-2020 21:03

Site No: 1210

Site Name: (1210) Medipol University Medical Faculty

Subject No: 12101029

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:11

#	Sponsor-Defined Identifier	Category for Medication	Concomitant Medications Pre-specified	Name of Medication	Start Date	Form Instance
1.	Not Applicable	Not Applicable	Not Applicable	Not Applicable	Not Applicable	Repeating Pages

Header Text: C4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1210

Subject No: 12101029

Generated By: (b) (4)

Form: CONCOMITANT MEDICATIONS - NON STUDY VACCINATIONS

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1210) Medipol University Medical Faculty

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:11

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[eCRF Audit Trail History](#)

Concomitant Medications

1.	What is the medication identifier?	Not Applicable _____ []	Comments
2.	Category:	Not Applicable _____	Comments
3.	Concomitant Medications Pre-specified:	Not Applicable _____	Comments
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).	Not Applicable _____ []	Comments
5.	Date:	Not Applicable _____ //	Comments

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Header Text: C4591001

Visit: Logs

Form: CONCOMITANT MEDICATIONS - PROHIBITED

Form Version: 22-Apr-2020 21:03

Site No: 1210

Site Name: (1210) Medipol University Medical Faculty

Subject No: 12101029

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:11

#	Sponsor-Defined Identifier	Category for Medication	Concomitant Medications Pre-specified	Name of Medication	Dose Description	Form Instance
1.	Not Applicable	Not Applicable	Not Applicable	Not Applicable	Not Applicable	Repeating Pages

Header Text: C4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1210

Subject No: 12101029

Generated By: (b) (4)

Form: CONCOMITANT MEDICATIONS - PROHIBITED

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1210) Medipol University Medical Faculty

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:11

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Concomitant Medications

1.	What is the medication identifier?	Not Applicable _____ []	Comments
2.	Category:	Not Applicable _____	Comments
3.	Concomitant Medications Pre-specified:	Not Applicable _____	Comments
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).	Not Applicable _____ []	Comments
5.	Dose:	Not Applicable _____ []	Comments
6.	Dose Unit:	Not Applicable _____	Comments
7.	Dose Frequency:	Not Applicable _____	Comments
8.	Route:	Not Applicable _____	Comments
9.	Start Date:	Not Applicable _____ //	Comments
10.	Ongoing?	Not Applicable _____	Comments

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Header Text: C4591001

Visit: Logs

Form: RADIATION TREATMENT

Form Version: 22-Apr-2020 21:02

Site No: 1210

Site Name: (1210) Medipol University Medical Faculty

Subject No: 12101029

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:11

#	Category	Treatment Identifier	Con Non-Drug Treatments Pre-specified	Treatment	Start Date	Form Instance
1.	Not Applicable	Not Applicable	Not Applicable	Not Applicable	Not Applicable	Repeating Pages

Header Text: C4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1210

Subject No: 12101029

Generated By: (b) (4)

Form: RADIATION TREATMENT

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1210) Medipol University Medical Faculty

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:11

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Radiation Treatment

1.	Category:	Not Applicable _____	Comments
2.	What is the treatment Identifier?	Not Applicable _____ []	Comments
3.	Concomitant Non-drug Treatment Pre-specified:	Not Applicable _____	Comments
4.	Treatment:	Not Applicable _____ []	Comments
5.	Start Date:	Not Applicable _____ //	Comments
6.	Ongoing?	Not Applicable _____	Comments

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Header Text: C4591001

Visit: Logs

Form: TRANSFUSIONS

Form Version: 22-Apr-2020 21:03

Site No: 1210

Site Name: (1210) Medipol University Medical Faculty

Subject No: 12101029

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:11

#	Transfusion Type	Date of Transfusion	Form Instance
1.	Not Applicable	Not Applicable	Repeating Pages

Header Text: C4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1210

Subject No: 12101029

Generated By: (b) (4)

Form: TRANSFUSIONS

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1210) Medipol University Medical Faculty

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:11

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1.	Transfusion Type:	Not Applicable _____	Comments
2.	Date of Transfusion:	Not Applicable _____ //	Comments

Header Text: C4591001

Visit: Unplanned 1 - Unscheduled Visit on
Nov/05/2020

Form: DATE OF VISIT

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen, Verified

Site No: 1210

Site Name: (1210) Medipol University Medical Faculty

Subject No: 12101029

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:11

[eCRF Audit Trail History](#)

Date of Visit

1.	Date of Visit	Nov/5/2020
2.	Erroneous Visit	

Header Text: C4591001

Visit: Unplanned 1 - Unscheduled Visit on
Nov/05/2020

Form: UNPLANNED VISIT

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Frozen, Verified

Site No: 1210

Site Name: (1210) Medipol University Medical Faculty

Subject No: 12101029

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:11

[eCRF Audit Trail History](#)

Unplanned Assessments

1.	Assessments	CONTACT OUTCOME
----	-------------	-----------------

Header Text: C4591001

Visit: Unplanned 1 - Unscheduled Visit on
Nov/05/2020

Form: CONTACT OUTCOME - UNPLANNED

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Frozen, Verified

Site No: 1210

Site Name: (1210) Medipol University Medical Faculty

Subject No: 12101029

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:11

[eCRF Audit Trail History](#)

Contact Outcome

1.	Contact Type:	TELEPHONE VISIT
2.	Was contact made?	YES Date of Contact: Nov/5/2020 Contact Outcome: VISIT NOT ARRANGED, REACTION NO LONGER PRESENT
3.	Comments:	[patient had joint pain which was started on 04 Nov 2020. Patient rides motorcycle in his daily life. Investigator evaluated this event as not reactogenicity. Joint pain recovered on 05 Nov 2020.]

Header Text: C4591001

Visit: Unplanned Vaccination - Unscheduled

Form: DATE OF VISIT

Form Version: 22-Apr-2020 21:02

Form Status: Not Started

Site No: 1210

Site Name: (1210) Medipol University Medical Faculty

Subject No: 12101029

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:11

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: 1210

Site Name: (1210) Medipol University Medical Faculty

Subject No: 12101029

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:11

Vital Signs

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

Vital Signs Details

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

Header Text: C4591001

Visit: Unplanned Vaccination - Unscheduled

Form: VACCINATION

Form Version: 10-Dec-2020 02:26

Form Status: Not Started

Site No: 1210

Site Name: (1210) Medipol University Medical Faculty

Subject No: 12101029

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:11

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?	

090177e196ae2fe0\Final\Final On: 01-Apr-2021 03:54 (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: 1210

Site Name: (1210) Medipol University Medical Faculty

Subject No: 12101029

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:11

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: 1210

Site Name: (1210) Medipol University Medical Faculty

Subject No: 12101029

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:11

Contact Outcome

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

Header Text: C4591001

Visit: End of Treatment - Unscheduled

Form Version: 10-Dec-2020 02:29

Site No: 1210

Subject No: 12101029

Generated By: (b) (4)

Form: DISPOSITION - TREATMENT

Form Status: Data Complete, Frozen, Verified

Site Name: (1210) Medipol University Medical Faculty

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:11

[eCRF Audit Trail History](#)

Disposition - Treatment

1.	Date of Completion/Discontinuation/Death :	Dec/18/2020
2.	Phase of Disposition:	VACCINATION
3.	Status:	COMPLETED
4.	Specify Status:	[]

Header Text: C4591001

Visit: Potential ReVax Initial Contact -
Unscheduled

Form: DATE OF VISIT

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen, Verified

Site No: 1210

Site Name: (1210) Medipol University Medical Faculty

Subject No: 12101029

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:11

[eCRF Audit Trail History](#)

Date of Visit

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

Header Text: C4591001

Visit: Potential ReVax Initial Contact -
Unscheduled

Form: FURTHER VACCINATION CONFIRMATION

Form Version: 10-Dec-2020 02:25

Form Status: Data Complete, Frozen, Verified

Site No: 1210

Site Name: (1210) Medipol University Medical Faculty

Subject No: 12101029

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:11

[eCRF Audit Trail History](#)

Further Vaccination Confirmation

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

Header Text: C4591001

Visit: Follow-Up - Unscheduled

Form Version: 15-Sep-2020 21:53

Site No: 1210

Subject No: 12101029

Generated By: (b) (4)

Form: DISPOSITION - FOLLOW-UP

Form Status: Not Started

Site Name: (1210) Medipol University Medical Faculty

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:11

Disposition - Follow-Up

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

Header Text: C4591001

Visit: V101_VAX3

Form Version: 22-Apr-2020 21:02

Site No: 1210

Subject No: 12101029

Generated By: (b) (4)

Form: DATE OF VISIT

Form Status: Data Complete, Frozen, Verified

Site Name: (1210) Medipol University Medical Faculty

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:11

[eCRF Audit Trail History](#)

Date of Visit

1.	Date of Visit	Dec/29/2020
2.	Erroneous Visit	

Header Text: C4591001

Visit: V101_VAX3

Form Version: 10-Dec-2020 02:31

Site No: 1210

Subject No: 12101029

Generated By: (b) (4)

Form: INFORMED CONSENT - FURTHER VACCINATION

Form Status: Data Complete, Frozen, Verified

Site Name: (1210) Medipol University Medical Faculty

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:11

[eCRF Audit Trail History](#)

Informed Consent - Further Vaccination

1.	Consent Was:	OBTAINED Date Written Consent Obtained Dec/29/2020
----	--------------	--

Header Text: C4591001

Visit: V101_VAX3

Form: INCLUSION/EXCLUSION CRITERIA - FURTHER VACCINATION

Form Version: 10-Dec-2020 02:30

Form Status: Data Complete, Frozen, Verified

Site No: 1210

Site Name: (1210) Medipol University Medical Faculty

Subject No: 12101029

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:11

Form Comments

Inclusion Criteria Not Met

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

Exclusion Criteria Met

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

Header Text: C4591001

Visit: V101_VAX3

Form Version: 10-Dec-2020 02:31

Site No: 1210

Subject No: 12101029

Generated By: (b) (4)

Form: DISPOSITION - SCREENING FOR FURTHER VACCINATION

Form Status: Data Complete, Frozen, Verified

Site Name: (1210) Medipol University Medical Faculty

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:11

[eCRF Audit Trail History](#)

Disposition - Screening for Further Vaccination

1.	Date of Completion/Discontinuation/Death :	Dec/29/2020
2.	Phase of Disposition:	REPEAT SCREENING 1
3.	Status:	COMPLETED
4.	Specify Status:	[]

Header Text: C4591001

Visit: V101_VAX3

Form Version: 22-Apr-2020 21:03

Site No: 1210

Subject No: 12101029

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Status: Data Complete, Frozen, Verified

Site Name: (1210) Medipol University Medical Faculty

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:11

[eCRF Audit Trail History](#)

Electronic Sample Tracking

1.	Data Origin	SITE
2.	Sample Type	SERUM
3.	Sample Collected?	YES Date of Collection: Dec/29/2020
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	[BR5DM4]
5.b	Sample ID	[BR5DM5]
5.c	Sample ID	[BSHB8X]
5.d	Sample ID	[BSHB8Y]

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Header Text: C4591001

Visit: V101_VAX3

Form Version: 22-Apr-2020 21:03

Site No: 1210

Subject No: 12101029

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB

Form Status: Data Complete, Frozen, Verified

Site Name: (1210) Medipol University Medical Faculty

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:11

[eCRF Audit Trail History](#)

Electronic Sample Tracking

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB
3.	Sample Collected?	YES Date of Collection: Dec/29/2020
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	[BR5DMB]
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090177e196ae2fe0\Final\Final On: 01-Apr-2021 03:54 (GMT)

Header Text: C4591001

Visit: V101_VAX3

Form Version: 10-Dec-2020 02:26

Site No: 1210

Subject No: 12101029

Generated By: (b) (4)

Form: VACCINATION

Form Status: Data Complete, Frozen, Verified

Site Name: (1210) Medipol University Medical Faculty

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:11

[eCRF Audit Trail History](#)

Vaccination

1.	Was there a temporary delay of vaccination?	NO
2.	Treatment Name	[BNT162b2]
3.	Formulation:	INJECTION
4.	Dose Date Time:	Dec/29/2020 14:25
5.	Anatomical Location:	DELTOID MUSCLE
6.	Body Side:	LEFT
7.	Route:	INTRAMUSCULAR
8.	Actual Dose:	[30.0]
9.	Unit:	ug
10.	Timeframe Subject Was Observed	30 MINUTES
11.	Was the subject observed for at least the protocol specified observation period after investigational product administration?	YES

090177e196ae2fe0\Final\Final On: 01-Apr-2021 03:54 (GMT)

Header Text: C4591001

Visit: Disposition - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1210

Subject No: 12101029

Generated By: (b) (4)

Form: TREATMENT UNBLINDED

Form Status: Data Complete, Frozen, Verified

Site Name: (1210) Medipol University Medical Faculty

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:11

[eCRF Audit Trail History](#)

Treatment Unblinded

1.	Date Treatment Unblinded :	Dec/28/2020
2.	Primary Reason for Unblinding:	ASSESS ELIGIBILITY FOR ADDITIONAL VACCINATION

Header Text: C4591001

Visit: Disposition - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1210

Subject No: 12101029

Generated By: (b) (4)

Form: WITHDRAWAL OF CONSENT

Form Status: Data Complete, Verified

Site Name: (1210) Medipol University Medical Faculty

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:11

[Form Comments](#)

[eCRF Audit Trail History](#)

Withdrawal Of Consent

			Comments
1.	Withdrawal of Consent Date :	Not Applicable _____ //	

Header Text: C4591001

Visit: Disposition - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1210

Subject No: 12101029

Generated By: (b) (4)

Form: DEATH DETAILS CODED

Form Status: Data Complete, Verified

Site Name: (1210) Medipol University Medical Faculty

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:11

[Form Comments](#)

[eCRF Audit Trail History](#)

Death Details

1.	Date of Collection / Notification of Death:	Not Applicable _____ //	Comments
----	---	-------------------------------	--------------------------

Cause of Death

2.	Cause of Death Status:	Not Applicable _____
	Cause of Death:	Not Applicable _____ []

090177e196ae2fe0\Final\Final On: 01-Apr-2021 03:54 (GMT)

Header Text: C4591001

Visit: V102_VAX4

Form Version: 22-Apr-2020 21:02

Site No: 1210

Subject No: 12101029

Generated By: (b) (4)

Form: DATE OF VISIT

Form Status: Data Complete, Frozen, Verified

Site Name: (1210) Medipol University Medical Faculty

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:11

[eCRF Audit Trail History](#)

Date of Visit

1.	Date of Visit	Jan/19/2021
2.	Erroneous Visit	

Header Text: C4591001

Visit: V102_VAX4

Form Version: 22-Apr-2020 21:03

Site No: 1210

Subject No: 12101029

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB

Form Status: Data Complete, Frozen, Verified

Site Name: (1210) Medipol University Medical Faculty

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:11

[eCRF Audit Trail History](#)

Electronic Sample Tracking

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB
3.	Sample Collected?	YES Date of Collection: Jan/19/2021
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	[BR0Z02]
-----	-----------	----------

090177e196ae2fe0\Final\Final On: 01-Apr-2021 03:54 (GMT)

Header Text: C4591001

Visit: V102_VAX4

Form Version: 10-Dec-2020 02:26

Site No: 1210

Subject No: 12101029

Generated By: (b) (4)

Form: VACCINATION

Form Status: Data Complete, Frozen, Verified

Site Name: (1210) Medipol University Medical Faculty

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:11

[eCRF Audit Trail History](#)

Vaccination

1.	Was there a temporary delay of vaccination?	NO
2.	Treatment Name	[BNT162b2]
3.	Formulation:	INJECTION
4.	Dose Date Time:	Jan/19/2021 09:55
5.	Anatomical Location:	DELTOID MUSCLE
6.	Body Side:	LEFT
7.	Route:	INTRAMUSCULAR
8.	Actual Dose:	[30.0]
9.	Unit:	ug
10.	Timeframe Subject Was Observed	30 MINUTES
11.	Was the subject observed for at least the protocol specified observation period after investigational product administration?	YES

090177e196ae2fe0\Final\Final On: 01-Apr-2021 03:54 (GMT)

Header Text: C4591001

Visit: V103_MONTH1

Form Version: 22-Apr-2020 21:02

Site No: 1210

Subject No: 12101029

Generated By: (b) (4)

Form: DATE OF VISIT

Form Status: Data Complete, Frozen, Verified

Site Name: (1210) Medipol University Medical Faculty

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:11

[eCRF Audit Trail History](#)

Date of Visit

1.	Date of Visit	Feb/16/2021
2.	Erroneous Visit	

Header Text: C4591001

Visit: V103_MONTH1

Form Version: 22-Apr-2020 21:04

Site No: 1210

Subject No: 12101029

Generated By: (b) (4)

Form: CONTACT OUTCOME

Form Status: Data Complete, Frozen, Verified

Site Name: (1210) Medipol University Medical Faculty

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:11

[eCRF Audit Trail History](#)

Contact Outcome

1.	Contact Type:	TELEPHONE VISIT
2.	Was contact made?	YES Date of Contact: Feb/16/2021
3.	Comments:	[]

Header Text: C4591001

Visit: V104_MONTH6

Form Version: 22-Apr-2020 21:02

Site No: 1210

Subject No: 12101029

Generated By: (b) (4)

Form: DATE OF VISIT

Form Status: Not Started

Site Name: (1210) Medipol University Medical Faculty

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:11

Date of Visit

1.	Date of Visit	//
2.	Erroneous Visit	

Header Text: C4591001

Visit: V104_MONTH6

Form Version: 22-Apr-2020 21:04

Site No: 1210

Subject No: 12101029

Generated By: (b) (4)

Form: CONTACT OUTCOME

Form Status: Not Started

Site Name: (1210) Medipol University Medical Faculty

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:11

Contact Outcome

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

Header Text: C4591001

Visit: V105_MONTH18

Form Version: 22-Apr-2020 21:02

Site No: 1210

Subject No: 12101029

Generated By: (b) (4)

Form: DATE OF VISIT

Form Status: Not Started

Site Name: (1210) Medipol University Medical Faculty

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:11

Date of Visit

1.	Date of Visit	//
2.	Erroneous Visit	

Header Text: C4591001

Visit: V105_MONTH18

Form Version: 22-Apr-2020 21:04

Site No: 1210

Subject No: 12101029

Generated By: (b) (4)

Form: CONTACT OUTCOME

Form Status: Not Started

Site Name: (1210) Medipol University Medical Faculty

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:11

Contact Outcome

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

Header Text: C4591001

Visit: FURTHER_VACCINATION_EOT -
Unscheduled

Form: DISPOSITION - TREATMENT

Form Version: 10-Dec-2020 02:29

Form Status: Data Complete, Frozen, Verified

Site No: 1210

Site Name: (1210) Medipol University Medical Faculty

Subject No: 12101029

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:11

[eCRF Audit Trail History](#)

Disposition - Treatment

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

Header Text: C4591001

Visit: Subject Status - Unscheduled

Form: SUBJECT STATUS

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Verified

Site No: 1210

Site Name: (1210) Medipol University Medical Faculty

Subject No: 12101029

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:11

[eCRF Audit Trail History](#)

Subject Status

1.	Subject Status	FOLLOW-UP
2.	Subject Status Date	Dec/18/2020

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: 1210

Site Name: (1210) Medipol University Medical Faculty

Subject No: 12101029

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:11

[eCRF Audit Trail History](#)

Casebook Signature Form

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

Header Text: C4591001

Visit: Investigator Signature - Unscheduled

Form: CASEBOOK SIGNATURE FORM

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Signed, Verified

Site No: 1210

Site Name: (1210) Medipol University Medical Faculty

Subject No: 12101029

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:11

[Audit Trail](#)

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

- CRF_Sign

Name	Signature Meaning	Date	Type	Action
Ali Mert	Approved	Feb-16-2021 15:08:47 (UTC+03:00) Istanbul	BOOK	Signed

Affidavit:

By my dated signature below, I, AliMert, 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.

090177e196ae2fe0\Final\Final On: 01-Apr-2021 03:54 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 10-Oct-2020 16:00

Site No: 1210

Subject No: 12101029

Generated By: (b) (4)

Form: INCLUSION/EXCLUSION CRITERIA - Comments

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1210) Medipol University Medical Faculty

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:11

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Item	Date	User	Comment
Form	Oct-30-2020 19:25:54 (UTC+03:00) Istanbul	(b) (4), (b) (6)	Not Applicable

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1210

Subject No: 12101029

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - Comments

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1210) Medipol University Medical Faculty

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:11

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Item	Date	User	Comment
Form	Oct-30-2020 19:26:28 (UTC+03:00) Istanbul	(b) (4), (b) (6)	Not Applicable

Header Text: C4591001

Visit: Logs - Unscheduled

Form Version: 17-Jul-2020 21:54

Site No: 1210

Subject No: 12101029

Generated By: (b) (4)

Form: MEDICATION ERROR - Comments

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1210) Medipol University Medical Faculty

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:11

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Item	Date	User	Comment
Form	Nov-05-2020 13:40:48 (UTC+03:00) Istanbul	(b) (4), (b) (6)	Not Applicable

Header Text: C4591001

Visit: Logs - Unscheduled

Form Version: 17-Jul-2020 21:54

Site No: 1210

Subject No: 12101029

Generated By: (b) (4)

Form: MEDICATION ERROR - Comments

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1210) Medipol University Medical Faculty

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:11

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Item	Date	User	Comment
1	Nov-05-2020 13:40:48 (UTC+03:00) Istanbul	(b) (4), (b) (6)	Not Applicable

Header Text: C4591001

Visit: Logs - Unscheduled

Form Version: 17-Jul-2020 21:54

Site No: 1210

Subject No: 12101029

Generated By: (b) (4)

Form: MEDICATION ERROR - Comments

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1210) Medipol University Medical Faculty

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:11

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Item	Date	User	Comment
2	Nov-05-2020 13:40:48 (UTC+03:00) Istanbul	(b) (4), (b) (6)	Not Applicable

Header Text: C4591001

Visit: Logs - Unscheduled

Form Version: 17-Jul-2020 21:54

Site No: 1210

Subject No: 12101029

Generated By: (b) (4)

Form: MEDICATION ERROR - Comments

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1210) Medipol University Medical Faculty

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:11

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Item	Date	User	Comment
3	Nov-05-2020 13:40:48 (UTC+03:00) Istanbul	(b) (4), (b) (6)	Not Applicable

Header Text: C4591001

Visit: Logs - Unscheduled

Form Version: 17-Jul-2020 21:54

Site No: 1210

Subject No: 12101029

Generated By: (b) (4)

Form: MEDICATION ERROR - Comments

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1210) Medipol University Medical Faculty

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:11

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Item	Date	User	Comment
4	Nov-05-2020 13:40:48 (UTC+03:00) Istanbul	(b) (4), (b) (6)	Not Applicable

Header Text: C4591001

Visit: Logs - Unscheduled

Form Version: 17-Jul-2020 21:54

Site No: 1210

Subject No: 12101029

Generated By: (b) (4)

Form: MEDICATION ERROR - Comments

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1210) Medipol University Medical Faculty

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:11

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Item	Date	User	Comment
5	Nov-05-2020 13:40:48 (UTC+03:00) Istanbul	(b) (4), (b) (6)	Not Applicable

Header Text: C4591001

Visit: Logs - Unscheduled

Form Version: 17-Jul-2020 21:54

Site No: 1210

Subject No: 12101029

Generated By: (b) (4)

Form: MEDICATION ERROR - Comments

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1210) Medipol University Medical Faculty

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:11

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Item	Date	User	Comment
6	Nov-05-2020 13:40:48 (UTC+03:00) Istanbul	(b) (4), (b) (6)	Not Applicable

Header Text: C4591001

Visit: Logs - Unscheduled

Form Version: 17-Jul-2020 21:54

Site No: 1210

Subject No: 12101029

Generated By: (b) (4)

Form: MEDICATION ERROR - Comments

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1210) Medipol University Medical Faculty

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:11

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Item	Date	User	Comment
7	Nov-05-2020 13:40:48 (UTC+03:00) Istanbul	(b) (4), (b) (6)	Not Applicable

Header Text: C4591001

Visit: Logs - Unscheduled

Form Version: 17-Jul-2020 21:54

Site No: 1210

Subject No: 12101029

Generated By: (b) (4)

Form: MEDICATION ERROR - Comments

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1210) Medipol University Medical Faculty

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:11

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Item	Date	User	Comment
8	Nov-05-2020 13:40:48 (UTC+03:00) Istanbul	(b) (4), (b) (6)	Not Applicable

Header Text: C4591001

Visit: Logs - Unscheduled

Form Version: 17-Jul-2020 21:54

Site No: 1210

Subject No: 12101029

Generated By: (b) (4)

Form: MEDICATION ERROR - Comments

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1210) Medipol University Medical Faculty

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:11

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Item	Date	User	Comment
9	Nov-05-2020 13:40:48 (UTC+03:00) Istanbul	(b) (4), (b) (6)	Not Applicable

Header Text: C4591001

Visit: Logs - Unscheduled

Form Version: 17-Jul-2020 21:54

Site No: 1210

Subject No: 12101029

Generated By: (b) (4)

Form: MEDICATION ERROR - Comments

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1210) Medipol University Medical Faculty

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:11

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Item	Date	User	Comment
10	Nov-05-2020 13:40:48 (UTC+03:00) Istanbul	(b) (4), (b) (6)	Not Applicable

Header Text: C4591001

Visit: Logs - Unscheduled

Form: CONCOMITANT MEDICATIONS - NON STUDY
VACCINATIONS - Comments

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1210

Site Name: (1210) Medipol University Medical Faculty

Subject No: 12101029

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:11

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Item	Date	User	Comment
Form	Nov-05-2020 13:41:15 (UTC+03:00) Istanbul	(b) (4), (b) (6)	Not Applicable

Header Text: C4591001

Visit: Logs - Unscheduled

Form: CONCOMITANT MEDICATIONS - NON STUDY
VACCINATIONS - Comments

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1210

Site Name: (1210) Medipol University Medical Faculty

Subject No: 12101029

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:11

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Item	Date	User	Comment
1	Nov-05-2020 13:41:15 (UTC+03:00) Istanbul	(b) (4), (b) (6)	Not Applicable

Header Text: C4591001

Visit: Logs - Unscheduled

Form: CONCOMITANT MEDICATIONS - NON STUDY
VACCINATIONS - Comments

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1210

Site Name: (1210) Medipol University Medical Faculty

Subject No: 12101029

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:11

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Item	Date	User	Comment
2	Nov-05-2020 13:41:15 (UTC+03:00) Istanbul	(b) (4), (b) (6)	Not Applicable

Header Text: C4591001

Visit: Logs - Unscheduled

Form: CONCOMITANT MEDICATIONS - NON STUDY
VACCINATIONS - Comments

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1210

Site Name: (1210) Medipol University Medical Faculty

Subject No: 12101029

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:11

[Back to Form](#)

Item	Date	User	Comment
3	Nov-05-2020 13:41:15 (UTC+03:00) Istanbul	(b) (4), (b) (6)	Not Applicable

Header Text: C4591001

Visit: Logs - Unscheduled

Form: CONCOMITANT MEDICATIONS - NON STUDY
VACCINATIONS - Comments

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1210

Site Name: (1210) Medipol University Medical Faculty

Subject No: 12101029

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:11

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Item	Date	User	Comment
4	Nov-05-2020 13:41:15 (UTC+03:00) Istanbul	(b) (4), (b) (6)	Not Applicable

Header Text: C4591001

Visit: Logs - Unscheduled

Form: CONCOMITANT MEDICATIONS - NON STUDY
VACCINATIONS - Comments

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1210

Site Name: (1210) Medipol University Medical Faculty

Subject No: 12101029

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:11

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Item	Date	User	Comment
5	Nov-05-2020 13:41:15 (UTC+03:00) Istanbul	(b) (4), (b) (6)	Not Applicable

Header Text: C4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1210

Subject No: 12101029

Generated By: (b) (4)

Form: CONCOMITANT MEDICATIONS - PROHIBITED - Comments

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1210) Medipol University Medical Faculty

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:11

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Item	Date	User	Comment
Form	Nov-05-2020 13:41:35 (UTC+03:00) Istanbul	(b) (4), (b) (6)	Not Applicable

Header Text: C4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1210

Subject No: 12101029

Generated By: (b) (4)

Form: CONCOMITANT MEDICATIONS - PROHIBITED - Comments

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1210) Medipol University Medical Faculty

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:11

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Item	Date	User	Comment
1	Nov-05-2020 13:41:35 (UTC+03:00) Istanbul	(b) (4), (b) (6)	Not Applicable

090177e196ae2fe0\Final\Final On: 01-Apr-2021 03:54 (GMT)

Header Text: C4591001
Visit: Logs - Unscheduled
Form Version: 22-Apr-2020 21:03
Site No: 1210
Subject No: 12101029
Generated By: (b) (4)

Form: CONCOMITANT MEDICATIONS - PROHIBITED - Comments
Form Status: Data Complete, Locked, Frozen, Verified
Site Name: (1210) Medipol University Medical Faculty
Subject Initials: ---
Generated Time (GMT): 29-Mar-2021 13:11

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Item	Date	User	Comment
2	Nov-05-2020 13:41:35 (UTC+03:00) Istanbul	(b) (4), (b) (6)	Not Applicable

Header Text: C4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1210

Subject No: 12101029

Generated By: (b) (4)

Form: CONCOMITANT MEDICATIONS - PROHIBITED - Comments

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1210) Medipol University Medical Faculty

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:11

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Item	Date	User	Comment
3	Nov-05-2020 13:41:35 (UTC+03:00) Istanbul	(b) (4), (b) (6)	Not Applicable

Header Text: C4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1210

Subject No: 12101029

Generated By: (b) (4)

Form: CONCOMITANT MEDICATIONS - PROHIBITED - Comments

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1210) Medipol University Medical Faculty

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:11

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Item	Date	User	Comment
4	Nov-05-2020 13:41:35 (UTC+03:00) Istanbul	(b) (4), (b) (6)	Not Applicable

Header Text: C4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1210

Subject No: 12101029

Generated By: (b) (4)

Form: CONCOMITANT MEDICATIONS - PROHIBITED - Comments

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1210) Medipol University Medical Faculty

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:11

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Item	Date	User	Comment
5	Nov-05-2020 13:41:35 (UTC+03:00) Istanbul	(b) (4), (b) (6)	Not Applicable

Header Text: C4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1210

Subject No: 12101029

Generated By: (b) (4)

Form: CONCOMITANT MEDICATIONS - PROHIBITED - Comments

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1210) Medipol University Medical Faculty

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:11

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Item	Date	User	Comment
6	Nov-05-2020 13:41:35 (UTC+03:00) Istanbul	(b) (4), (b) (6)	Not Applicable

Header Text: C4591001
Visit: Logs - Unscheduled
Form Version: 22-Apr-2020 21:03
Site No: 1210
Subject No: 12101029
Generated By: (b) (4)

Form: CONCOMITANT MEDICATIONS - PROHIBITED - Comments
Form Status: Data Complete, Locked, Frozen, Verified
Site Name: (1210) Medipol University Medical Faculty
Subject Initials: ---
Generated Time (GMT): 29-Mar-2021 13:11

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Item	Date	User	Comment
7	Nov-05-2020 13:41:35 (UTC+03:00) Istanbul	(b) (4), (b) (6)	Not Applicable

Header Text: C4591001
Visit: Logs - Unscheduled
Form Version: 22-Apr-2020 21:03
Site No: 1210
Subject No: 12101029
Generated By: (b) (4)

Form: CONCOMITANT MEDICATIONS - PROHIBITED - Comments
Form Status: Data Complete, Locked, Frozen, Verified
Site Name: (1210) Medipol University Medical Faculty
Subject Initials: ---
Generated Time (GMT): 29-Mar-2021 13:11

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Item	Date	User	Comment
8	Nov-05-2020 13:41:35 (UTC+03:00) Istanbul	(b) (4), (b) (6)	Not Applicable

Header Text: C4591001
Visit: Logs - Unscheduled
Form Version: 22-Apr-2020 21:03
Site No: 1210
Subject No: 12101029
Generated By: (b) (4)

Form: CONCOMITANT MEDICATIONS - PROHIBITED - Comments
Form Status: Data Complete, Locked, Frozen, Verified
Site Name: (1210) Medipol University Medical Faculty
Subject Initials: ---
Generated Time (GMT): 29-Mar-2021 13:11

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Item	Date	User	Comment
9	Nov-05-2020 13:41:35 (UTC+03:00) Istanbul	(b) (4), (b) (6)	Not Applicable

Header Text: C4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1210

Subject No: 12101029

Generated By: (b) (4)

Form: CONCOMITANT MEDICATIONS - PROHIBITED - Comments

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1210) Medipol University Medical Faculty

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:11

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Item	Date	User	Comment
10	Nov-05-2020 13:41:35 (UTC+03:00) Istanbul	(b) (4), (b) (6)	Not Applicable

Header Text: C4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1210

Subject No: 12101029

Generated By: (b) (4)

Form: RADIATION TREATMENT - Comments

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1210) Medipol University Medical Faculty

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:11

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Item	Date	User	Comment
Form	Nov-05-2020 13:41:56 (UTC+03:00) Istanbul	(b) (4), (b) (6)	Not Applicable

Header Text: C4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1210

Subject No: 12101029

Generated By: (b) (4)

Form: RADIATION TREATMENT - Comments

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1210) Medipol University Medical Faculty

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:11

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Item	Date	User	Comment
1	Nov-05-2020 13:41:56 (UTC+03:00) Istanbul	(b) (4), (b) (6)	Not Applicable

Header Text: C4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1210

Subject No: 12101029

Generated By: (b) (4)

Form: RADIATION TREATMENT - Comments

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1210) Medipol University Medical Faculty

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:11

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Item	Date	User	Comment
2	Nov-05-2020 13:41:56 (UTC+03:00) Istanbul	(b) (4), (b) (6)	Not Applicable

Header Text: C4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1210

Subject No: 12101029

Generated By: (b) (4)

Form: RADIATION TREATMENT - Comments

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1210) Medipol University Medical Faculty

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:11

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Item	Date	User	Comment
3	Nov-05-2020 13:41:56 (UTC+03:00) Istanbul	(b) (4), (b) (6)	Not Applicable

Header Text: C4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1210

Subject No: 12101029

Generated By: (b) (4)

Form: RADIATION TREATMENT - Comments

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1210) Medipol University Medical Faculty

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:11

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Item	Date	User	Comment
4	Nov-05-2020 13:41:56 (UTC+03:00) Istanbul	(b) (4), (b) (6)	Not Applicable

Header Text: C4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1210

Subject No: 12101029

Generated By: (b) (4)

Form: RADIATION TREATMENT - Comments

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1210) Medipol University Medical Faculty

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:11

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Item	Date	User	Comment
5	Nov-05-2020 13:41:56 (UTC+03:00) Istanbul	(b) (4), (b) (6)	Not Applicable

Header Text: C4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1210

Subject No: 12101029

Generated By: (b) (4)

Form: RADIATION TREATMENT - Comments

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1210) Medipol University Medical Faculty

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:11

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Item	Date	User	Comment
6	Nov-05-2020 13:41:56 (UTC+03:00) Istanbul	(b) (4), (b) (6)	Not Applicable

Header Text: C4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1210

Subject No: 12101029

Generated By: (b) (4)

Form: TRANSFUSIONS - Comments

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1210) Medipol University Medical Faculty

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:11

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Item	Date	User	Comment
Form	Nov-05-2020 13:42:19 (UTC+03:00) Istanbul	(b) (4), (b) (6)	Not Applicable

Header Text: C4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1210

Subject No: 12101029

Generated By: (b) (4)

Form: TRANSFUSIONS - Comments

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1210) Medipol University Medical Faculty

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:11

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Item	Date	User	Comment
1	Nov-05-2020 13:42:19 (UTC+03:00) Istanbul	(b) (4), (b) (6)	Not Applicable

Header Text: C4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1210

Subject No: 12101029

Generated By: (b) (4)

Form: TRANSFUSIONS - Comments

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1210) Medipol University Medical Faculty

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:11

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Item	Date	User	Comment
2	Nov-05-2020 13:42:19 (UTC+03:00) Istanbul	(b) (4), (b) (6)	Not Applicable

Header Text: C4591001

Visit: V101_VAX3

Form: INCLUSION/EXCLUSION CRITERIA - FURTHER
VACCINATION - Comments

Form Version: 10-Dec-2020 02:30

Form Status: Data Complete, Frozen, Verified

Site No: 1210

Site Name: (1210) Medipol University Medical Faculty

Subject No: 12101029

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:11

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Item	Date	User	Comment
Form	Dec-30-2020 15:40:33 (UTC+03:00) Istanbul	(b) (4), (b) (6)	Not Applicable

Header Text: C4591001

Visit: Disposition - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1210

Subject No: 12101029

Generated By: (b) (4)

Form: WITHDRAWAL OF CONSENT - Comments

Form Status: Data Complete, Verified

Site Name: (1210) Medipol University Medical Faculty

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:11

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Item	Date	User	Comment
Form	Dec-29-2020 16:31:43 (UTC+03:00) Istanbul	(b) (4), (b) (6)	Not Applicable

Header Text: C4591001

Visit: Disposition

Form Version: 22-Apr-2020 21:03

Site No: 1210

Subject No: 12101029

Generated By: (b) (4)

Form: WITHDRAWAL OF CONSENT - Comments

Form Status: Data Complete, Verified

Site Name: (1210) Medipol University Medical Faculty

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:11

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Item	Date	User	Comment
1	Dec-29-2020 16:31:43 (UTC+03:00) Istanbul	(b) (4), (b) (6)	Not Applicable

Header Text: C4591001

Visit: Disposition - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1210

Subject No: 12101029

Generated By: (b) (4)

Form: DEATH DETAILS CODED - Comments

Form Status: Data Complete, Verified

Site Name: (1210) Medipol University Medical Faculty

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:11

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Item	Date	User	Comment
Form	Dec-29-2020 16:32:03 (UTC+03:00) Istanbul	(b) (4), (b) (6)	Not Applicable

Header Text: C4591001

Visit: Disposition

Form Version: 22-Apr-2020 21:03

Site No: 1210

Subject No: 12101029

Generated By: (b) (4)

Form: DEATH DETAILS CODED - Comments

Form Status: Data Complete, Verified

Site Name: (1210) Medipol University Medical Faculty

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:11

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Item	Date	User	Comment
1	Dec-29-2020 16:32:03 (UTC+03:00) Istanbul	(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: 1210

Site Name: (1210) Medipol University Medical Faculty

Subject No: 12101029

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:11

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

- CRF_Sign

Name	Signature Meaning	Date	Type	Action
Ali Mert	Approved	Feb-16-2021 15:08:47 (UTC+03:00) Istanbul	BOOK	Signed

Affidavit:

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

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

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

(b) (6)	N/A	Feb-16-2021 14:08:05 (UTC+03:00) Istanbul		Edit - All signatures invalidated
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Affidavit:

N/A

Ali Mert	Approved	Feb-03-2021 16:36:29 (UTC+03:00) Istanbul	BOOK	Signed
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Affidavit:

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

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

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

(b) (6)	N/A	Feb-02-2021 13:50:51 (UTC+03:00) Istanbul		Edit - All signatures invalidated
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Affidavit:

N/A

Ali Mert	Approved	Feb-02-2021 11:35:57 (UTC+03:00) Istanbul	BOOK	Signed
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090177e196ae2fe0\Final\Final On: 01-Apr-2021 03:54 (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: 1210

Site Name: (1210) Medipol University Medical Faculty

Subject No: 12101029

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:11

Affidavit:

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

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

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

(b) (6)	N/A	Jan-27-2021 09:29:00 (UTC+03:00) Istanbul		Edit - All signatures invalidated
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Affidavit:

N/A

Ali Mert	Approved	Jan-22-2021 17:55:06 (UTC+03:00) Istanbul	BOOK	Signed
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Affidavit:

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

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

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

(b) (6)	N/A	Jan-22-2021 12:35:23 (UTC+03:00) Istanbul		Edit - All signatures invalidated
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Affidavit:

N/A

Ali Mert	Approved	Jan-19-2021 15:06:14 (UTC+03:00) Istanbul	BOOK	Signed
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Affidavit:

By my dated signature below, I, AliMert, 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.

090177e196ae2fe0\Final\Final On: 01-Apr-2021 03:54 (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: 1210

Site Name: (1210) Medipol University Medical Faculty

Subject No: 12101029

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:11

(b) (6)	N/A	Jan-19-2021 12:15:42 (UTC+03:00) Istanbul		Edit - All signatures invalidated
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Affidavit:

N/A

Ali Mert	Approved	Jan-05-2021 16:55:32 (UTC+03:00) Istanbul	BOOK	Signed
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Affidavit:

By my dated signature below, I, AliMert, 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	Dec-29-2020 12:07:30 (UTC+03:00) Istanbul		Edit - All signatures invalidated
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Affidavit:

N/A

Ali Mert	Approved	Dec-22-2020 13:56:54 (UTC+03:00) Istanbul	BOOK	Signed
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Affidavit:

By my dated signature below, I, AliMert, 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	Dec-18-2020 12:33:47 (UTC+03:00) Istanbul		Edit - All signatures invalidated
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Affidavit:

N/A

Ali Mert	Approved	Nov-25-2020 13:49:58 (UTC+03:00) Istanbul	BOOK	Signed
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090177e196ae2fe0\Final\Final On: 01-Apr-2021 03:54 (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: 1210

Site Name: (1210) Medipol University Medical Faculty

Subject No: 12101029

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:11

Affidavit:

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

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

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

(b) (6)	N/A	Nov-20-2020 10:49:25 (UTC+03:00) Istanbul		Edit - All signatures invalidated
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Affidavit:

N/A

Ali Mert	Approved	Nov-05-2020 13:53:08 (UTC+03:00) Istanbul	BOOK	Signed
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Affidavit:

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

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

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

(b) (6)	N/A	Nov-05-2020 13:40:01 (UTC+03:00) Istanbul		Edit - All signatures invalidated
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Affidavit:

N/A

(b) (6)	Approved	Nov-03-2020 17:18:18 (UTC+03:00) Istanbul	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.

090177e196ae2fe0\Final\Final On: 01-Apr-2021 03:54 (GMT)

Header Text: C4591001

Visit: COHORT_SELECTION

Form Version: 10-Oct-2020 16:01

Site No: 1210

Subject No: 12101029

Generated By: (b) (4)

Form: COHORT_SELECTION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1210) Medipol University Medical Faculty

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:11

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1. Select appropriate response - Protocol version

Date	Location	User	Value	Reason
Oct-30-2020 19:24:45 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 08 SEP 2020	Initial Entry

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

Date	Location	User	Value	Reason
Oct-30-2020 19:24:45 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: STAGE 3 COHORTS	Initial Entry

Header Text: C4591001

Visit: COHORT_SELECTION

Form Version: 22-Apr-2020 21:02

Site No: 1210

Subject No: 12101029

Generated By: (b) (4)

Form: MAIN INFORMED CONSENT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1210) Medipol University Medical Faculty

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:11

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1. Consent Was:

Date	Location	User	Value	Reason
Oct-30-2020 19:24:55 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: OBTAINED Date Written Consent Obtained Oct/30/2020	Initial Entry

Header Text: C4591001

Visit: COHORT_SELECTION

Form Version: 15-Sep-2020 21:54

Site No: 1210

Subject No: 12101029

Generated By: (b) (4)

Form: DEMOGRAPHY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1210) Medipol University Medical Faculty

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:11

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1. Subject ID

Date	Location	User	Value	Reason
Oct-30-2020 19:24:35 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 12101029	Item copied from previous form

2. Birth Date:

Date	Location	User	Value	Reason
Oct-30-2020 19:24:31 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: (b) (6) 1983	Enrollment Entry

3. Sex:

Date	Location	User	Value	Reason
Oct-30-2020 19:28:59 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: MALE	Transcription Error
Oct-30-2020 19:25:10 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: FEMALE	Initial Entry

4. Ethnicity:

Date	Location	User	Value	Reason
Oct-30-2020 19:25:10 (UTC+03:00) Istanbul	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
Oct-30-2020 19:25:10 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: WHITE	Initial Entry

090177e196ae2fe0\Final\Final On: 01-Apr-2021 03:54 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:02

Site No: 1210

Subject No: 12101029

Generated By: (b) (4)

Form: DATE OF VISIT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1210) Medipol University Medical Faculty

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:11

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I. Date of Visit

Date	Location	User	Value	Reason
Oct-30-2020 19:25:27 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Oct/30/2020	Initial Entry

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 15-Sep-2020 21:52

Site No: 1210

Subject No: 12101029

Generated By: (b) (4)

Form: DISPOSITION - SCREENING - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1210) Medipol University Medical Faculty

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:11

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1. Date of Completion/Discontinuation/Death

Date	Location	User	Value	Reason
Oct-30-2020 19:26:12 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Oct/30/2020	Initial Entry

2. Phase of Disposition:

Date	Location	User	Value	Reason
Oct-30-2020 19:26:12 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SCREENING	Initial Entry

3. Status:

Date	Location	User	Value	Reason
Oct-30-2020 19:26:12 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: COMPLETED	Initial Entry

090177e196ae2fe0\Final\Final On: 01-Apr-2021 03:54 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 15-Sep-2020 21:57

Site No: 1210

Subject No: 12101029

Generated By: (b) (4)

Form: HIV STATUS - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1210) Medipol University Medical Faculty

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:11

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

Date	Location	User	Value	Reason
Oct-30-2020 19:26:40 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: The subject is NOT known to be HIV POSITIVE	Initial Entry

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 10-Oct-2020 16:04

Site No: 1210

Subject No: 12101029

Generated By: (b) (4)

Form: VITAL SIGNS - BASELINE - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1210) Medipol University Medical Faculty

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:11

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1. Date:

Date	Location	User	Value	Reason
Oct-30-2020 19:28:32 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Oct/30/2020	Initial Entry

2. Weight:

Date	Location	User	Value	Reason
Oct-30-2020 19:28:32 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 105.0	Initial Entry

3. Unit:

Date	Location	User	Value	Reason
Oct-30-2020 19:28:32 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: kg	Initial Entry

4. Height:

Date	Location	User	Value	Reason
Oct-30-2020 19:28:32 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 173.0	Initial Entry

5. Unit:

Date	Location	User	Value	Reason
Oct-30-2020 19:28:32 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: cm	Initial Entry

6. Body Mass Index:

Date	Location	User	Value	Reason
Oct-30-2020 19:28:32 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 35.1	Initial Entry

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Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 10-Oct-2020 16:04

Site No: 1210

Subject No: 12101029

Generated By: (b) (4)

Form: VITAL SIGNS - BASELINE - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1210) Medipol University Medical Faculty

Subject Initials: ---

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7.a

Date	Location	User	Value	Reason
Oct-30-2020 19:29:40 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Record Identifier:: 1 Temperature: 36.1 Temperature Unit: C Temperature Location:: FOREHE AD	Transcription Error
Oct-30-2020 19:28:32 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Record Identifier:: 1 Temperature: 36.0 Temperature Unit: C Temperature Location:: FOREHE AD	Initial Entry

7.a Record Identifier:

Date	Location	User	Value	Reason
Oct-30-2020 19:28:32 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 1	Initial Entry

7.a Temperature:

Date	Location	User	Value	Reason
Oct-30-2020 19:29:40 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Oct-30-2020 19:29:40 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 36.1	Transcription Error
Oct-30-2020 19:28:32 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	Temperature 36 C is outside of Normal Range 36.1 - 37.5 C.
Oct-30-2020 19:28:32 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 36.0	Initial Entry

7.a Unit:

Date	Location	User	Value	Reason
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090177e196ae2fe0\Final\Final On: 01-Apr-2021 03:54 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 10-Oct-2020 16:04

Site No: 1210

Subject No: 12101029

Generated By: (b) (4)

Form: VITAL SIGNS - BASELINE - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

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Generated Time (GMT): 29-Mar-2021 13:11

Oct-30-2020 19:28:32 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: C	Initial Entry
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7.a Temperature Location:

Date	Location	User	Value	Reason
Oct-30-2020 19:28:32 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: FOREHEAD	Initial Entry

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1210

Subject No: 12101029

Generated By: (b) (4)

Form: RANDOMIZATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1210) Medipol University Medical Faculty

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:11

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1. Randomization Date :

Date	Location	User	Value	Reason
Oct-30-2020 19:30:39 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Oct/30/2020	Initial Entry

2. Randomization Number:

Date	Location	User	Value	Reason
Oct-30-2020 19:30:39 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 114945	Initial Entry

Header Text: C4591001**Visit:** V1_DAY1_VAX1_L**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - eCRF Audit Trail History**Form Version:** 22-Apr-2020 21:03**Form Status:** Data Complete, Locked, Frozen, Verified**Site No:** 1210**Site Name:** (1210) Medipol University Medical Faculty**Subject No:** 12101029**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 13:11[Back to Form](#)**1. Data Origin**

Date	Location	User	Value	Reason
Oct-30-2020 19:30:47 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Oct-30-2020 19:30:47 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SERUM	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Oct-30-2020 19:33:31 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Oct-30-2020 19:30:47 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Oct-30-2020 19:30:47 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Date of Collection: Oct/30/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Oct-30-2020 19:33:31 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BSHB2Z	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
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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: 1210

Site Name: (1210) Medipol University Medical Faculty

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Subject Initials: ---

Generated By: (b) (4)

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Oct-30-2020 19:33:31 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BSHB2Z	Initial Entry
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5.b

Date	Location	User	Value	Reason
Oct-30-2020 19:33:43 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BSHB30	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Oct-30-2020 19:33:43 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BSHB30	Initial Entry

5.c

Date	Location	User	Value	Reason
Oct-30-2020 19:33:57 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BRCXNM	Initial Entry

5.c Sample ID

Date	Location	User	Value	Reason
Oct-30-2020 19:33:57 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BRCXNM	Initial Entry

5.d

Date	Location	User	Value	Reason
Oct-30-2020 19:34:09 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BRCXNN	Initial Entry

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Header Text: C4591001

Visit: V1_DAY1_VAX1_L

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Subject Initials: ---

Generated By: (b) (4)

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5.d Sample ID

Date	Location	User	Value	Reason
Oct-30-2020 19:34:09 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BRCXNN	Initial Entry

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1210

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Subject No: 12101029

Subject Initials: ---

Generated By: (b) (4)

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1. Data Origin

Date	Location	User	Value	Reason
Oct-30-2020 19:31:10 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Oct-30-2020 19:31:10 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: NASAL_SWAB	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Oct-30-2020 19:33:09 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto query (autoquery)	Query 3: Deleted	Close Auto Query
Oct-30-2020 19:32:53 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto query (autoquery)	Query 3: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Oct-30-2020 19:32:37 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Closed	Close Auto Query
Oct-30-2020 19:31:49 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Opened	There are more than 1 barcode present for sample collection. Please review and correct as appropriate.
Oct-30-2020 19:31:34 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Oct-30-2020 19:31:10 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct

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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: 1210

Site Name: (1210) Medipol University Medical Faculty

Subject No: 12101029

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:11

				as appropriate.
Oct-30-2020 19:31:10 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Date of Collection: Oct/30/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Oct-30-2020 19:32:37 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BSHB2Z	Transcription Error (DELETED)
Oct-30-2020 19:31:34 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BSHB2Z	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Oct-30-2020 19:32:37 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BSHB2Z	Transcription Error (DELETED)
Oct-30-2020 19:31:34 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BSHB2Z	Initial Entry

5.b

Date	Location	User	Value	Reason
Oct-30-2020 19:32:53 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BSHB30	Transcription Error (DELETED)
Oct-30-2020 19:31:49 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BSHB30	Initial Entry

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Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB - eCRF
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Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1210

Site Name: (1210) Medipol University Medical Faculty

Subject No: 12101029

Subject Initials: ---

Generated By: (b) (4)

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5.b Sample ID

Date	Location	User	Value	Reason
Oct-30-2020 19:32:53 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> BSHB30	Transcription Error (DELETED)
Oct-30-2020 19:31:49 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> BSHB30	Initial Entry

5.c

Date	Location	User	Value	Reason
Oct-30-2020 19:33:09 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Sample ID: BRCXP3	Initial Entry

5.c Sample ID

Date	Location	User	Value	Reason
Oct-30-2020 19:33:09 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> BRCXP3	Initial Entry

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Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:04

Site No: 1210

Subject No: 12101029

Generated By: (b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1210) Medipol University Medical Faculty

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:11

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1. Was there a temporary delay of vaccination?

Date	Location	User	Value	Reason
Oct-30-2020 19:34:53 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2. Treatment Name

Date	Location	User	Value	Reason
Oct-30-2020 19:34:53 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: BLINDED THERAPY	Initial Entry

3. Formulation:

Date	Location	User	Value	Reason
Oct-30-2020 19:34:53 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: INJECTION	Initial Entry

4. Dose Date Time:

Date	Location	User	Value	Reason
Oct-30-2020 19:34:53 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Oct/30/2020 15:57	Initial Entry

5. Anatomical Location:

Date	Location	User	Value	Reason
Oct-30-2020 19:34:53 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: DELTOID MUSCLE	Initial Entry

6. Body Side:

Date	Location	User	Value	Reason
Oct-30-2020 19:34:53 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: LEFT	Initial Entry

7. Route:

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Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:04

Site No: 1210

Subject No: 12101029

Generated By: (b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1210) Medipol University Medical Faculty

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:11

Date	Location	User	Value	Reason
Oct-30-2020 19:34:53 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: INTRAMUSCULAR	Initial Entry

10. Timeframe Subject Was Observed

Date	Location	User	Value	Reason
Oct-30-2020 19:34:53 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: THE PROTOCOL SPECIFIED OB SERVATION PERIOD	Initial Entry

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

Date	Location	User	Value	Reason
Oct-30-2020 19:34:53 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

090177e196ae2fe0\Final\Final On: 01-Apr-2021 03:54 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 06-Jul-2020 21:53

Site No: 1210

Subject No: 12101029

Generated By: (b) (4)

Form: REACTOGENICITY DIARY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1210) Medipol University Medical Faculty

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:11

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1. Select appropriate response - Reactogenicity diary collection

Date	Location	User	Value	Reason
Oct-30-2020 19:35:05 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES - REACTOGENICITY E-DIARY COLLECTED FOR THIS SUBJECT	Initial Entry

Header Text: C4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:02

Site No: 1210

Subject No: 12101029

Generated By: (b) (4)

Form: DATE OF VISIT - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1210) Medipol University Medical Faculty

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:11

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I. Date of Visit

Date	Location	User	Value	Reason
Nov-20-2020 10:49:25 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Nov/20/2020	Initial Entry

Header Text: C4591001

Visit: V2_VAX2_L

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

Form Version: 10-Oct-2020 16:03

Form Status: Data Complete, Frozen, Verified

Site No: 1210

Site Name: (1210) Medipol University Medical Faculty

Subject No: 12101029

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:11

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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
Nov-20-2020 10:49:54 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2.a

Date	Location	User	Value	Reason
Nov-20-2020 10:49:54 (UTC+03:00) Istanbul	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
Nov-20-2020 10:49:54 (UTC+03:00) Istanbul	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
Nov-20-2020 10:49:54 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2.b

Date	Location	User	Value	Reason
Nov-20-2020 10:49:54 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom:: FA TIG	Initial Entry

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Header Text: C4591001

Visit: V2_VAX2_L

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

Form Version: 10-Oct-2020 16:03

Form Status: Data Complete, Frozen, Verified

Site No: 1210

Site Name: (1210) Medipol University Medical Faculty

Subject No: 12101029

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:11

			UE NO	
Were fever or systemic symptoms present on the last day the Subject Diary was completed?:				

2.b Symptom:

Date	Location	User	Value	Reason
Nov-20-2020 10:49:54 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> 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
Nov-20-2020 10:49:54 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NO	Initial Entry

2.c

Date	Location	User	Value	Reason
Nov-20-2020 10:49:54 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Symptom:: HE AD AC HE Were fever or systemic symptoms present on the last day the Subject Diary was completed?: NO	Initial Entry

090177e196ae2fe0\Final\Final On: 01-Apr-2021 03:54 (GMT)

Header Text: C4591001**Visit:** V2_VAX2_L**Form:** VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED
DATES - eCRF Audit Trail History**Form Version:** 10-Oct-2020 16:03**Form Status:** Data Complete, Frozen, Verified**Site No:** 1210**Site Name:** (1210) Medipol University Medical Faculty**Subject No:** 12101029**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 13:11**2.c Symptom:**

Date	Location	User	Value	Reason
Nov-20-2020 10:49:54 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 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
Nov-20-2020 10:49:54 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2.d

Date	Location	User	Value	Reason
Nov-20-2020 10:49:54 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom:: CH IL LS Were fever or systemic sym NO ptoms present on the last d ay the Subject Diary was co mpleted?:	Initial Entry

2.d Symptom:

Date	Location	User	Value	Reason
Nov-20-2020 10:49:54 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 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
Nov-20-2020 10:49:54 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2.e

Date	Location	User	Value	Reason
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Header Text: C4591001

Visit: V2_VAX2_L

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

Form Version: 10-Oct-2020 16:03

Form Status: Data Complete, Frozen, Verified

Site No: 1210

Site Name: (1210) Medipol University Medical Faculty

Subject No: 12101029

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:11

Nov-20-2020 10:49:54 (UTC+03:00) Istanbul	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
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2.e Symptom:

Date	Location	User	Value	Reason
Nov-20-2020 10:49:54 (UTC+03:00) Istanbul	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
Nov-20-2020 10:49:54 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2.f

Date	Location	User	Value	Reason
Nov-20-2020 10:49:54 (UTC+03:00) Istanbul	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

090177e196ae2fe0\Final\Final On: 01-Apr-2021 03:54 (GMT)

Header Text: C4591001

Visit: V2_VAX2_L

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

Form Version: 10-Oct-2020 16:03

Form Status: Data Complete, Frozen, Verified

Site No: 1210

Site Name: (1210) Medipol University Medical Faculty

Subject No: 12101029

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:11

2.f Symptom:

Date	Location	User	Value	Reason
Nov-20-2020 10:49:54 (UTC+03:00) Istanbul	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
Nov-20-2020 10:49:54 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2.g

Date	Location	User	Value	Reason
Nov-20-2020 10:49:54 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom:: NEW OR WORSE ED MUS CLE PAI N Were fever or system NO ic symptoms present on the last day the S ubject Diary was co mpleted?:	Initial Entry

2.g Symptom:

Date	Location	User	Value	Reason
Nov-20-2020 10:49:54 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NEW OR WORSE NED MUSCL E 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
Nov-20-2020 10:49:54 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

090177e196ae2fe0\Final\Final On: 01-Apr-2021 03:54 (GMT)

Header Text: C4591001

Visit: V2_VAX2_L

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

Form Version: 10-Oct-2020 16:03

Form Status: Data Complete, Frozen, Verified

Site No: 1210

Site Name: (1210) Medipol University Medical Faculty

Subject No: 12101029

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:11

2.h

Date	Location	User	Value	Reason
Nov-20-2020 10:49:54 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom:: NEW OR WORSE NED JOINT PAIN Were fever or systemic symptoms present on the last day the Subject Diary was completed?: NO	Initial Entry

2.h Symptom:

Date	Location	User	Value	Reason
Nov-20-2020 10:49:54 (UTC+03:00) Istanbul	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
Nov-20-2020 10:49:54 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

3. Injection Site Location:

Date	Location	User	Value	Reason
Nov-20-2020 10:49:54 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: DELTOID MUSCLE	Initial Entry

4. Injection Site Body Side:

Date	Location	User	Value	Reason
Nov-20-2020 10:49:54 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: LEFT	Initial Entry

5.a

090177e196ae2fe0\Final\Final On: 01-Apr-2021 03:54 (GMT)

Header Text: C4591001

Visit: V2_VAX2_L

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

Form Version: 10-Oct-2020 16:03

Form Status: Data Complete, Frozen, Verified

Site No: 1210

Site Name: (1210) Medipol University Medical Faculty

Subject No: 12101029

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:11

Date	Location	User	Value	Reason
Nov-20-2020 10:49:54 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Injection Site Reaction:: RE DN ESS Were injection site reactions present on the last day the Subject Diary was completed?: NO	Initial Entry

5.a Injection Site Reaction:

Date	Location	User	Value	Reason
Nov-20-2020 10:49:54 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: REDNESS	Initial Entry

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

Date	Location	User	Value	Reason
Nov-20-2020 10:49:54 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

5.b

Date	Location	User	Value	Reason
Nov-20-2020 10:49:54 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Injection Site Reaction:: SWE LLI NG Were injection site reactions present on the last day the Subject Diary was completed?: NO	Initial Entry

090177e196ae2fe0\Final\Final On: 01-Apr-2021 03:54 (GMT)

Header Text: C4591001

Visit: V2_VAX2_L

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

Form Version: 10-Oct-2020 16:03

Form Status: Data Complete, Frozen, Verified

Site No: 1210

Site Name: (1210) Medipol University Medical Faculty

Subject No: 12101029

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:11

5.b Injection Site Reaction:

Date	Location	User	Value	Reason
Nov-20-2020 10:49:54 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: SWELLING	Initial Entry

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

Date	Location	User	Value	Reason
Nov-20-2020 10:49:54 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

5.c

Date	Location	User	Value	Reason
Nov-20-2020 10:49:54 (UTC+03:00) Istanbul	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
Nov-20-2020 10:49:54 (UTC+03:00) Istanbul	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
Nov-20-2020 10:49:54 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

090177e196ae2fe0\Final\Final On: 01-Apr-2021 03:54 (GMT)

Header Text: C4591001

Visit: V2_VAX2_L

Form Version: 10-Oct-2020 16:01

Site No: 1210

Subject No: 12101029

Generated By: (b) (4)

Form: VITAL SIGNS - TEMP - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1210) Medipol University Medical Faculty

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:11

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1. Date:

Date	Location	User	Value	Reason
Nov-20-2020 10:50:23 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Nov/20/2020	Initial Entry

2.a

Date	Location	User	Value	Reason
Nov-20-2020 10:50:23 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Record Identifier:: 1 Temperature: 36.1 Temperature Unit: C Temperature Location:: FOREHE AD	Initial Entry

2.a Record Identifier:

Date	Location	User	Value	Reason
Nov-20-2020 10:50:23 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 1	Initial Entry

2.a Temperature:

Date	Location	User	Value	Reason
Nov-20-2020 10:50:23 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 36.1	Initial Entry

2.a Unit:

Date	Location	User	Value	Reason
Nov-20-2020 10:50:23 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: C	Initial Entry

2.a Temperature Location:

090177e196ae2fe0\Final\Final On: 01-Apr-2021 03:54 (GMT)

Header Text: C4591001

Visit: V2_VAX2_L

Form Version: 10-Oct-2020 16:01

Site No: 1210

Subject No: 12101029

Generated By: (b) (4)

Form: VITAL SIGNS - TEMP - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1210) Medipol University Medical Faculty

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:11

Date	Location	User	Value	Reason
Nov-20-2020 10:50:23 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: FOREHEAD	Initial Entry

Header Text: C4591001**Visit:** V2_VAX2_L**Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB - eCRF
Audit Trail History**Form Version:** 22-Apr-2020 21:03**Form Status:** Data Complete, Frozen, Verified**Site No:** 1210**Site Name:** (1210) Medipol University Medical Faculty**Subject No:** 12101029**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 13:11[Back to Form](#)**1. Data Origin**

Date	Location	User	Value	Reason
Nov-20-2020 10:51:37 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Nov-20-2020 10:51:37 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: NASAL_SWAB	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Nov-20-2020 10:51:55 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Nov-20-2020 10:51:37 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Nov-20-2020 10:51:37 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Date of Collection: Nov/20/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Nov-20-2020 10:51:55 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BR5DKX	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
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Header Text: C4591001

Visit: V2_VAX2_L

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1210

Site Name: (1210) Medipol University Medical Faculty

Subject No: 12101029

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:11

Nov-20-2020 10:51:55 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BR5DKX	Initial Entry
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Header Text: C4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:04

Site No: 1210

Subject No: 12101029

Generated By: (b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1210) Medipol University Medical Faculty

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:11

[Back to Form](#)

1. Was there a temporary delay of vaccination?

Date	Location	User	Value	Reason
Nov-20-2020 10:52:19 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2. Treatment Name

Date	Location	User	Value	Reason
Nov-20-2020 10:52:19 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: BLINDED THERAPY	Initial Entry

3. Formulation:

Date	Location	User	Value	Reason
Nov-20-2020 10:52:19 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: INJECTION	Initial Entry

4. Dose Date Time:

Date	Location	User	Value	Reason
Nov-20-2020 10:52:19 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Nov/20/2020 10:07	Initial Entry

5. Anatomical Location:

Date	Location	User	Value	Reason
Nov-20-2020 10:52:19 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: DELTOID MUSCLE	Initial Entry

6. Body Side:

Date	Location	User	Value	Reason
Nov-20-2020 10:52:19 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: LEFT	Initial Entry

7. Route:

090177e196ae2fe0\Final\Final On: 01-Apr-2021 03:54 (GMT)

Header Text: C4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:04

Site No: 1210

Subject No: 12101029

Generated By: (b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1210) Medipol University Medical Faculty

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:11

Date	Location	User	Value	Reason
Nov-20-2020 10:52:19 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: INTRAMUSCULAR	Initial Entry

10. Timeframe Subject Was Observed

Date	Location	User	Value	Reason
Nov-20-2020 10:52:19 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: THE PROTOCOL SPECIFIED OB SERVATION 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
Nov-20-2020 10:52:19 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

090177e196ae2fe0\Final\Final On: 01-Apr-2021 03:54 (GMT)

Header Text: C4591001

Visit: V3_MONTH1_POSTVAX2_L

Form Version: 22-Apr-2020 21:02

Site No: 1210

Subject No: 12101029

Generated By: (b) (4)

Form: DATE OF VISIT - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1210) Medipol University Medical Faculty

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:11

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I. Date of Visit

Date	Location	User	Value	Reason
Dec-18-2020 12:33:47 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Dec/18/2020	Initial Entry

Header Text: C4591001**Visit:** V3_MONTH1_POSTVAX2_L**Form:** VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History**Form Version:** 10-Oct-2020 16:03**Form Status:** Data Complete, Frozen, Verified**Site No:** 1210**Site Name:** (1210) Medipol University Medical Faculty**Subject No:** 12101029**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 13:11[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
Dec-18-2020 12:35:31 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2.a

Date	Location	User	Value	Reason
Dec-18-2020 12:35:31 (UTC+03:00) Istanbul	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
Dec-18-2020 12:35:31 (UTC+03:00) Istanbul	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
Dec-18-2020 12:35:31 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2.b

Date	Location	User	Value	Reason
Dec-18-2020 12:35:31 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom:: FA TIG	Initial Entry

Header Text: C4591001

Visit: V3_MONTH1_POSTVAX2_L

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

Form Version: 10-Oct-2020 16:03

Form Status: Data Complete, Frozen, Verified

Site No: 1210

Site Name: (1210) Medipol University Medical Faculty

Subject No: 12101029

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:11

			UE NO	
Were fever or systemic symptoms present on the last day the Subject Diary was completed?:				

2.b Symptom:

Date	Location	User	Value	Reason
Dec-18-2020 12:35:31 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> 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
Dec-18-2020 12:35:31 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NO	Initial Entry

2.c

Date	Location	User	Value	Reason
Dec-18-2020 12:35:31 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Symptom:: HE AD AC HE Were fever or systemic symptoms present on the last day the Subject Diary was completed?: NO	Initial Entry

090177e196ae2fe0\Final\Final On: 01-Apr-2021 03:54 (GMT)

Header Text: C4591001

Visit: V3_MONTH1_POSTVAX2_L

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

Form Version: 10-Oct-2020 16:03

Form Status: Data Complete, Frozen, Verified

Site No: 1210

Site Name: (1210) Medipol University Medical Faculty

Subject No: 12101029

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:11

2.c Symptom:

Date	Location	User	Value	Reason
Dec-18-2020 12:35:31 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 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
Dec-18-2020 12:35:31 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2.d

Date	Location	User	Value	Reason
Dec-18-2020 12:35:31 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom:: CH IL LS Were fever or systemic symptoms present on the last day the Subject Diary was completed?: NO	Initial Entry

2.d Symptom:

Date	Location	User	Value	Reason
Dec-18-2020 12:35:31 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 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
Dec-18-2020 12:35:31 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2.e

Date	Location	User	Value	Reason
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090177e196ae2fe0\Final\Final On: 01-Apr-2021 03:54 (GMT)

Header Text: C4591001

Visit: V3_MONTH1_POSTVAX2_L

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

Form Version: 10-Oct-2020 16:03

Form Status: Data Complete, Frozen, Verified

Site No: 1210

Site Name: (1210) Medipol University Medical Faculty

Subject No: 12101029

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:11

Dec-18-2020 12:35:31 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom:: VO MIT ING Were fever or systemic sy mptoms present on the las t day the Subject Diary w as completed?: NO	Initial Entry
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2.e Symptom:

Date	Location	User	Value	Reason
Dec-18-2020 12:35:31 (UTC+03:00) Istanbul	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
Dec-18-2020 12:35:31 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2.f

Date	Location	User	Value	Reason
Dec-18-2020 12:35:31 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom:: DIA RR HE A Were fever or systemic sy mptoms present on the las t day the Subject Diary wa s completed?: NO	Initial Entry

090177e196ae2fe0\Final\Final On: 01-Apr-2021 03:54 (GMT)

Header Text: C4591001

Visit: V3_MONTH1_POSTVAX2_L

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

Form Version: 10-Oct-2020 16:03

Form Status: Data Complete, Frozen, Verified

Site No: 1210

Site Name: (1210) Medipol University Medical Faculty

Subject No: 12101029

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:11

2.f Symptom:

Date	Location	User	Value	Reason
Dec-18-2020 12:35:31 (UTC+03:00) Istanbul	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
Dec-18-2020 12:35:31 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2.g

Date	Location	User	Value	Reason
Dec-18-2020 12:35:31 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom:: NEW OR WORSE ED MUS CLE PAI N Were fever or system NO ic symptoms present on the last day the S ubject Diary was co mpleted?:	Initial Entry

2.g Symptom:

Date	Location	User	Value	Reason
Dec-18-2020 12:35:31 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NEW OR WORSE NED MUSCL E 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
Dec-18-2020 12:35:31 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

090177e196ae2fe0\Final\Final On: 01-Apr-2021 03:54 (GMT)

Header Text: C4591001

Visit: V3_MONTH1_POSTVAX2_L

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

Form Version: 10-Oct-2020 16:03

Form Status: Data Complete, Frozen, Verified

Site No: 1210

Site Name: (1210) Medipol University Medical Faculty

Subject No: 12101029

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:11

2.h

Date	Location	User	Value	Reason
Dec-18-2020 12:35:31 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom:: NEW OR WORSE NED JOINT PAIN Were fever or systemic symptoms present on the last day the Subject Diary was completed?: NO	Initial Entry

2.h Symptom:

Date	Location	User	Value	Reason
Dec-18-2020 12:35:31 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NEW OR WORSE NED 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
Dec-18-2020 12:35:31 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

3. Injection Site Location:

Date	Location	User	Value	Reason
Dec-18-2020 12:35:31 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: DELTOID MUSCLE	Initial Entry

4. Injection Site Body Side:

Date	Location	User	Value	Reason
Dec-18-2020 12:35:31 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: LEFT	Initial Entry

5.a

090177e196ae2fe0\Final\Final On: 01-Apr-2021 03:54 (GMT)

Header Text: C4591001

Visit: V3_MONTH1_POSTVAX2_L

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

Form Version: 10-Oct-2020 16:03

Form Status: Data Complete, Frozen, Verified

Site No: 1210

Site Name: (1210) Medipol University Medical Faculty

Subject No: 12101029

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:11

Date	Location	User	Value	Reason
Dec-18-2020 12:35:31 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Injection Site Reaction:: RE DN ESS Were injection site reactions present on the last day the Subject Diary was completed?: NO	Initial Entry

5.a Injection Site Reaction:

Date	Location	User	Value	Reason
Dec-18-2020 12:35:31 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: REDNESS	Initial Entry

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

Date	Location	User	Value	Reason
Dec-18-2020 12:35:31 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

5.b

Date	Location	User	Value	Reason
Dec-18-2020 12:35:31 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Injection Site Reaction:: SWE LLI NG Were injection site reactions present on the last day the Subject Diary was completed?: NO	Initial Entry

090177e196ae2fe0\Final\Final On: 01-Apr-2021 03:54 (GMT)

Header Text: C4591001

Visit: V3_MONTH1_POSTVAX2_L

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

Form Version: 10-Oct-2020 16:03

Form Status: Data Complete, Frozen, Verified

Site No: 1210

Site Name: (1210) Medipol University Medical Faculty

Subject No: 12101029

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:11

5.b Injection Site Reaction:

Date	Location	User	Value	Reason
Dec-18-2020 12:35:31 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: SWELLING	Initial Entry

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

Date	Location	User	Value	Reason
Dec-18-2020 12:35:31 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

5.c

Date	Location	User	Value	Reason
Dec-18-2020 12:35:31 (UTC+03:00) Istanbul	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
Dec-18-2020 12:35:31 (UTC+03:00) Istanbul	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
Dec-18-2020 12:35:31 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

090177e196ae2fe0\Final\Final On: 01-Apr-2021 03:54 (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, Frozen, Verified

Site No: 1210

Site Name: (1210) Medipol University Medical Faculty

Subject No: 12101029

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:11

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1. Data Origin

Date	Location	User	Value	Reason
Dec-18-2020 12:35:54 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Dec-18-2020 12:35:54 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SERUM	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Dec-18-2020 15:26:57 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Dec-18-2020 12:59:20 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Dec-18-2020 12:35:54 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Dec-18-2020 12:35:54 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Date of Collection: Dec/18/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
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090177e196ae2fe0\Final\Final On: 01-Apr-2021 03:54 (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, Frozen, Verified

Site No: 1210

Site Name: (1210) Medipol University Medical Faculty

Subject No: 12101029

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:11

Dec-18-2020 15:26:57 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BRCXWC	Initial Entry
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5.a Sample ID

Date	Location	User	Value	Reason
Dec-18-2020 15:26:57 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BRCXWC	Initial Entry

5.b

Date	Location	User	Value	Reason
Dec-18-2020 15:27:11 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BRCXWD	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Dec-18-2020 15:27:11 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BRCXWD	Initial Entry

5.c

Date	Location	User	Value	Reason
Dec-18-2020 15:27:25 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BSHB6R	Initial Entry

5.c Sample ID

Date	Location	User	Value	Reason
Dec-18-2020 15:27:25 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BSHB6R	Initial Entry

5.d

Date	Location	User	Value	Reason
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090177e196ae2fe0\Final\Final On: 01-Apr-2021 03:54 (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, Frozen, Verified

Site No: 1210

Site Name: (1210) Medipol University Medical Faculty

Subject No: 12101029

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:11

Dec-18-2020 15:27:37 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BSHB6S	Initial Entry
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5.d Sample ID

Date	Location	User	Value	Reason
Dec-18-2020 15:27:37 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BSHB6S	Initial Entry

Header Text: C4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1210

Subject No: 12101029

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - Audit Trail

Form Status:

Site Name: (1210) Medipol University Medical Faculty

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:11

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Date	Location	User	Value	Reason
Nov-05-2020 13:40:01 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Created	

Header Text: C4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1210

Subject No: 12101029

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - Audit Trail

Form Status:

Site Name: (1210) Medipol University Medical Faculty

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:11

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Date	Location	User	Value	Reason
Jan-22-2021 12:35:23 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Created	

Header Text: C4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1210

Subject No: 12101029

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1210) Medipol University Medical Faculty

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:11

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1. Category:

Date	Location	User	Value	Reason
Nov-05-2020 13:40:01 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: ADVERSE EVENT	Initial Entry

2. AE ID:

Date	Location	User	Value	Reason
Nov-05-2020 13:40:01 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 1	Initial Entry

3. Adverse Event:

(If possible specify diagnosis, not individual symptoms)

Date	Location	User	Value	Reason
Nov-09-2020 10:52:00 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Nov-06-2020 18:30:44 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	As it was not evaluated as reactogenicity, it was entered as adverse.
Nov-06-2020 13:45:18 (UTC+03:00) Istanbul	ACV0PFEINFP6000.InFormAdapter.Discrepancy	PFE SDQ PROD (b) (4)	Query 1: Opened	eDiary: AE Joint pain reported with start date 04-Nov-2020 and End Date 05-Nov-2020 seems to be same as e-Diary occurrence Joint pain reported on 04-Nov-2020. Please reconcile or confirm in the

090177e196ae2fe0\Final\Final On: 01-Apr-2021 03:54 (GMT)

Header Text: C4591001

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Form Version: 22-Apr-2020 21:02

Site No: 1210

Subject No: 12101029

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1210) Medipol University Medical Faculty

Subject Initials: ---

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				query response as appropriate (b) (4)
Nov-05-2020 13:40:01 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: joint pain	Initial Entry

4. Start Date Time:

Date	Location	User	Value	Reason
Nov-05-2020 13:40:01 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Nov/4/2020 20:00	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Nov-05-2020 13:40:01 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO End Date Time: Nov/5/2020 08:00	Initial Entry

6. Toxicity Grade:

Date	Location	User	Value	Reason
Nov-05-2020 13:40:01 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 3	Initial Entry

7. Is the adverse event serious?

If Yes, NOTIFY PFIZER IMMEDIATELY.

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

Date	Location	User	Value	Reason
Nov-05-2020 13:40:01 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

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Header Text: C4591001

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Form Version: 22-Apr-2020 21:02

Site No: 1210

Subject No: 12101029

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1210) Medipol University Medical Faculty

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:11

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
Nov-05-2020 13:40:01 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

9. Is this event related to study treatment:

Date	Location	User	Value	Reason
Nov-05-2020 13:40:01 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NOT RELATED If Not Related to study treatment (s), this event is due to: OTHER If Other, specify: ride motorcycle	Initial Entry

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Nov-05-2020 13:40:01 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NOT APPLICABLE	Initial Entry

11. Was a Concomitant Medication given?

Date	Location	User	Value	Reason
Nov-05-2020 13:40:01 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Nov-05-2020 13:40:01 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

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

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Header Text: C4591001

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Form Version: 22-Apr-2020 21:02

Site No: 1210

Subject No: 12101029

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1210) Medipol University Medical Faculty

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:11

Date	Location	User	Value	Reason
Nov-05-2020 13:40:01 (UTC+03:00) Istanbul	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
Nov-05-2020 13:40:01 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

Header Text: C4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1210

Subject No: 12101029

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1210) Medipol University Medical Faculty

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:11

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1. Category:

Date	Location	User	Value	Reason
Jan-22-2021 12:35:23 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: ADVERSE EVENT	Initial Entry

2. AE ID:

Date	Location	User	Value	Reason
Jan-22-2021 12:35:23 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 2	Initial Entry

3. Adverse Event:

(If possible specify diagnosis, not individual symptoms)

Date	Location	User	Value	Reason
Jan-29-2021 05:32:31 (UTC+03:00) Istanbul	ACV0PFEINFP6000	Quan Jason Gong (b) (4)	Query 1: Closed	Response satisfies query
Jan-27-2021 09:29:00 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Transcription Error
Jan-27-2021 09:29:00 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Axillary lymphadenopathy on the left.	Transcription Error
Jan-26-2021 21:45:46 (UTC+03:00) Istanbul	ACV0PFEINFP6000	Quan Jason Gong (b) (4)	Query 1: Opened	GPDClin: Please add information on the laterality, e.g., left, right, or both sides.
Jan-22-2021 12:35:23 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Axillary lymphadenopathy	Initial Entry

4. Start Date Time:

Date	Location	User	Value	Reason
Jan-22-2021 12:35:23 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Jan/20/2021 UNK:UNK	Initial Entry

090177e196ae2fe0\Final\Final On: 01-Apr-2021 03:54 (GMT)

Header Text: C4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1210

Subject No: 12101029

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1210) Medipol University Medical Faculty

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:11

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Feb-02-2021 13:50:51 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO End Date Time: Jan/23/2021 UNK:UNK	New Information
Jan-22-2021 12:35:23 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

6. Toxicity Grade:

Date	Location	User	Value	Reason
Jan-22-2021 12:35:23 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 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
Jan-22-2021 12:35:23 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

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

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

Date	Location	User	Value	Reason
Jan-22-2021 12:35:23 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

9. Is this event related to study treatment:

Date	Location	User	Value	Reason
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090177e196ae2fe0\Final\Final On: 01-Apr-2021 03:54 (GMT)

Header Text: C4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1210

Subject No: 12101029

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1210) Medipol University Medical Faculty

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:11

Jan-22-2021 12:35:23 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: RELATED	Initial Entry
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10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Jan-22-2021 12:35:23 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NOT APPLICABLE	Initial Entry

11. Was a Concomitant Medication given?

Date	Location	User	Value	Reason
Jan-22-2021 12:35:23 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Jan-22-2021 12:35:23 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

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

Date	Location	User	Value	Reason
Feb-02-2021 13:51:15 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Feb-02-2021 13:51:15 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: RECOVERED/RESOLVED	New Information
Feb-02-2021 13:50:51 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	For AE Axillary lymphadenopathy on the left.: Response to "What was the outcome of this adverse event?" is 'Recovering/Resolving' but AE End Date/Time is present.

090177e196ae2fe0\Final\Final On: 01-Apr-2021 03:54 (GMT)

Header Text: C4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1210

Subject No: 12101029

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1210) Medipol University Medical Faculty

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:11

Jan-22-2021 12:35:23 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: RECOVERING/RESOLVING	Initial Entry
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14. Did the adverse event cause the subject to be discontinued from the study?

Date	Location	User	Value	Reason
Jan-22-2021 12:35:23 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

Header Text: C4591001

Visit: Logs - Unscheduled

Form Version: 17-Jul-2020 21:54

Site No: 1210

Subject No: 12101029

Generated By: (b) (4)

Form: MEDICATION ERROR - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1210) Medipol University Medical Faculty

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:11

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1. Category:

Date	Location	User	Value	Reason
Nov-05-2020 13:40:48 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

2. Medication Error (Type of Medication Error):

Date	Location	User	Value	Reason
Nov-05-2020 13:40:48 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

3. Start Date:

Date	Location	User	Value	Reason
Nov-05-2020 13:40:48 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

4. Is the medication error still ongoing?

Date	Location	User	Value	Reason
Nov-05-2020 13:40:48 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Nov-05-2020 13:40:48 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

6. Was a Concomitant Medication given?

Date	Location	User	Value	Reason
Nov-05-2020 13:40:48 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

090177e196ae2fe0\Final\Final On: 01-Apr-2021 03:54 (GMT)

Header Text: C4591001

Visit: Logs - Unscheduled

Form Version: 17-Jul-2020 21:54

Site No: 1210

Subject No: 12101029

Generated By: (b) (4)

Form: MEDICATION ERROR - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1210) Medipol University Medical Faculty

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:11

7. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Nov-05-2020 13:40:48 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

8. Did the Medication Error cause the subject to be discontinued from the study?

Date	Location	User	Value	Reason
Nov-05-2020 13:40:48 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

9. Was this medication error associated with any adverse events?

Date	Location	User	Value	Reason
Nov-05-2020 13:40:48 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

10. Serious Adverse Event Number: For Pfizer Use Only

Date	Location	User	Value	Reason
Nov-05-2020 13:40:48 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

090177e196ae2fe0\Final\Final On: 01-Apr-2021 03:54 (GMT)

Header Text: C4591001

Visit: Logs - Unscheduled

Form: CONCOMITANT MEDICATIONS - NON STUDY
VACCINATIONS - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1210

Site Name: (1210) Medipol University Medical Faculty

Subject No: 12101029

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:11

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1. What is the medication identifier?

Date	Location	User	Value	Reason
Nov-05-2020 13:41:15 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

2. Category:

Date	Location	User	Value	Reason
Nov-05-2020 13:41:15 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

3. Concomitant Medications Pre-specified:

Date	Location	User	Value	Reason
Nov-05-2020 13:41:15 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

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).

Date	Location	User	Value	Reason
Nov-05-2020 13:41:15 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5. Date:

Date	Location	User	Value	Reason
Nov-05-2020 13:41:15 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

090177e196ae2fe0\Final\Final On: 01-Apr-2021 03:54 (GMT)

Header Text: C4591001

Visit: Logs - Unscheduled

Form: CONCOMITANT MEDICATIONS - PROHIBITED - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1210

Site Name: (1210) Medipol University Medical Faculty

Subject No: 12101029

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:11

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1. What is the medication identifier?

Date	Location	User	Value	Reason
Nov-05-2020 13:41:35 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

2. Category:

Date	Location	User	Value	Reason
Nov-05-2020 13:41:35 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

3. Concomitant Medications Pre-specified:

Date	Location	User	Value	Reason
Nov-05-2020 13:41:35 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

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).

Date	Location	User	Value	Reason
Nov-05-2020 13:41:35 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5. Dose:

Date	Location	User	Value	Reason
Nov-05-2020 13:41:35 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

6. Dose Unit:

090177e196ae2fe0\Final\Final On: 01-Apr-2021 03:54 (GMT)

Header Text: C4591001

Visit: Logs - Unscheduled

Form: CONCOMITANT MEDICATIONS - PROHIBITED - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1210

Site Name: (1210) Medipol University Medical Faculty

Subject No: 12101029

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:11

Date	Location	User	Value	Reason
Nov-05-2020 13:41:35 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

7. Dose Frequency:

Date	Location	User	Value	Reason
Nov-05-2020 13:41:35 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

8. Route:

Date	Location	User	Value	Reason
Nov-05-2020 13:41:35 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

9. Start Date:

Date	Location	User	Value	Reason
Nov-05-2020 13:41:35 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

10. Ongoing?

Date	Location	User	Value	Reason
Nov-05-2020 13:41:35 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

090177e196ae2fe0\Final\Final On: 01-Apr-2021 03:54 (GMT)

Header Text: C4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1210

Subject No: 12101029

Generated By: (b) (4)

Form: RADIATION TREATMENT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1210) Medipol University Medical Faculty

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:11

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1. Category:

Date	Location	User	Value	Reason
Nov-05-2020 13:41:56 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

2. What is the treatment Identifier?

Date	Location	User	Value	Reason
Nov-05-2020 13:41:56 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

3. Concomitant Non-drug Treatment Pre-specified:

Date	Location	User	Value	Reason
Nov-05-2020 13:41:56 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

4. Treatment:

Date	Location	User	Value	Reason
Nov-05-2020 13:41:56 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5. Start Date:

Date	Location	User	Value	Reason
Nov-05-2020 13:41:56 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

6. Ongoing?

Date	Location	User	Value	Reason
Nov-05-2020 13:41:56 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

090177e196ae2fe0\Final\Final On: 01-Apr-2021 03:54 (GMT)

Header Text: C4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1210

Subject No: 12101029

Generated By: (b) (4)

Form: TRANSFUSIONS - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1210) Medipol University Medical Faculty

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:11

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1. Transfusion Type:

Date	Location	User	Value	Reason
Nov-05-2020 13:42:19 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

2. Date of Transfusion:

Date	Location	User	Value	Reason
Nov-05-2020 13:42:19 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

Header Text: C4591001

Visit: Unplanned 1 - Unscheduled Visit on
Nov/05/2020

Form: DATE OF VISIT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen, Verified

Site No: 1210

Site Name: (1210) Medipol University Medical Faculty

Subject No: 12101029

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:11

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I. Date of Visit

Date	Location	User	Value	Reason
Nov-05-2020 13:42:47 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Nov/5/2020	Initial Entry

Header Text: C4591001

Visit: Unplanned 1 - Unscheduled Visit on
Nov/05/2020

Form: UNPLANNED VISIT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Frozen, Verified

Site No: 1210

Site Name: (1210) Medipol University Medical Faculty

Subject No: 12101029

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:11

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I. Assessments

Date	Location	User	Value	Reason
Nov-05-2020 13:50:55 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Nov-05-2020 13:42:57 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Contact Outcome is ticked however 'CONTACT OUTCOME' form is not entered. Please review and update as appropriate.
Nov-05-2020 13:42:57 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: CONTACT OUTCOME	Initial Entry

090177e196ae2fe0\Final\Final On: 01-Apr-2021 03:54 (GMT)

Header Text: C4591001

Visit: Unplanned 1 - Unscheduled Visit on
Nov/05/2020

Form Version: 22-Apr-2020 21:04

Site No: 1210

Subject No: 12101029

Generated By: (b) (4)

Form: CONTACT OUTCOME - UNPLANNED - eCRF Audit Trail
History

Form Status: Data Complete, Frozen, Verified

Site Name: (1210) Medipol University Medical Faculty

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:11

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1. Contact Type:

Date	Location	User	Value	Reason
Nov-05-2020 13:50:55 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: TELEPHONE VISIT	Initial Entry

2. Was contact made?

Date	Location	User	Value	Reason
Nov-05-2020 13:50:55 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Date of Contact: Nov/5/2020 Contact Outcome: VISIT NOT ARRANGED, RE ACTION NO LONGER PRES ENT	Initial Entry

3. Comments:

Date	Location	User	Value	Reason
Nov-05-2020 13:50:55 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: patient had joint pain which was st arted on 04 Nov 2020. Patient ride s motorcycle in his daily life. Inve stigator evaluated this event as not reactogeneity. Joint pain recovere d on 05 Nov 2020.	Initial Entry

090177e196ae2fe0\Final\Final On: 01-Apr-2021 03:54 (GMT)

Header Text: C4591001

Visit: End of Treatment - Unscheduled

Form Version: 10-Dec-2020 02:29

Site No: 1210

Subject No: 12101029

Generated By: (b) (4)

Form: DISPOSITION - TREATMENT - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1210) Medipol University Medical Faculty

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:11

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1. Date of Completion/Discontinuation/Death :

Date	Location	User	Value	Reason
Dec-18-2020 16:51:32 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Dec/18/2020	Initial Entry

2. Phase of Disposition:

Date	Location	User	Value	Reason
Dec-18-2020 16:51:32 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: VACCINATION	Initial Entry

3. Status:

Date	Location	User	Value	Reason
Dec-18-2020 16:51:32 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: COMPLETED	Initial Entry

090177e196ae2fe0\Final\Final On: 01-Apr-2021 03:54 (GMT)

Header Text: C4591001

Visit: Potential ReVax Initial Contact -
Unscheduled

Form: DATE OF VISIT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen, Verified

Site No: 1210

Site Name: (1210) Medipol University Medical Faculty

Subject No: 12101029

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:11

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I. Date of Visit

Date	Location	User	Value	Reason
Dec-29-2020 12:07:30 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Dec/28/2020	Initial Entry

Header Text: C4591001

Visit: Potential ReVax Initial Contact -
Unscheduled

Form Version: 10-Dec-2020 02:25

Site No: 1210

Subject No: 12101029

Generated By: (b) (4)

Form: FURTHER VACCINATION CONFIRMATION - eCRF Audit
Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1210) Medipol University Medical Faculty

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:11

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1. Select appropriate response - Is participant willing to return for Vaccination 3?

Date	Location	User	Value	Reason
Dec-29-2020 16:31:28 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Dec-29-2020 12:35:13 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	The response indicates participant was unblinded, however the TREATMENT UNBLINDED date is missing in the DISP visit. Please complete this date.
Dec-29-2020 12:07:57 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Participant is willing to return for Vaccination 3 Participant is: eligible per local/national recommendations and confirmed to have received only placebo at Vaccination 1/2	Transcription Error
Dec-29-2020 12:07:39 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	The response indicates participant was unblinded, however the TREATMENT UNBLINDED date is missing in the DISP visit. Please complete this date.
Dec-29-2020 12:07:39 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Participant is willing to return for Vaccination 3 Participant is: eligible and NOT confirmed to have received only placebo at Vaccination 1/2	Initial Entry

090177e196ae2fe0\Final\Final On: 01-Apr-2021 03:54 (GMT)

Header Text: C4591001

Visit: V101_VAX3

Form Version: 22-Apr-2020 21:02

Site No: 1210

Subject No: 12101029

Generated By: (b) (4)

Form: DATE OF VISIT - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1210) Medipol University Medical Faculty

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:11

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I. Date of Visit

Date	Location	User	Value	Reason
Dec-30-2020 15:40:13 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Dec/29/2020	Initial Entry

Header Text: C4591001

Visit: V101_VAX3

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

Form Version: 10-Dec-2020 02:31

Form Status: Data Complete, Frozen, Verified

Site No: 1210

Site Name: (1210) Medipol University Medical Faculty

Subject No: 12101029

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:11

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1. Consent Was:

Date	Location	User	Value	Reason
Dec-30-2020 15:40:22 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: OBTAINED Date Written Consent Obtained Dec/29/2020	Initial Entry

Header Text: C4591001

Visit: V101_VAX3

Form: DISPOSITION - SCREENING FOR FURTHER VACCINATION - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:31

Form Status: Data Complete, Frozen, Verified

Site No: 1210

Site Name: (1210) Medipol University Medical Faculty

Subject No: 12101029

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:11

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1. Date of Completion/Discontinuation/Death :

Date	Location	User	Value	Reason
Dec-30-2020 15:41:00 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Dec/29/2020	Initial Entry

2. Phase of Disposition:

Date	Location	User	Value	Reason
Dec-30-2020 15:41:00 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: REPEAT SCREENING 1	Initial Entry

3. Status:

Date	Location	User	Value	Reason
Dec-30-2020 15:41:00 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: COMPLETED	Initial Entry

090177e196ae2fe0\Final\Final On: 01-Apr-2021 03:54 (GMT)

Header Text: C4591001

Visit: V101_VAX3

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1210

Site Name: (1210) Medipol University Medical Faculty

Subject No: 12101029

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:11

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1. Data Origin

Date	Location	User	Value	Reason
Dec-30-2020 15:41:12 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Dec-30-2020 15:41:12 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SERUM	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Dec-30-2020 15:42:12 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Dec-30-2020 15:41:12 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Dec-30-2020 15:41:12 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Date of Collection: Dec/29/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Dec-30-2020 15:42:12 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BR5DM4	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
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090177e196ae2fe0\Final\Final On: 01-Apr-2021 03:54 (GMT)

Header Text: C4591001

Visit: V101_VAX3

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1210

Site Name: (1210) Medipol University Medical Faculty

Subject No: 12101029

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:11

Dec-30-2020 15:42:12 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BR5DM4	Initial Entry
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5.b

Date	Location	User	Value	Reason
Dec-30-2020 15:42:25 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BR5DM5	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Dec-30-2020 15:42:25 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BR5DM5	Initial Entry

5.c

Date	Location	User	Value	Reason
Dec-30-2020 15:42:48 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BSHB8X	Initial Entry

5.c Sample ID

Date	Location	User	Value	Reason
Dec-30-2020 15:42:48 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BSHB8X	Initial Entry

5.d

Date	Location	User	Value	Reason
Dec-30-2020 15:43:04 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BSHB8Y	Initial Entry

090177e196ae2fe0\Final\Final On: 01-Apr-2021 03:54 (GMT)

Header Text: C4591001

Visit: V101_VAX3

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1210

Site Name: (1210) Medipol University Medical Faculty

Subject No: 12101029

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:11

5.d Sample ID

Date	Location	User	Value	Reason
Dec-30-2020 15:43:04 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> BSHB8Y	Initial Entry

Header Text: C4591001

Visit: V101_VAX3

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1210

Site Name: (1210) Medipol University Medical Faculty

Subject No: 12101029

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:11

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1. Data Origin

Date	Location	User	Value	Reason
Dec-30-2020 15:43:23 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Dec-30-2020 15:43:23 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: NASAL_SWAB	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Dec-30-2020 15:43:40 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Dec-30-2020 15:43:23 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Dec-30-2020 15:43:23 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Date of Collection: Dec/29/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Dec-30-2020 15:43:40 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BR5DMB	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
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090177e196ae2fe0\Final\Final On: 01-Apr-2021 03:54 (GMT)

Header Text: C4591001

Visit: V101_VAX3

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1210

Site Name: (1210) Medipol University Medical Faculty

Subject No: 12101029

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:11

Dec-30-2020 15:43:40 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BR5DMB	Initial Entry
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Header Text: C4591001

Visit: V101_VAX3

Form Version: 10-Dec-2020 02:26

Site No: 1210

Subject No: 12101029

Generated By: (b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1210) Medipol University Medical Faculty

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:11

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1. Was there a temporary delay of vaccination?

Date	Location	User	Value	Reason
Dec-30-2020 15:49:38 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2. Treatment Name

Date	Location	User	Value	Reason
Dec-30-2020 15:49:38 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: BNT162b2	Initial Entry

3. Formulation:

Date	Location	User	Value	Reason
Dec-30-2020 15:49:38 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: INJECTION	Initial Entry

4. Dose Date Time:

Date	Location	User	Value	Reason
Dec-30-2020 15:49:38 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Dec/29/2020 14:25	Initial Entry

5. Anatomical Location:

Date	Location	User	Value	Reason
Dec-30-2020 15:49:38 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: DELTOID MUSCLE	Initial Entry

6. Body Side:

Date	Location	User	Value	Reason
Dec-30-2020 15:49:38 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: LEFT	Initial Entry

7. Route:

090177e196ae2fe0\Final\Final On: 01-Apr-2021 03:54 (GMT)

Header Text: C4591001

Visit: V101_VAX3

Form Version: 10-Dec-2020 02:26

Site No: 1210

Subject No: 12101029

Generated By: (b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1210) Medipol University Medical Faculty

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:11

Date	Location	User	Value	Reason
Dec-30-2020 15:49:38 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: INTRAMUSCULAR	Initial Entry

8. Actual Dose:

Date	Location	User	Value	Reason
Dec-30-2020 15:49:38 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 30.0	Initial Entry

9. Unit:

Date	Location	User	Value	Reason
Dec-30-2020 15:49:38 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: ug	Initial Entry

10. Timeframe Subject Was Observed

Date	Location	User	Value	Reason
Dec-30-2020 15:49:38 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 30 MINUTES	Initial Entry

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

Date	Location	User	Value	Reason
Dec-30-2020 15:49:38 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

090177e196ae2fe0\Final\Final On: 01-Apr-2021 03:54 (GMT)

Header Text: C4591001

Visit: Disposition - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1210

Subject No: 12101029

Generated By: (b) (4)

Form: TREATMENT UNBLINDED - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1210) Medipol University Medical Faculty

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:11

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1. Date Treatment Unblinded :

Date	Location	User	Value	Reason
Dec-29-2020 16:31:28 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Dec/28/2020	Initial Entry

2. Primary Reason for Unblinding:

Date	Location	User	Value	Reason
Dec-29-2020 16:31:28 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: ASSESS ELIGIBILITY FOR AD DITIONAL VACCINATION	Initial Entry

090177e196ae2fe0\Final\Final On: 01-Apr-2021 03:54 (GMT)

Header Text: C4591001

Visit: Disposition - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1210

Subject No: 12101029

Generated By: (b) (4)

Form: WITHDRAWAL OF CONSENT - eCRF Audit Trail History

Form Status: Data Complete, Verified

Site Name: (1210) Medipol University Medical Faculty

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:11

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1. Withdrawal of Consent Date :

Date	Location	User	Value	Reason
Dec-29-2020 16:31:43 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

Header Text: C4591001

Visit: Disposition - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1210

Subject No: 12101029

Generated By: (b) (4)

Form: DEATH DETAILS CODED - eCRF Audit Trail History

Form Status: Data Complete, Verified

Site Name: (1210) Medipol University Medical Faculty

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:11

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1. Date of Collection / Notification of Death:

Date	Location	User	Value	Reason
Jan-06-2021 09:42:22 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Clo sed	Query raised in error
Dec-31-2020 13:33:24 (UTC+03:00) Istanbul	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (b) (4)	Query 1: Op ened	DMW6657961;Date of Collection/Notification of Death is not expected to be Unknown or Not Applicable. Please review and update appropriately or clarify
Dec-29-2020 16:32:03 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry : Not A pplica ble	Initial Entry

090177e196ae2fe0\Final\Final On: 01-Apr-2021 03:54 (GMT)

Header Text: C4591001

Visit: V102_VAX4

Form Version: 22-Apr-2020 21:02

Site No: 1210

Subject No: 12101029

Generated By: (b) (4)

Form: DATE OF VISIT - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1210) Medipol University Medical Faculty

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:11

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I. Date of Visit

Date	Location	User	Value	Reason
Jan-19-2021 12:15:42 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Jan/19/2021	Initial Entry

Header Text: C4591001

Visit: V102_VAX4

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1210

Site Name: (1210) Medipol University Medical Faculty

Subject No: 12101029

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:11

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1. Data Origin

Date	Location	User	Value	Reason
Jan-19-2021 12:15:51 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Jan-19-2021 12:15:51 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: NASAL_SWAB	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Jan-19-2021 12:16:23 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Jan-19-2021 12:15:51 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Jan-19-2021 12:15:51 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Date of Collection: Jan/19/2021	Initial Entry

5.a

Date	Location	User	Value	Reason
Jan-19-2021 12:16:23 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BR0Z02	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
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090177e196ae2fe0\Final\Final On: 01-Apr-2021 03:54 (GMT)

Header Text: C4591001

Visit: V102_VAX4

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1210

Site Name: (1210) Medipol University Medical Faculty

Subject No: 12101029

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:11

Jan-19-2021 12:16:23 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BR0Z02	Initial Entry
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Header Text: C4591001

Visit: V102_VAX4

Form Version: 10-Dec-2020 02:26

Site No: 1210

Subject No: 12101029

Generated By: (b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1210) Medipol University Medical Faculty

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:11

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1. Was there a temporary delay of vaccination?

Date	Location	User	Value	Reason
Jan-19-2021 13:06:56 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2. Treatment Name

Date	Location	User	Value	Reason
Jan-19-2021 13:06:56 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: BNT162b2	Initial Entry

3. Formulation:

Date	Location	User	Value	Reason
Jan-19-2021 13:06:56 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: INJECTION	Initial Entry

4. Dose Date Time:

Date	Location	User	Value	Reason
Jan-19-2021 13:06:56 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Jan/19/2021 09:55	Initial Entry

5. Anatomical Location:

Date	Location	User	Value	Reason
Jan-19-2021 13:06:56 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: DELTOID MUSCLE	Initial Entry

6. Body Side:

Date	Location	User	Value	Reason
Jan-19-2021 13:06:56 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: LEFT	Initial Entry

7. Route:

090177e196ae2fe0\Final\Final On: 01-Apr-2021 03:54 (GMT)

Header Text: C4591001

Visit: V102_VAX4

Form Version: 10-Dec-2020 02:26

Site No: 1210

Subject No: 12101029

Generated By: (b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1210) Medipol University Medical Faculty

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:11

Date	Location	User	Value	Reason
Jan-19-2021 13:06:56 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: INTRAMUSCULAR	Initial Entry

8. Actual Dose:

Date	Location	User	Value	Reason
Jan-19-2021 13:06:56 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 30.0	Initial Entry

9. Unit:

Date	Location	User	Value	Reason
Jan-19-2021 13:06:56 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: ug	Initial Entry

10. Timeframe Subject Was Observed

Date	Location	User	Value	Reason
Jan-19-2021 13:06:56 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 30 MINUTES	Initial Entry

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

Date	Location	User	Value	Reason
Jan-19-2021 13:06:56 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

090177e196ae2fe0\Final\Final On: 01-Apr-2021 03:54 (GMT)

Header Text: C4591001

Visit: V103_MONTH1

Form Version: 22-Apr-2020 21:02

Site No: 1210

Subject No: 12101029

Generated By: (b) (4)

Form: DATE OF VISIT - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1210) Medipol University Medical Faculty

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:11

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I. Date of Visit

Date	Location	User	Value	Reason
Feb-16-2021 14:08:05 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Feb/16/2021	Initial Entry

Header Text: C4591001

Visit: V103_MONTH1

Form Version: 22-Apr-2020 21:04

Site No: 1210

Subject No: 12101029

Generated By: (b) (4)

Form: CONTACT OUTCOME - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1210) Medipol University Medical Faculty

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:11

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1. Contact Type:

Date	Location	User	Value	Reason
Feb-16-2021 14:08:17 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: TELEPHONE VISIT	Initial Entry

2. Was contact made?

Date	Location	User	Value	Reason
Feb-16-2021 14:08:17 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Date of Contact: Feb/16/2021	Initial Entry

Header Text: C4591001**Visit:** FURTHER_VACCINATION_EOT -
Unscheduled**Form:** DISPOSITION - TREATMENT - eCRF Audit Trail History**Form Version:** 10-Dec-2020 02:29**Form Status:** Data Complete, Frozen, Verified**Site No:** 1210**Site Name:** (1210) Medipol University Medical Faculty**Subject No:** 12101029**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 13:11[Back to Form](#)**1. Date of Completion/Discontinuation/Death :**

Date	Location	User	Value	Reason
Feb-17-2021 12:51:57 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Clos ed	Incorrect query
Feb-17-2021 10:58:53 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Ans wered	EOT2 date must be the same day as visit103
Feb-16-2021 17:45:07 (UTC+03:00) Istanbul	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (b) (4)	Query 1: Ope ned	DMW7268938;Status on the Disposition - Treatment form is COMPLETED, but Date is different than Visit 3 Date. Please review and update as appropriate.
Feb-16-2021 14:08:37 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Feb/16 /2021	Initial Entry

2. Phase of Disposition:

Date	Location	User	Value	Reason
Feb-16-2021 14:08:37 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: OPEN LABEL TREATMENT	Initial Entry

3. Status:

Date	Location	User	Value	Reason
Feb-16-2021 14:08:37 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: COMPLETED	Initial Entry

Header Text: C4591001

Visit: Subject Status - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1210

Subject No: 12101029

Generated By: (b) (4)

Form: SUBJECT STATUS - eCRF Audit Trail History

Form Status: Data Complete, Verified

Site Name: (1210) Medipol University Medical Faculty

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:11

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1. Subject Status

Date	Location	User	Value	Reason
Dec-18-2020 16:51:32 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: FOLLOW-UP	Initial Entry
Oct-30-2020 19:30:39 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: ENROLLED/RANDOMIZED	Initial Entry
Oct-30-2020 19:26:12 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SCREENED	Initial Entry

2. Subject Status Date

Date	Location	User	Value	Reason
Dec-18-2020 16:51:32 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Dec/18/2020	Initial Entry
Oct-30-2020 19:30:39 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Oct/30/2020	Initial Entry
Oct-30-2020 19:26:12 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Oct/30/2020	Initial Entry

090177e196ae2fe0\Final\Final On: 01-Apr-2021 03:54 (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: 1210

Site Name: (1210) Medipol University Medical Faculty

Subject No: 12101029

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:11

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I. Casebook Signature

Date	Location	User	Value	Reason
Nov-03-2020 17:16:35 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Click Here to Enable	Initial Entry