

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: 12101026

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: 12101026

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
----	--------------	--

Header Text: C4591001

Visit: COHORT_SELECTION

Form Version: 15-Sep-2020 21:54

Site No: 1210

Subject No: 12101026

Generated By: (b) (4)

Form: DEMOGRAPHY

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](#)

Demography

1.	Subject ID	[12101026]
2.	Birth Date:	(b) (6) 1973
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: 12101026

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: 12101026

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
----	---	----------------

Exclusion Criteria Met

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

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 15-Sep-2020 21:52

Site No: 1210

Subject No: 12101026

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: 12101026

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 _____

090177e196ae2fe1\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: 12101026

Generated By: (b) (4)

Form: HIV STATUS

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](#)

HIV Status

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

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 10-Oct-2020 16:04

Site No: 1210

Subject No: 12101026

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:	[86.0]
3.	Unit:	kg
4.	Height:	[183.0]
5.	Unit:	cm
6.	Body Mass Index:	[25.7]

Vital Signs Details

7.a	Record Identifier:	1
	Temperature:	[36.3]
	Unit:	C
	Temperature Location:	FOREHEAD

090177e196ae2fe1\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: 12101026

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:	[114315]
3.	Randomization Group:	[]

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1210

Subject No: 12101026

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	[BRCXND]
5.b	Sample ID	[BRCXNC]
5.c	Sample ID	[BSHB2S]
5.d	Sample ID	[BSHB2T]

090177e196ae2fe1\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: 12101026

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	[BRCXNF]
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090177e196ae2fe1\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: 12101026

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 10:50
5.	Anatomical Location:	DELTOID MUSCLE
6.	Body Side:	LEFT
7.	Route:	INTRAMUSCULAR
8.	Actual Dose:	[]
9.	Unit:	
10.	Timeframe Subject Was Observed	THE PROTOCOL SPECIFIED OBSERVATION PERIOD
11.	Was the subject observed for at least the protocol specified observation period after investigational product administration?	YES

090177e196ae2fe1\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: 12101026

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: 12101026

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/11/2020
2.	Erroneous Visit	

Header Text: C4591001

Visit: V2_VAX2_L

Form Version: 10-Oct-2020 16:03

Site No: 1210

Subject No: 12101026

Generated By: (b) (4)

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES

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 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

090177e196ae2fe1\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: 12101026

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

090177e196ae2fe1\Final\Final On: 01-Apr-2021 03:54 (GMT)

Header Text: C4591001

Visit: V2_VAX2_L

Form Version: 10-Dec-2020 02:27

Site No: 1210

Subject No: 12101026

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:	Dec/11/2020
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Vital Signs Details

2.a	Record Identifier:	1
	Temperature:	[36.4]
	Unit:	C
	Temperature Location:	FOREHEAD

Header Text: C4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:03

Site No: 1210

Subject No: 12101026

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/11/2020
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	[BRCXVM]
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090177e196ae2fe1\Final\Final On: 01-Apr-2021 03:54 (GMT)

Header Text: C4591001

Visit: V2_VAX2_L

Form Version: 10-Dec-2020 02:26

Site No: 1210

Subject No: 12101026

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:	Dec/11/2020 10:20
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

090177e196ae2fe1\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: 12101026

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

[Form Comments](#)

[eCRF Audit Trail History](#)

Date of Visit

			Comments
1.	Date of Visit	Jan/13/2021	
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: 12101026

Subject Initials: ---

Generated By: (b) (4)

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

[Form Comments](#)
[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	Comments
2.a	Symptom:	FEVER	
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO	Comments
2.b	Symptom:	FATIGUE	
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO	Comments
2.c	Symptom:	HEADACHE	
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO	Comments
2.d	Symptom:	CHILLS	
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO	Comments
2.e	Symptom:	VOMITING	
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO	Comments
2.f	Symptom:	DIARRHEA	
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO	Comments

090177e196ae2fe1\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: 12101026

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

090177e196ae2fe1\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: 12101026

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

[Form Comments](#)

[eCRF Audit Trail History](#)

Electronic Sample Tracking

1.	Data Origin	SITE	Comments
2.	Sample Type	SERUM	Comments
3.	Sample Collected?	YES Date of Collection: Jan/13/2021	Comments
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[]	Comments

Aliquot

Please enter barcode for each aliquot.

5.a	Sample ID	[BNLLLB]
5.b	Sample ID	[BNLLLC]
5.c	Sample ID	[BR0YZL]
5.d	Sample ID	[BR0YZM]

090177e196ae2fe1\Final\Final On: 01-Apr-2021 03:54 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** DATE OF VISIT - ILLNESS ONSET
on Nov/10/2020

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: 12101026

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/10/2020
2.	Erroneous Visit	

COVID-19 Illness Visit

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

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 on Nov/10/2020

Form Version: 10-Oct-2020 16:02

Form Status: Data Complete, Frozen, Verified

Site No: 1210

Site Name: (1210) Medipol University Medical Faculty

Subject No: 12101026

Subject Initials: ---

Generated By: (b) (4)

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

[eCRF Audit Trail History](#)

Signs and Symptoms

1.	Date of Assessment:	Nov/10/2020
2.	Date of First Symptom Started:	Nov/7/2020
3.	Symptoms Ongoing?	NO
	Date of Last Symptom Resolved:	Dec/7/2020

Symptoms

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

090177e196ae2fe1\Final\Final On: 01-Apr-2021 03:54 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 on Nov/10/2020

Form Version: 10-Oct-2020 16:02

Form Status: Data Complete, Frozen, Verified

Site No: 1210

Site Name: (1210) Medipol University Medical Faculty

Subject No: 12101026

Subject Initials: ---

Generated By: (b) (4)

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

Symptoms - Other

5.a

Symptoms - Other Text:

[fatigue]

Header Text: C4591001

Visit: POT_COVID_ILL 1

Form: MICROBIOLOGY SPECIMEN

Form Version: 06-Jul-2020 21:54

Site No: 1210

Site Name: (1210) Medipol University Medical Faculty

Subject No: 12101026

Subject Initials: ---

Generated By: (b) (4)

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

#	Date of Collection	Specimen Type	Specimen Collection Location	Assay Code and Description	Device Type	Form Instance
1.	Nov/7/2020	SWABBED MATERIAL	NASOPHARYNX	SEVERE ACUTE RESP SYNDROME CORONAVIRUS 2	SARS-COV-2 DIAGNOSTIC TEST	Repeating Pages
2.	Nov/9/2020	SWABBED MATERIAL	NASOPHARYNX	SEVERE ACUTE RESP SYNDROME CORONAVIRUS 2	SARS-COV-2 DIAGNOSTIC TEST	Repeating Pages

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** MICROBIOLOGY SPECIMEN
on Nov/10/2020

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen, Verified

Site No: 1210

Site Name: (1210) Medipol University Medical Faculty

Subject No: 12101026

Subject Initials: ---

Generated By: (b) (4)

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

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[eCRF Audit Trail History](#)
[Form Audit Trail](#)

Microbiology Specimen

1.	Actual Date of Collection:	Nov/7/2020
2.	Specimen Type:	SWABBED MATERIAL
3.	Specimen Collection Location:	NASOPHARYNX
4.	Assay Code and Description:	SEVERE ACUTE RESP SYNDROME CORONAVIRUS 2
5.	Device Type:	SARS-COV-2 DIAGNOSTIC TEST
6.	Trade Name:	OTHER
7.	Test Result:	NEGATIVE
8.	Comments/Findings/Details:	[]
9.	Trade Name Other, Specify:	[Bioeksen Bio-Speedy Direct RT-qPCR SARS-CoV-2]

090177e196ae2fe1\Final\Final On: 01-Apr-2021 03:54 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** MICROBIOLOGY SPECIMEN
on Nov/10/2020

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen, Verified

Site No: 1210

Site Name: (1210) Medipol University Medical Faculty

Subject No: 12101026

Subject Initials: ---

Generated By: (b) (4)

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

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[Form Audit Trail](#)

Microbiology Specimen

1.	Actual Date of Collection:	Nov/9/2020
2.	Specimen Type:	SWABBED MATERIAL
3.	Specimen Collection Location:	NASOPHARYNX
4.	Assay Code and Description:	SEVERE ACUTE RESP SYNDROME CORONAVIRUS 2
5.	Device Type:	SARS-COV-2 DIAGNOSTIC TEST
6.	Trade Name:	OTHER
7.	Test Result:	NEGATIVE
8.	Comments/Findings/Details:	[]
9.	Trade Name Other, Specify:	[Bioeksen Bio-Speedy Direct RT-qPCR SARS-CoV-2]

090177e196ae2fe1\Final\Final On: 01-Apr-2021 03:54 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB SELF on Nov/10/2020

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: 12101026

Subject Initials: ---

Generated By: (b) (4)

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

[eCRF Audit Trail History](#)

Electronic Sample Tracking

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB_SELF
3.	Sample Collected?	YES Date of Collection: Nov/10/2020
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[]

Aliquot

Please enter barcode for each aliquot.

5.a	Sample ID	[BRCXT1]
-----	-----------	----------

090177e196ae2fe1\Final\Final On: 01-Apr-2021 03:54 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB
on Nov/10/2020

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: 12101026

Subject Initials: ---

Generated By: (b) (4)

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?	NO
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[collected self swab]

Aliquot

Please enter barcode for each aliquot.

5.a	Sample ID	[BRCXT1]
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090177e196ae2fe1\Final\Final On: 01-Apr-2021 03:54 (GMT)

Header Text: C4591001**Visit:** POT_COVID_ILL 1 - Unscheduled Visit **Form:** HEALTH CARE UTILIZATION
on Nov/10/2020**Form Version:** 10-Oct-2020 15:59**Form Status:** Data Complete, Frozen, Verified**Site No:** 1210**Site Name:** (1210) Medipol University Medical Faculty**Subject No:** 12101026**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 13:11[eCRF Audit Trail History](#)**Health Care Utilization**

1.a	Physician or Healthcare Professional:	SPECIALIST
	Occurrence of Visits or Contacts:	NO
1.b	Physician or Healthcare Professional:	EMERGENCY ROOM
	Occurrence of Visits or Contacts:	YES Number of Visits or Contacts: [2]
1.c	Physician or Healthcare Professional:	PRIMARY CARE PHYSICIAN
	Occurrence of Visits or Contacts:	NO
1.d	Physician or Healthcare Professional:	URGENT CARE
	Occurrence of Visits or Contacts:	NO
1.e	Physician or Healthcare Professional:	TELEPHONE CONSULTATION
	Occurrence of Visits or Contacts:	NO
1.f	Physician or Healthcare Professional:	OTHER
	Occurrence of Visits or Contacts:	NO

Health Care Utilization Other

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

Health Care Utilization

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

Header Text: C4591001

Visit: POT_COVID_ILL 1

Form Version: 22-Apr-2020 21:02

Site No: 1210

Subject No: 12101026

Generated By: (b) (4)

Form: HOSPITALIZATION DETAILS

Site Name: (1210) Medipol University Medical Faculty

Subject Initials: ---

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

#	Hospitalization Category	Hospitalization Term	Admission Date	Ongoing	Form Instance
1. DELETED	HOSPITALIZATION STATUS	HOSPITAL	Nov/16/2020	NO Discharge Date: Nov/23/2020	Repeating Pages

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** HOSPITALIZATION DETAILS
on Nov/10/2020

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Deleted, Verified

Site No: 1210

Site Name: (1210) Medipol University Medical Faculty

Subject No: 12101026

Subject Initials: ---

Generated By: (b) (4)

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

*** THIS REPEATING FORM HAS BEEN DELETED ***

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Hospitalization Details

1.	Hospitalization Category:	HOSPITALIZATION STATUS
2.	Hospitalization Term:	HOSPITAL
3.	Admission Date:	Nov/16/2020
4.	Ongoing?	NO Discharge Date: Nov/23/2020

Header Text: C4591001

Visit: POT_COVID_ILL 1

Form: RESPIRATORY TREATMENT

Form Version: 06-Jul-2020 21:53

Site No: 1210

Site Name: (1210) Medipol University Medical Faculty

Subject No: 12101026

Subject Initials: ---

Generated By: (b) (4)

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

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

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** RESPIRATORY TREATMENT
on Nov/10/2020

Form Version: 06-Jul-2020 21:53

Form Status: Data Complete, Frozen, Verified

Site No: 1210

Site Name: (1210) Medipol University Medical Faculty

Subject No: 12101026

Subject Initials: ---

Generated By: (b) (4)

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

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Respiratory Treatment

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

090177e196ae2fe1\Final\Final On: 01-Apr-2021 03:54 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** ILLNESS DETAILS
on Nov/10/2020

Form Version: 06-Jul-2020 21:52

Form Status: Data Complete, Frozen, Verified

Site No: 1210

Site Name: (1210) Medipol University Medical Faculty

Subject No: 12101026

Subject Initials: ---

Generated By: (b) (4)

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

[eCRF Audit Trail History](#)

Illness Details

1.	Category of Clinical Event:	POTENTIAL COVID-19 ILLNESS
2.	Was a diagnosis obtained for Potential COVID-19 Illness?	NO
3.	Toxicity Grade:	2

Header Text: C4591001

Visit: POT_COVID_ILL 1

Form: ILLNESS DETAILS - SEVERE

Form Version: 17-Jul-2020 21:55

Site No: 1210

Site Name: (1210) Medipol University Medical Faculty

Subject No: 12101026

Subject Initials: ---

Generated By: (b) (4)

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

#	Category of Clinical Event	Subcategory of Clinical Event	Diagnosis Obtained	Toxicity Grade	Form Instance
1.	Not Applicable	Not Applicable	Not Applicable	Not Applicable	Repeating Pages

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** ILLNESS DETAILS - SEVERE
on Nov/10/2020

Form Version: 17-Jul-2020 21:55

Form Status: Data Complete, Frozen, Verified

Site No: 1210

Site Name: (1210) Medipol University Medical Faculty

Subject No: 12101026

Subject Initials: ---

Generated By: (b) (4)

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

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[eCRF Audit Trail History](#)

Illness Details

1.	Category of Clinical Event:	Not Applicable _____	Comments
2.	Subcategory of Clinical Event:	Not Applicable _____	Comments
3.	Was a diagnosis obtained?	Not Applicable _____	Comments
4.	Toxicity Grade:	Not Applicable _____	Comments

Header Text: C4591001

Visit: POT_COVID_ILL 1

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY

Form Version: 10-Oct-2020 15:58

Site No: 1210

Site Name: (1210) Medipol University Medical Faculty

Subject No: 12101026

Subject Initials: ---

Generated By: (b) (4)

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

#	Category for Lab Test	Vendor Name	Collection Date:	Specimen Type	Lab Result			Form Instance
1.	Not Applicable	Not Applicable	Not Applicable	Not Applicable	Sponsor-Defined Identifier	Test:	Result:	Repeating Pages
					Not Applicable	Not Applicable	Not Applicable	
					Not Applicable	Not Applicable	Not Applicable	
					Not Applicable	Not Applicable	Not Applicable	
					Not Applicable	Not Applicable	Not Applicable	
					Not Applicable	Not Applicable	Not Applicable	
					Not Applicable	Not Applicable	Not Applicable	
					Not Applicable	Not Applicable	Not Applicable	

090177e196ae2fe1\Final\Final On: 01-Apr-2021 03:54 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY
on Nov/10/2020

Form Version: 10-Oct-2020 15:58

Form Status: Data Complete, Frozen, Verified

Site No: 1210

Site Name: (1210) Medipol University Medical Faculty

Subject No: 12101026

Subject Initials: ---

Generated By: (b) (4)

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

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Lab Chemistry Details

1.	Lab Panel:	Not Applicable _____	Comments
2.	Laboratory Name and Address	Not Applicable _____ []	Comments
3.	Collection Date:	Not Applicable _____ //	Comments
4.	Specimen Type:	Not Applicable _____ _____	Comments

Lab Result

5.a	Sponsor ID:	Not Applicable _____ []	Comments
	Test:	C Reactive Protein_PX329	
	Result:	Not Applicable _____ []	Comments
	Not Done:	Not Applicable _____ _____	Comments
	LNMT	Not Applicable _____ Low [] High [] Unit	Comments

090177e196ae2fe1\Final\Final On: 01-Apr-2021 03:54 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY
on Nov/10/2020

Form Version: 10-Oct-2020 15:58

Form Status: Data Complete, Frozen, Verified

Site No: 1210

Site Name: (1210) Medipol University Medical Faculty

Subject No: 12101026

Subject Initials: ---

Generated By: (b) (4)

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

5.b	Sponsor ID:	Not Applicable _____ []	Comments
	Test:	Alanine Aminotransferase_PX30	
	Result:	Not Applicable _____ []	Comments
	Not Done:	Not Applicable _____	Comments
	LNMT	Not Applicable _____ Low [] High [] Unit	Comments
5.c	Sponsor ID:	Not Applicable _____ []	Comments
	Test:	Aspartate Aminotransferase_PX28	
	Result:	Not Applicable _____ []	Comments
	Not Done:	Not Applicable _____	Comments
	LNMT	Not Applicable _____ Low [] High [] Unit	Comments

090177e196ae2fe1\Final\Final On: 01-Apr-2021 03:54 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY
on Nov/10/2020

Form Version: 10-Oct-2020 15:58

Form Status: Data Complete, Frozen, Verified

Site No: 1210

Site Name: (1210) Medipol University Medical Faculty

Subject No: 12101026

Subject Initials: ---

Generated By: (b) (4)

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

5.d	Sponsor ID:	Not Applicable _____ []	Comments
	Test:	Alkaline Phosphatase_PX35	
	Result:	Not Applicable _____ []	Comments
	Not Done:	Not Applicable _____	Comments
	LNMT	Not Applicable _____ Low [] High [] Unit	Comments
5.e	Sponsor ID:	Not Applicable _____ []	Comments
	Test:	Bilirubin_PX21	
	Result:	Not Applicable _____ []	Comments
	Not Done:	Not Applicable _____	Comments
	LNMT	Not Applicable _____ Low [] High [] Unit	Comments

090177e196ae2fe1\Final\Final On: 01-Apr-2021 03:54 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY
on Nov/10/2020

Form Version: 10-Oct-2020 15:58

Form Status: Data Complete, Frozen, Verified

Site No: 1210

Site Name: (1210) Medipol University Medical Faculty

Subject No: 12101026

Subject Initials: ---

Generated By: (b) (4)

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

5.f	Sponsor ID:	Not Applicable _____ []	Comments
	Test:	Blood Urea Nitrogen_PX47	
	Result:	Not Applicable _____ []	Comments
	Not Done:	Not Applicable _____	Comments
	LNMT	Not Applicable _____ Low [] High [] Unit	Comments
5.g	Sponsor ID:	Not Applicable _____ []	Comments
	Test:	Creatinine_PX48	
	Result:	Not Applicable _____ []	Comments
	Not Done:	Not Applicable _____	Comments
	LNMT	Not Applicable _____ Low [] High [] Unit	Comments

090177e196ae2fe1\Final\Final On: 01-Apr-2021 03:54 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1

Form: LOCAL LABORATORY DATA - REPEATING Hematology

Form Version: 10-Oct-2020 16:02

Site No: 1210

Site Name: (1210) Medipol University Medical Faculty

Subject No: 12101026

Subject Initials: ---

Generated By: (b) (4)

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

#	Category for Lab Test	Vendor Name (DERIVED)	Collection Date:	Specimen Type	Lab Result			Form Instance
1.	Not Applicable	Not Applicable	Not Applicable	Not Applicable	Sponsor-Defined Identifier	Test:	Result:	Repeating Pages
					Not Applicable	Not Applicable	Not Applicable	
					Not Applicable	Not Applicable	Not Applicable	
					Not Applicable	Not Applicable	Not Applicable	
					Not Applicable	Not Applicable	Not Applicable	
					Not Applicable	Not Applicable	Not Applicable	
					Not Applicable	Not Applicable	Not Applicable	
					Not Applicable	Not Applicable	Not Applicable	
					Not Applicable	Not Applicable	Not Applicable	
					Not Applicable	Not Applicable	Not Applicable	
					Not Applicable	Not Applicable	Not Applicable	

090177e196ae2fe1\Final\Final On: 01-Apr-2021 03:54 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** LOCAL LABORATORY DATA - REPEATING Hematology on Nov/10/2020

Form Version: 10-Oct-2020 16:02

Form Status: Data Complete, Frozen, Verified

Site No: 1210

Site Name: (1210) Medipol University Medical Faculty

Subject No: 12101026

Subject Initials: ---

Generated By: (b) (4)

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

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Laboratory Data Hematology

1.	Lab Panel:	Not Applicable _____	Comments
2.	Laboratory Name and Address	Not Applicable _____ []	Comments
3.	Collection Date:	Not Applicable _____ //	Comments
4.	Specimen Type:	Not Applicable _____ _____	Comments

Lab Result

5.a	Sponsor ID:	Not Applicable _____ []	Comments
	Test:	Hemoglobin_PX1	
	Result:	Not Applicable _____ []	Comments
	Not Done:	Not Applicable _____ _____	Comments
	LNMT	Not Applicable _____ Low [] High [] Unit	Comments

090177e196ae2fe1\Final\Final On: 01-Apr-2021 03:54 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** LOCAL LABORATORY DATA - REPEATING Hematology on Nov/10/2020

Form Version: 10-Oct-2020 16:02

Form Status: Data Complete, Frozen, Verified

Site No: 1210

Site Name: (1210) Medipol University Medical Faculty

Subject No: 12101026

Subject Initials: ---

Generated By: (b) (4)

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

5.b	Sponsor ID:	Not Applicable _____ []	Comments
	Test:	Hematocrit_PX2	
	Result:	Not Applicable _____ []	Comments
	Not Done:	Not Applicable _____	Comments
	LNMT	Not Applicable _____ Low [] High [] Unit	Comments

5.c	Sponsor ID:	Not Applicable _____ []	Comments
	Test:	Erythrocytes_PX3	
	Result:	Not Applicable _____ []	Comments
	Not Done:	Not Applicable _____	Comments
	LNMT	Not Applicable _____ Low [] High [] Unit	Comments

090177e196ae2fe1\Final\Final On: 01-Apr-2021 03:54 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** LOCAL LABORATORY DATA - REPEATING Hematology on Nov/10/2020

Form Version: 10-Oct-2020 16:02

Form Status: Data Complete, Frozen, Verified

Site No: 1210

Site Name: (1210) Medipol University Medical Faculty

Subject No: 12101026

Subject Initials: ---

Generated By: (b) (4)

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

5.d	Sponsor ID:	Not Applicable _____ []	Comments
	Test:	Platelets_PX5	
	Result:	Not Applicable _____ []	Comments
	Not Done:	Not Applicable _____	Comments
	LNMT	Not Applicable _____ Low [] High [] Unit	Comments

5.e	Sponsor ID:	Not Applicable _____ []	Comments
	Test:	Leukocytes_PX7	
	Result:	Not Applicable _____ []	Comments
	Not Done:	Not Applicable _____	Comments
	LNMT	Not Applicable _____ Low [] High [] Unit	Comments

090177e196ae2fe1\Final\Final On: 01-Apr-2021 03:54 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** LOCAL LABORATORY DATA - REPEATING Hematology on Nov/10/2020

Form Version: 10-Oct-2020 16:02

Form Status: Data Complete, Frozen, Verified

Site No: 1210

Site Name: (1210) Medipol University Medical Faculty

Subject No: 12101026

Subject Initials: ---

Generated By: (b) (4)

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

5.f	Sponsor ID:	Not Applicable _____ []	Comments
	Test:	Neutrophils_PX608	
	Result:	Not Applicable _____ []	Comments
	Not Done:	Not Applicable _____	Comments
	LNMT	Not Applicable _____ Low [] High [] Unit	Comments

5.g	Sponsor ID:	Not Applicable _____ []	Comments
	Test:	Eosinophils_PX609	
	Result:	Not Applicable _____ []	Comments
	Not Done:	Not Applicable _____	Comments
	LNMT	Not Applicable _____ Low [] High [] Unit	Comments

090177e196ae2fe1\Final\Final On: 01-Apr-2021 03:54 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** LOCAL LABORATORY DATA - REPEATING Hematology on Nov/10/2020

Form Version: 10-Oct-2020 16:02

Form Status: Data Complete, Frozen, Verified

Site No: 1210

Site Name: (1210) Medipol University Medical Faculty

Subject No: 12101026

Subject Initials: ---

Generated By: (b) (4)

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

5.h	Sponsor ID:	Not Applicable _____ []	Comments
	Test:	Monocytes_PX612	
	Result:	Not Applicable _____ []	Comments
	Not Done:	Not Applicable _____	Comments
	LNMT	Not Applicable _____ Low [] High [] Unit	Comments

5.i	Sponsor ID:	Not Applicable _____ []	Comments
	Test:	Basophils_PX610	
	Result:	Not Applicable _____ []	Comments
	Not Done:	Not Applicable _____	Comments
	LNMT	Not Applicable _____ Low [] High [] Unit	Comments

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Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** LOCAL LABORATORY DATA - REPEATING Hematology on Nov/10/2020

Form Version: 10-Oct-2020 16:02

Form Status: Data Complete, Frozen, Verified

Site No: 1210

Site Name: (1210) Medipol University Medical Faculty

Subject No: 12101026

Subject Initials: ---

Generated By: (b) (4)

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

5.j	Sponsor ID:	Not Applicable _____ []	Comments
	Test:	Lymphocytes_PX611	
	Result:	Not Applicable _____ []	Comments
	Not Done:	Not Applicable _____ []	Comments
	LNMT	Not Applicable _____ Low [] High [] Unit	Comments

090177e196ae2fe1\Final\Final On: 01-Apr-2021 03:54 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1

Form: VITAL SIGNS - COVID

Form Version: 10-Oct-2020 15:59

Site No: 1210

Site Name: (1210) Medipol University Medical Faculty

Subject No: 12101026

Subject Initials: ---

Generated By: (b) (4)

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

#	Date:	Vital Signs Details			Form Instance
1.	Not Applicable	Record Identifier:	Systolic:	Diastolic:	Repeating Pages
		Not Applicable	Not Applicable	Not Applicable	

090177e196ae2fe1\Final\Final On: 01-Apr-2021 03:54 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** VITAL SIGNS - COVID
on Nov/10/2020

Form Version: 10-Oct-2020 15:59

Form Status: Data Complete, Frozen, Verified

Site No: 1210

Site Name: (1210) Medipol University Medical Faculty

Subject No: 12101026

Subject Initials: ---

Generated By: (b) (4)

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

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Vital Signs

1.	Date:	Not Applicable _____ //	Comments
----	-------	-------------------------------	--------------------------

Vital Signs Details

2.a	Record Identifier:	Not Applicable _____ 1	
	Systolic:	Not Applicable _____ []	Comments
	Diastolic:	Not Applicable _____ []	Comments
	Respiratory Rate in respirations/minute:	Not Applicable _____ []	Comments
	Heart Rate in beats/minute:	Not Applicable _____ []	Comments

090177e196ae2fe1\Final\Final On: 01-Apr-2021 03:54 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1

Form: VITAL SIGNS - PULSE OX ROOM AIR

Form Version: 10-Oct-2020 16:04

Site No: 1210

Site Name: (1210) Medipol University Medical Faculty

Subject No: 12101026

Subject Initials: ---

Generated By: (b) (4)

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

#	Date:	Vital Signs Details		Form Instance
1.	Nov/17/2020	Record Identifier:	Oxygen Saturation	Repeating Pages
		1	92.0	

090177e196ae2fe1\Final\Final On: 01-Apr-2021 03:54 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** VITAL SIGNS - PULSE OX ROOM AIR
on Nov/10/2020

Form Version: 10-Oct-2020 16:04

Form Status: Data Complete, Frozen, Verified

Site No: 1210

Site Name: (1210) Medipol University Medical Faculty

Subject No: 12101026

Subject Initials: ---

Generated By: (b) (4)

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

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[Form Audit Trail](#)

Vital Signs

1.	Date:	Nov/17/2020
----	-------	-------------

Vital Signs Details

2.a	Record Identifier:	1
	SPO2 Pulse Oximetry %	[92.0]

Header Text: C4591001

Visit: POT_COVID_ILL 1

Form: OXYGENATION PARAMETERS

Form Version: 06-Jul-2020 21:52

Site No: 1210

Site Name: (1210) Medipol University Medical Faculty

Subject No: 12101026

Subject Initials: ---

Generated By: (b) (4)

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

#	Date Time of Assessment	Arterial Blood Gases PaO2	FiO2 (Fraction of Inhaled Oxygen)	Form Instance
1.	Not Applicable	Not Applicable	Not Applicable	Repeating Pages

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** OXYGENATION PARAMETERS
on Nov/10/2020

Form Version: 06-Jul-2020 21:52

Form Status: Data Complete, Frozen, Verified

Site No: 1210

Site Name: (1210) Medipol University Medical Faculty

Subject No: 12101026

Subject Initials: ---

Generated By: (b) (4)

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

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[Form Comments](#)

[eCRF Audit Trail History](#)

Oxygenation Parameters

1.	Date Time of Assessment:	Not Applicable _____ //	Comments
2.	Arterial Blood Gases PaO2 (mmHg):	Not Applicable _____ []	Comments
3.	FiO2 (Fraction of Inhaled Oxygen):	Not Applicable _____ []	Comments

Header Text: C4591001

Visit: POT_COVID_ILL 1

Form: CONCOMITANT MEDICATIONS - VASOPRESSORS

Form Version: 06-Jul-2020 21:55

Site No: 1210

Site Name: (1210) Medipol University Medical Faculty

Subject No: 12101026

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

090177e196ae2fe1\Final\Final On: 01-Apr-2021 03:54 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** CONCOMITANT MEDICATIONS - VASOPRESSORS
on Nov/10/2020

Form Version: 06-Jul-2020 21:55

Form Status: Data Complete, Frozen, Verified

Site No: 1210

Site Name: (1210) Medipol University Medical Faculty

Subject No: 12101026

Subject Initials: ---

Generated By: (b) (4)

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.	Start Date:	Not Applicable _____ //	Comments
6.	Ongoing?	Not Applicable _____	Comments

090177e196ae2fe1\Final\Final On: 01-Apr-2021 03:54 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1

Form: IMAGING

Form Version: 06-Jul-2020 21:53

Site No: 1210

Site Name: (1210) Medipol University Medical Faculty

Subject No: 12101026

Subject Initials: ---

Generated By: (b) (4)

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

#	Date of Assessment	Location of Assessment	Imaging Method	Overall Assessment	Form Instance
1.	Nov/16/2020	CHEST	CT SCAN	ABNORMAL <i>If abnormal, specify findings:</i> In both lungs, ground glass appearance and areas of increased density consistent with consolidation are observed.	Repeating Pages

090177e196ae2fe1\Final\Final On: 01-Apr-2021 03:54 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** IMAGING
on Nov/10/2020

Form Version: 06-Jul-2020 21:53

Form Status: Data Complete, Frozen, Verified

Site No: 1210

Site Name: (1210) Medipol University Medical Faculty

Subject No: 12101026

Subject Initials: ---

Generated By: (b) (4)

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

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Imaging

1.	Date of Assessment:	Nov/16/2020
2.	Location of Assessment:	CHEST
3.	Type of Imaging Exam:	CT SCAN
4.	Assessment:	ABNORMAL If abnormal, specify findings: [In both lungs, ground glass appearance and areas of increased density consistent with consolidation are observed.]

Header Text: C4591001

Visit: POT_COVID_CONVA 1 - Unscheduled
Visit on Dec/11/2020

Form: DATE OF VISIT - ILLNESS CONVALESCENT

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: 12101026

Subject Initials: ---

Generated By: (b) (4)

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

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Date of Visit

1.	Date of Visit	Dec/11/2020
2.	Erroneous Visit	

COVID-19 Illness Visit

3.	COVID-19 Illness Visit:	COVID_A1
----	-------------------------	----------

Header Text: C4591001

Visit: POT_COVID_CONVA 1 - Unscheduled
Visit on Dec/11/2020

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

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: 12101026

Subject Initials: ---

Generated By: (b) (4)

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/11/2020
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	[BRCXVL]
5.b	Sample ID	[BRCXVK]
5.c	Sample ID	[BSHB5L]
5.d	Sample ID	[BSHB5K]

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: 12101026

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: 12101026

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: 12101026

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	Acute upper respiratory tract infections	Nov/16/2020 UNK:UNK	NO End Date Time: Dec/7/2020 UNK:UNK	Repeating Pages
2.	ADVERSE EVENT	2	Acute upper respiratory tract infections	Nov/7/2020 UNK:UNK	NO End Date Time: Nov/16/2020 UNK:UNK	Repeating Pages

090177e196ae2fe1\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: 12101026

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:	[1]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[Acute upper respiratory tract infections]
4.	Start Date Time:	Nov/16/2020 UNK:UNK
5.	Is the adverse event still ongoing?	NO End Date Time: Dec/7/2020 UNK:UNK
6.	Toxicity Grade:	3
7.	Is the adverse event serious? If Yes, NOTIFY PFIZER IMMEDIATELY. Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).	YES Is this serious event associated with congenital anomaly or birth defect? NO Did this serious event result in death? NO Did this serious event require or prolong hospitalization? YES Did this serious event result in persistent or significant disability/incapacity? NO Is this serious event life threatening? NO Other medically important serious event 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

090177e196ae2fe1\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: 12101026

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

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: [Suspected COVID19]
10.	Latest Action Taken with Study Treatment:	NOT APPLICABLE
11.	Was a Concomitant Medication given?	YES
12.	Was a Non-Drug Treatment given?	NO
13.	What was the outcome of this adverse event?:	RECOVERED/RESOLVED
14.	Did the adverse event cause the subject to be discontinued from the study?	NO
15.	Serious Adverse Event Number: For Pfizer Use Only	[2020470537]

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Header Text: C4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1210

Subject No: 12101026

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)	[Acute upper respiratory tract infections]
4.	Start Date Time:	Nov/7/2020 UNK:UNK
5.	Is the adverse event still ongoing?	NO End Date Time: Nov/16/2020 UNK:UNK
6.	Toxicity Grade:	1
7.	Is the adverse event serious? If Yes, NOTIFY PFIZER IMMEDIATELY. Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).	NO
8.	Is this adverse event the result of a study Medication Error? If Yes, record the type of medication error on the Medication Error Log.	NO
9.	Is this event related to study treatment:	NOT RELATED If Not Related to study treatment(s), this event is due to: OTHER If Other, specify: [suspected covid 19]

090177e196ae2fe1\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: 12101026

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

10.	Latest Action Taken with Study Treatment:	NOT APPLICABLE
11.	Was a Concomitant Medication given?	NO
12.	Was a Non-Drug Treatment given?	NO
13.	What was the outcome of this adverse event?:	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	[]

090177e196ae2fe1\Final\Final On: 01-Apr-2021 03:54 (GMT)

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: 12101026

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.						Repeating Pages

Header Text: C4591001

Visit: Logs - Unscheduled

Form Version: 17-Jul-2020 21:54

Site No: 1210

Subject No: 12101026

Generated By: (b) (4)

Form: MEDICATION ERROR

Form Status: Not Started

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:	
2.	Medication Error (Type of Medication Error):	[]
3.	Start Date:	//
4.	Is the medication error still ongoing?	
5.	Latest Action Taken with Study Treatment:	
6.	Was a Concomitant Medication given?	
7.	Was a Non-Drug Treatment given?	
8.	Did the Medication Error cause the subject to be discontinued from the study?	
9.	Was this medication error associated with any adverse events?	
10.	Serious Adverse Event Number: For Pfizer Use Only	[]

090177e196ae2fe1\Final\Final On: 01-Apr-2021 03:54 (GMT)

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: 12101026

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.						Repeating Pages

Header Text: C4591001

Visit: Logs - Unscheduled

Form: CONCOMITANT MEDICATIONS - NON STUDY
VACCINATIONS

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1210

Site Name: (1210) Medipol University Medical Faculty

Subject No: 12101026

Subject Initials: ---

Generated By: (b) (4)

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

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Concomitant Medications

1.	What is the medication identifier?	[]
2.	Category:	
3.	Concomitant Medications Pre-specified:	
4.	Medication: Provide the complete generic drug name (including salt form, where applicable). Where generic name is unknown, enter the full trade or proprietary name. Include clarifying information in the Medication text (e.g., Ingredient(s), route, use, formulation).	[]
5.	Date:	//

090177e196ae2fe1\Final\Final On: 01-Apr-2021 03:54 (GMT)

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: 12101026

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.						Repeating Pages

Header Text: C4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1210

Subject No: 12101026

Generated By: (b) (4)

Form: CONCOMITANT MEDICATIONS - PROHIBITED

Form Status: Not Started

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?	[]
2.	Category:	
3.	Concomitant Medications Pre-specified:	
4.	Medication: Provide the complete generic drug name (including salt form, where applicable). Where generic name is unknown, enter the full trade or proprietary name. Include clarifying information in the Medication text (e.g., Ingredient(s), route, use, formulation).	[]
5.	Dose:	[]
6.	Dose Unit:	
7.	Dose Frequency:	
8.	Route:	
9.	Start Date:	//
10.	Ongoing?	

090177e196ae2fe1\Final\Final On: 01-Apr-2021 03:54 (GMT)

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: 12101026

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.						Repeating Pages

Header Text: C4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1210

Subject No: 12101026

Generated By: (b) (4)

Form: RADIATION TREATMENT

Form Status: Not Started

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

Header Text: C4591001

Visit: Logs

Form: TRANSFUSIONS

Form Version: 22-Apr-2020 21:03

Site No: 1210

Site Name: (1210) Medipol University Medical Faculty

Subject No: 12101026

Subject Initials: ---

Generated By: (b) (4)

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

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

Header Text: C4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1210

Subject No: 12101026

Generated By: (b) (4)

Form: TRANSFUSIONS

Form Status: Not Started

Site Name: (1210) Medipol University Medical Faculty

Subject Initials: ---

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

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

Header Text: C4591001

Visit: Unplanned - New Unscheduled Visit

Form: DATE OF VISIT

Form Version: 22-Apr-2020 21:02

Form Status: Not Started

Site No: 1210

Site Name: (1210) Medipol University Medical Faculty

Subject No: 12101026

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 - New Unscheduled Visit

Form: UNPLANNED VISIT

Form Version: 22-Apr-2020 21:04

Form Status: Not Started

Site No: 1210

Site Name: (1210) Medipol University Medical Faculty

Subject No: 12101026

Subject Initials: ---

Generated By: (b) (4)

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

Unplanned Assessments

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

090177e196ae2fe1\Final\Final On: 01-Apr-2021 03:54 (GMT)

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: 12101026

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: 12101026

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: 12101026

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?	

090177e196ae2fe1\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: 12101026

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: 12101026

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: 15-Sep-2020 21:55

Site No: 1210

Subject No: 12101026

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

[Form Comments](#)
[eCRF Audit Trail History](#)

Disposition - Treatment

1.	Date of Completion/Discontinuation/Death :	Jan/13/2021	Comments
2.	Phase of Disposition:	VACCINATION	Comments
3.	Status:	COMPLETED	Comments
4.	Specify Status:	[]	Comments

Header Text: C4591001

Visit: Potential ReVax Initial Contact -
Unscheduled

Form: DATE OF VISIT

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen, Verified

Site No: 1210

Site Name: (1210) Medipol University Medical Faculty

Subject No: 12101026

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	Jan/19/2021
2.	Erroneous Visit	

Header Text: C4591001

Visit: Potential ReVax Initial Contact -
Unscheduled

Form: FURTHER VACCINATION CONFIRMATION

Form Version: 10-Dec-2020 02:25

Form Status: Data Complete, Frozen, Verified

Site No: 1210

Site Name: (1210) Medipol University Medical Faculty

Subject No: 12101026

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: 12101026

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: Disposition - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1210

Subject No: 12101026

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 :	Jan/19/2021
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: 12101026

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 <hr/> //	

Header Text: C4591001

Visit: Disposition - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1210

Subject No: 12101026

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
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Cause of Death

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

090177e196ae2fe1\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: 12101026

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/20/2021
2.	Erroneous Visit	

Header Text: C4591001

Visit: V101_VAX3

Form Version: 10-Dec-2020 02:31

Site No: 1210

Subject No: 12101026

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 Jan/20/2021
----	--------------	--

Header Text: C4591001

Visit: V101_VAX3

Form: INCLUSION/EXCLUSION CRITERIA - FURTHER VACCINATION

Form Version: 10-Dec-2020 02:30

Form Status: Data Complete, Frozen, Verified

Site No: 1210

Site Name: (1210) Medipol University Medical Faculty

Subject No: 12101026

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
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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: 12101026

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 :	Jan/20/2021
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: 12101026

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: Jan/20/2021
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	[BR0Z0F]
5.b	Sample ID	[BR0Z0G]
5.c	Sample ID	[BNLLLP]
5.d	Sample ID	[BNLLLR]

090177e196ae2fe1\Final\Final On: 01-Apr-2021 03:54 (GMT)

Header Text: C4591001

Visit: V101_VAX3

Form Version: 22-Apr-2020 21:03

Site No: 1210

Subject No: 12101026

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/20/2021
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	[BR0Z0D]
-----	-----------	----------

090177e196ae2fe1\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: 12101026

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/20/2021 09:50
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

090177e196ae2fe1\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: 12101026

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/12/2021
2.	Erroneous Visit	

090177e196ae2fe1\Final\Final On: 01-Apr-2021 03:54 (GMT)

Header Text: C4591001

Visit: V102_VAX4

Form Version: 22-Apr-2020 21:03

Site No: 1210

Subject No: 12101026

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: Feb/12/2021
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	[BR0Z1B]
-----	-----------	----------

090177e196ae2fe1\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: 12101026

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:	Feb/12/2021 11:00
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

090177e196ae2fe1\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: 12101026

Generated By: (b) (4)

Form: DATE OF VISIT

Form Status: Data Complete, 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	Mar/12/2021
2.	Erroneous Visit	

Header Text: C4591001

Visit: V103_MONTH1

Form Version: 22-Apr-2020 21:04

Site No: 1210

Subject No: 12101026

Generated By: (b) (4)

Form: CONTACT OUTCOME

Form Status: Data Complete, 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: Mar/12/2021
3.	Comments:	[]

Header Text: C4591001

Visit: V104_MONTH6

Form Version: 22-Apr-2020 21:02

Site No: 1210

Subject No: 12101026

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: 12101026

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: 12101026

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: 12101026

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: 20-Feb-2021 02:26

Form Status: Data Complete, Verified

Site No: 1210

Site Name: (1210) Medipol University Medical Faculty

Subject No: 12101026

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 :	Mar/12/2021
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: 12101026

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	Jan/13/2021

Header Text: C4591001

Visit: Investigator Signature - Unscheduled

Form: CASEBOOK SIGNATURE FORM

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Verified

Site No: 1210

Site Name: (1210) Medipol University Medical Faculty

Subject No: 12101026

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, Verified

Site No: 1210

Site Name: (1210) Medipol University Medical Faculty

Subject No: 12101026

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
- CRF_Sign_1

Name	Signature Meaning	Date	Type	Action
------	-------------------	------	------	--------

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 10-Oct-2020 16:00

Site No: 1210

Subject No: 12101026

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 18:38:28 (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: 12101026

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

[Back to Form](#)

Item	Date	User	Comment
Form	Oct-30-2020 18:40:16 (UTC+03:00) Istanbul	(b) (4), (b) (6)	Not Applicable

Header Text: C4591001

Visit: V3_MONTH1_POSTVAX2_L

Form Version: 22-Apr-2020 21:02

Site No: 1210

Subject No: 12101026

Generated By: (b) (4)

Form: DATE OF VISIT - Comments

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](#)

Item	Date	User	Comment
Form	Dec-21-2020 09:59:48 (UTC+03:00) Istanbul	(b) (4), (b) (6)	Could you please delete 18Dec2020 date on this form. It was entered by mistake.

Header Text: C4591001

Visit: V3_MONTH1_POSTVAX2_L

Form Version: 22-Apr-2020 21:02

Site No: 1210

Subject No: 12101026

Generated By: (b) (4)

Form: DATE OF VISIT - Comments

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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Item	Date	User	Comment
1	Dec-21-2020 10:01:25 (UTC+03:00) Istanbul	(b) (4), (b) (6)	Could you please delete 18Dec2020 date on this form. It was entered by mistake.

090177e196ae2fe1\Final\Final On: 01-Apr-2021 03:54 (GMT)

Header Text: C4591001

Visit: V3_MONTH1_POSTVAX2_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM
RESOLVED DATES - Comments

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: 12101026

Subject Initials: ---

Generated By: (b) (4)

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

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Item	Date	User	Comment
Form	Jan-13-2021 09:53:25 (UTC+03:00) Istanbul	(b) (4), (b) (6)	
Form	Dec-22-2020 11:48:27 (UTC+03:00) Istanbul	(b) (4), (b) (6)	not applicable Not Applicable
Form	Dec-18-2020 12:30:05 (UTC+03:00) Istanbul	(b) (4), (b) (6)	not applicable

Header Text: C4591001

Visit: V3_MONTH1_POSTVAX2_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM
RESOLVED DATES - Comments

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: 12101026

Subject Initials: ---

Generated By: (b) (4)

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

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Item	Date	User	Comment
1	Jan-13-2021 09:53:25 (UTC+03:00) Istanbul	(b) (4), (b) (6)	
1	Dec-22-2020 11:48:27 (UTC+03:00) Istanbul	(b) (4), (b) (6)	not applicable <hr/> Not Applicable

Header Text: C4591001

Visit: V3_MONTH1_POSTVAX2_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM
RESOLVED DATES - Comments

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: 12101026

Subject Initials: ---

Generated By: (b) (4)

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

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Item	Date	User	Comment
2.a	Jan-13-2021 09:53:25 (UTC+03:00) Istanbul	(b) (4), (b) (6)	
2.a	Dec-22-2020 11:48:27 (UTC+03:00) Istanbul	(b) (4), (b) (6)	not applicable <hr/> Not Applicable

Header Text: C4591001

Visit: V3_MONTH1_POSTVAX2_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM
RESOLVED DATES - Comments

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: 12101026

Subject Initials: ---

Generated By: (b) (4)

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

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Item	Date	User	Comment
2.b	Jan-13-2021 09:53:25 (UTC+03:00) Istanbul	(b) (4), (b) (6)	
2.b	Dec-22-2020 11:48:27 (UTC+03:00) Istanbul	(b) (4), (b) (6)	not applicable <hr/> Not Applicable

Header Text: C4591001

Visit: V3_MONTH1_POSTVAX2_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - Comments

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: 12101026

Subject Initials: ---

Generated By: (b) (4)

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

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Item	Date	User	Comment
2.c	Jan-13-2021 09:53:25 (UTC+03:00) Istanbul	(b) (4), (b) (6)	
2.c	Dec-22-2020 11:48:27 (UTC+03:00) Istanbul	(b) (4), (b) (6)	not applicable <hr/> Not Applicable

Header Text: C4591001

Visit: V3_MONTH1_POSTVAX2_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - Comments

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: 12101026

Subject Initials: ---

Generated By: (b) (4)

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

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Item	Date	User	Comment
2.d	Jan-13-2021 09:53:25 (UTC+03:00) Istanbul	(b) (4), (b) (6)	
2.d	Dec-22-2020 11:48:27 (UTC+03:00) Istanbul	(b) (4), (b) (6)	not applicable <hr/> Not Applicable

Header Text: C4591001

Visit: V3_MONTH1_POSTVAX2_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM
RESOLVED DATES - Comments

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: 12101026

Subject Initials: ---

Generated By: (b) (4)

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

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Item	Date	User	Comment
2.e	Jan-13-2021 09:53:25 (UTC+03:00) Istanbul	(b) (4), (b) (6)	
2.e	Dec-22-2020 11:48:27 (UTC+03:00) Istanbul	(b) (4), (b) (6)	not applicable <hr/> Not Applicable

Header Text: C4591001

Visit: V3_MONTH1_POSTVAX2_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM
RESOLVED DATES - Comments

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: 12101026

Subject Initials: ---

Generated By: (b) (4)

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

[Back to Form](#)

Item	Date	User	Comment
2 f	Jan-13-2021 09:53:25 (UTC+03:00) Istanbul	(b) (4), (b) (6)	
2 f	Dec-22-2020 11:48:27 (UTC+03:00) Istanbul	(b) (4), (b) (6)	not applicable <hr/> Not Applicable

Header Text: C4591001

Visit: V3_MONTH1_POSTVAX2_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM
RESOLVED DATES - Comments

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: 12101026

Subject Initials: ---

Generated By: (b) (4)

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

[Back to Form](#)

Item	Date	User	Comment
2.g	Jan-13-2021 09:53:25 (UTC+03:00) Istanbul	(b) (4), (b) (6)	
2.g	Dec-22-2020 11:48:27 (UTC+03:00) Istanbul	(b) (4), (b) (6)	not applicable <hr/> Not Applicable

Header Text: C4591001

Visit: V3_MONTH1_POSTVAX2_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM
RESOLVED DATES - Comments

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: 12101026

Subject Initials: ---

Generated By: (b) (4)

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

[Back to Form](#)

Item	Date	User	Comment
2 h	Jan-13-2021 09:53:25 (UTC+03:00) Istanbul	(b) (4), (b) (6)	
2 h	Dec-22-2020 11:48:27 (UTC+03:00) Istanbul	(b) (4), (b) (6)	not applicable <hr/> Not Applicable

Header Text: C4591001

Visit: V3_MONTH1_POSTVAX2_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM
RESOLVED DATES - Comments

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: 12101026

Subject Initials: ---

Generated By: (b) (4)

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

[Back to Form](#)

Item	Date	User	Comment
3	Jan-13-2021 09:53:25 (UTC+03:00) Istanbul	(b) (4), (b) (6)	
3	Dec-22-2020 11:48:27 (UTC+03:00) Istanbul	(b) (4), (b) (6)	not applicable <hr/> Not Applicable

Header Text: C4591001

Visit: V3_MONTH1_POSTVAX2_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM
RESOLVED DATES - Comments

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: 12101026

Subject Initials: ---

Generated By: (b) (4)

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

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Item	Date	User	Comment
4	Jan-13-2021 09:53:25 (UTC+03:00) Istanbul	(b) (4), (b) (6)	
4	Dec-22-2020 11:48:27 (UTC+03:00) Istanbul	(b) (4), (b) (6)	not applicable <hr/> Not Applicable

Header Text: C4591001

Visit: V3_MONTH1_POSTVAX2_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM
RESOLVED DATES - Comments

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: 12101026

Subject Initials: ---

Generated By: (b) (4)

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

[Back to Form](#)

Item	Date	User	Comment
5.a	Jan-13-2021 09:53:25 (UTC+03:00) Istanbul	(b) (4), (b) (6)	
5.a	Dec-22-2020 11:48:27 (UTC+03:00) Istanbul	(b) (4), (b) (6)	not applicable <hr/> Not Applicable

Header Text: C4591001

Visit: V3_MONTH1_POSTVAX2_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM
RESOLVED DATES - Comments

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: 12101026

Subject Initials: ---

Generated By: (b) (4)

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

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Item	Date	User	Comment
5.b	Jan-13-2021 09:53:25 (UTC+03:00) Istanbul	(b) (4), (b) (6)	
5.b	Dec-22-2020 11:48:27 (UTC+03:00) Istanbul	(b) (4), (b) (6)	not applicable <hr/> Not Applicable

Header Text: C4591001

Visit: V3_MONTH1_POSTVAX2_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM
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Form Version: 10-Oct-2020 16:03

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5.c	Dec-22-2020 11:48:27 (UTC+03:00) Istanbul	(b) (4), (b) (6)	not applicable <hr/> Not Applicable

Header Text: C4591001

Visit: V3_MONTH1_POSTVAX2_L

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - Comments

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: 12101026

Subject Initials: ---

Generated By: (b) (4)

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Item	Date	User	Comment
Form	Jan-13-2021 09:54:23 (UTC+03:00) Istanbul	(b) (4), (b) (6)	
Form	Dec-23-2020 11:15:05 (UTC+03:00) Istanbul	(b) (4), (b) (6)	Not Applicable

090177e196ae2fe1\Final\Final On: 01-Apr-2021 03:54 (GMT)

Header Text: C4591001

Visit: V3_MONTH1_POSTVAX2_L

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - Comments

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1210

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Item	Date	User	Comment
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1	Dec-23-2020 11:15:05 (UTC+03:00) Istanbul	(b) (4), (b) (6)	Not Applicable

Header Text: C4591001

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Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** RESPIRATORY TREATMENT - Comments
on Nov/10/2020

Form Version: 06-Jul-2020 21:53

Form Status: Data Complete, Frozen, Verified

Site No: 1210

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Form	Nov-27-2020 18:18:56 (UTC+03:00) Istanbul	(b) (4), (b) (6)	Not Applicable

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** RESPIRATORY TREATMENT - Comments
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Form Version: 06-Jul-2020 21:53

Form Status: Data Complete, Frozen, Verified

Site No: 1210

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Header Text: C4591001

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Header Text: C4591001

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on Nov/10/2020

Form Version: 17-Jul-2020 21:55

Form Status: Data Complete, 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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Item	Date	User	Comment
Form	Nov-27-2020 18:19:29 (UTC+03:00) Istanbul	(b) (4), (b) (6)	Not Applicable

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** ILLNESS DETAILS - SEVERE - Comments
on Nov/10/2020

Form Version: 17-Jul-2020 21:55

Form Status: Data Complete, Frozen, Verified

Site No: 1210

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Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/10/2020

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY - Comments

Form Version: 10-Oct-2020 15:58

Form Status: Data Complete, Frozen, Verified

Site No: 1210

Site Name: (1210) Medipol University Medical Faculty

Subject No: 12101026

Subject Initials: ---

Generated By: (b) (4)

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

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Item	Date	User	Comment
Form	Nov-27-2020 18:36:43 (UTC+03:00) Istanbul	(b) (4), (b) (6)	Not Applicable

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/10/2020

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY - Comments

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Form Status: Data Complete, Frozen, Verified

Site No: 1210

Site Name: (1210) Medipol University Medical Faculty

Subject No: 12101026

Subject Initials: ---

Generated By: (b) (4)

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

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Item	Date	User	Comment
5 f	Nov-27-2020 18:37:32 (UTC+03:00) Istanbul	(b) (4), (b) (6)	Not Applicable

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/10/2020

Form: LOCAL LABORATORY DATA - REPEATING Hematology - Comments

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Item	Date	User	Comment
5.g	Nov-27-2020 18:37:32 (UTC+03:00) Istanbul	(b) (4), (b) (6)	Not Applicable

Header Text: C4591001

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Item	Date	User	Comment
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Header Text: C4591001

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5.j	Nov-27-2020 18:37:32 (UTC+03:00) Istanbul	(b) (4), (b) (6)	Not Applicable

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** VITAL SIGNS - COVID - Comments
on Nov/10/2020

Form Version: 10-Oct-2020 15:59

Form Status: Data Complete, Frozen, Verified

Site No: 1210

Site Name: (1210) Medipol University Medical Faculty

Subject No: 12101026

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Form	Nov-27-2020 18:38:14 (UTC+03:00) Istanbul	(b) (4), (b) (6)	Not Applicable

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** VITAL SIGNS - COVID - Comments
on Nov/10/2020

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Form Status: Data Complete, Frozen, Verified

Site No: 1210

Site Name: (1210) Medipol University Medical Faculty

Subject No: 12101026

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Item	Date	User	Comment
1	Nov-27-2020 18:38:14 (UTC+03:00) Istanbul	(b) (4), (b) (6)	Not Applicable

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** VITAL SIGNS - COVID - Comments
on Nov/10/2020

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Form Status: Data Complete, Frozen, Verified

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Item	Date	User	Comment
2.a	Nov-27-2020 18:38:14 (UTC+03:00) Istanbul	(b) (4), (b) (6)	Not Applicable

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** VITAL SIGNS - COVID - Comments
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2.a	Nov-27-2020 18:38:14 (UTC+03:00) Istanbul	(b) (4), (b) (6)	Not Applicable

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** OXYGENATION PARAMETERS - Comments
on Nov/10/2020

Form Version: 06-Jul-2020 21:52

Form Status: Data Complete, Frozen, Verified

Site No: 1210

Site Name: (1210) Medipol University Medical Faculty

Subject No: 12101026

Subject Initials: ---

Generated By: (b) (4)

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

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Form	Nov-27-2020 18:38:37 (UTC+03:00) Istanbul	(b) (4), (b) (6)	Not Applicable

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** OXYGENATION PARAMETERS - Comments
on Nov/10/2020

Form Version: 06-Jul-2020 21:52

Form Status: Data Complete, Frozen, Verified

Site No: 1210

Site Name: (1210) Medipol University Medical Faculty

Subject No: 12101026

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Generated By: (b) (4)

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Item	Date	User	Comment
1	Nov-27-2020 18:38:37 (UTC+03:00) Istanbul	(b) (4), (b) (6)	Not Applicable

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** OXYGENATION PARAMETERS - Comments
on Nov/10/2020

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Form Status: Data Complete, Frozen, Verified

Site No: 1210

Site Name: (1210) Medipol University Medical Faculty

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Item	Date	User	Comment
2	Nov-27-2020 18:38:37 (UTC+03:00) Istanbul	(b) (4), (b) (6)	Not Applicable

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Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** OXYGENATION PARAMETERS - Comments
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Item	Date	User	Comment
3	Nov-27-2020 18:38:37 (UTC+03:00) Istanbul	(b) (4), (b) (6)	Not Applicable

Header Text: C4591001

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Form: CONCOMITANT MEDICATIONS - VASOPRESSORS - Comments

Form Version: 06-Jul-2020 21:55

Form Status: Data Complete, Frozen, Verified

Site No: 1210

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Header Text: C4591001

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6	Nov-27-2020 18:39:19 (UTC+03:00) Istanbul	(b) (4), (b) (6)	Not Applicable

Header Text: C4591001

Visit: End of Treatment - Unscheduled

Form: DISPOSITION - TREATMENT - Comments

Form Version: 15-Sep-2020 21:55

Form Status: Data Complete, Frozen, Verified

Site No: 1210

Site Name: (1210) Medipol University Medical Faculty

Subject No: 12101026

Subject Initials: ---

Generated By: (b) (4)

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Item	Date	User	Comment
Form	Jan-13-2021 10:28:00 (UTC+03:00) Istanbul	(b) (4), (b) (6)	
Form	Dec-01-2020 11:52:51 (UTC+03:00) Istanbul	(b) (4), (b) (6)	Not Done

Header Text: C4591001

Visit: End of Treatment

Form Version: 15-Sep-2020 21:55

Site No: 1210

Subject No: 12101026

Generated By: (b) (4)

Form: DISPOSITION - TREATMENT - Comments

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1	Dec-01-2020 11:52:51 (UTC+03:00) Istanbul	(b) (4), (b) (6)	Not Done

Header Text: C4591001

Visit: End of Treatment

Form Version: 15-Sep-2020 21:55

Site No: 1210

Subject No: 12101026

Generated By: (b) (4)

Form: DISPOSITION - TREATMENT - Comments

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2	Dec-01-2020 11:52:51 (UTC+03:00) Istanbul	(b) (4), (b) (6)	Not Done

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Visit: End of Treatment

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3	Dec-01-2020 11:52:51 (UTC+03:00) Istanbul	(b) (4), (b) (6)	Not Done

Header Text: C4591001

Visit: End of Treatment

Form Version: 15-Sep-2020 21:55

Site No: 1210

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4	Dec-01-2020 11:52:51 (UTC+03:00) Istanbul	(b) (4), (b) (6)	Not Done

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Header Text: C4591001

Visit: Disposition - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1210

Subject No: 12101026

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	Jan-19-2021 15:36:38 (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: 12101026

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	Jan-19-2021 15:36:38 (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: 12101026

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

[Back to Form](#)

Item	Date	User	Comment
Form	Jan-19-2021 15:36:52 (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: 12101026

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

[Back to Form](#)

Item	Date	User	Comment
1	Jan-19-2021 15:36:52 (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: 12101026

Subject Initials: ---

Generated By: (b) (4)

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

[Back to Form](#)

Item	Date	User	Comment
Form	Jan-20-2021 13:05:31 (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, Verified

Site No: 1210

Site Name: (1210) Medipol University Medical Faculty

Subject No: 12101026

Subject Initials: ---

Generated By: (b) (4)

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

[Back to Form](#)

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

- CRF_Sign
- CRF_Sign_1

Name	Signature Meaning	Date	Type	Action
(b) (6)	N/A	Mar-12-2021 13:11:39 (UTC+03:00) Istanbul		Edit - All signatures invalidated

Affidavit:

N/A

Ali Mert	Approved	Feb-16-2021 15:08:17 (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-12-2021 16:23:37 (UTC+03:00) Istanbul		Edit - All signatures invalidated
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Affidavit:

N/A

Ali Mert	Approved	Feb-10-2021 10:52:47 (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.

090177e196ae2fe1\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, Verified

Site No: 1210

Site Name: (1210) Medipol University Medical Faculty

Subject No: 12101026

Subject Initials: ---

Generated By: (b) (4)

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

(b) (6)	N/A	Feb-09-2021 09:56:02 (UTC+03:00) Istanbul		Edit - All signatures invalidated
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Affidavit:

N/A

Ali Mert	Approved	Jan-21-2021 11:49:58 (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-19-2021 15:21:37 (UTC+03:00) Istanbul		Edit - All signatures invalidated
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Affidavit:

N/A

Ali Mert	Approved	Jan-19-2021 15:05:18 (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-13-2021 09:50:41 (UTC+03:00) Istanbul		Edit - All signatures invalidated
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Affidavit:

N/A

Ali Mert	Approved	Jan-05-2021 16:53:22 (UTC+03:00) Istanbul	BOOK	Signed
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090177e196ae2fe1\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, Verified

Site No: 1210

Site Name: (1210) Medipol University Medical Faculty

Subject No: 12101026

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	Dec-23-2020 11:15:05 (UTC+03:00) Istanbul		Edit - All signatures invalidated
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Affidavit:

N/A

Ali Mert	Approved	Dec-22-2020 13:55:45 (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 12:23:29 (UTC+03:00) Istanbul		Edit - All signatures invalidated
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Affidavit:

N/A

Ali Mert	Approved	Dec-14-2020 17:35:24 (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.

090177e196ae2fe1\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, Verified

Site No: 1210

Site Name: (1210) Medipol University Medical Faculty

Subject No: 12101026

Subject Initials: ---

Generated By: (b) (4)

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

(b) (6)	N/A	Dec-14-2020 10:04:40 (UTC+03:00) Istanbul		Edit - All signatures invalidated
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Affidavit:

N/A

Ali Mert	Approved	Dec-07-2020 16:16:23 (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-07-2020 11:27:17 (UTC+03:00) Istanbul		Edit - All signatures invalidated
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Affidavit:

N/A

Ali Mert	Approved	Dec-02-2020 13:51:29 (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	Dec-01-2020 15:17:27 (UTC+03:00) Istanbul		Edit - All signatures invalidated
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Affidavit:

N/A

Ali Mert	Approved	Dec-01-2020 14:23:25 (UTC+03:00) Istanbul	BOOK	Signed
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090177e196ae2fe1\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, Verified

Site No: 1210

Site Name: (1210) Medipol University Medical Faculty

Subject No: 12101026

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-27-2020 18:18:56 (UTC+03:00) Istanbul		Edit - All signatures invalidated
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Affidavit:

N/A

Ali Mert	Approved	Nov-27-2020 16:14:14 (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.

(b) (6)	N/A	Nov-26-2020 12:23:47 (UTC+03:00) Istanbul		Edit - All signatures invalidated
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Affidavit:

N/A

Ali Mert	Approved	Nov-25-2020 13:48:42 (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.

090177e196ae2fe1\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, Verified

Site No: 1210

Site Name: (1210) Medipol University Medical Faculty

Subject No: 12101026

Subject Initials: ---

Generated By: (b) (4)

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

(b) (6)	N/A	Nov-23-2020 16:50:52 (UTC+03:00) Istanbul		Edit - All signatures invalidated
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Affidavit:

N/A

Ali Mert	Approved	Nov-17-2020 16:25:05 (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-17-2020 16:24:29 (UTC+03:00) Istanbul		Edit - All signatures invalidated
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Affidavit:

N/A

Ali Mert	Approved	Nov-17-2020 16:24:28 (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-12-2020 15:46:36 (UTC+03:00) Istanbul		Edit - All signatures invalidated
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Affidavit:

N/A

Ali Mert	Approved	Nov-10-2020 17:38:26 (UTC+03:00) Istanbul	BOOK	Signed
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090177e196ae2fe1\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, Verified

Site No: 1210

Site Name: (1210) Medipol University Medical Faculty

Subject No: 12101026

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-10-2020 14:16:02 (UTC+03:00) Istanbul		Edit - All signatures invalidated
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Affidavit:

N/A

Ali Mert	Approved	Nov-10-2020 14:15:53 (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-10-2020 09:31:05 (UTC+03:00) Istanbul		Edit - All signatures invalidated
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Affidavit:

N/A

(b) (6)	Approved	Nov-03-2020 17:14:33 (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.

090177e196ae2fe1\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: 12101026

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

[Back to Form](#)

1. Select appropriate response - Protocol version

Date	Location	User	Value	Reason
Oct-30-2020 11:48:00 (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 11:48:00 (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: 12101026

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

[Back to Form](#)

I. Consent Was:

Date	Location	User	Value	Reason
Oct-30-2020 11:48:12 (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: 12101026

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

[Back to Form](#)

1. Subject ID

Date	Location	User	Value	Reason
Oct-30-2020 11:47:45 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 12101026	Item copied from previous form

2. Birth Date:

Date	Location	User	Value	Reason
Oct-30-2020 11:47:41 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: (b) (6) 1973	Enrollment Entry

3. Sex:

Date	Location	User	Value	Reason
Oct-30-2020 11:48:24 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: MALE	Initial Entry

4. Ethnicity:

Date	Location	User	Value	Reason
Oct-30-2020 11:48:24 (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 11:48:24 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: WHITE	Initial Entry

090177e196ae2fe1\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: 12101026

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

[Back to Form](#)

1. Date of Visit

Date	Location	User	Value	Reason
Oct-30-2020 18:38:16 (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: 12101026

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

[Back to Form](#)

1. Date of Completion/Discontinuation/Death

Date	Location	User	Value	Reason
Oct-30-2020 18:38:46 (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 18:38:46 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SCREENING	Initial Entry

3. Status:

Date	Location	User	Value	Reason
Oct-30-2020 18:38:46 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: COMPLETED	Initial Entry

090177e196ae2fe1\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: 12101026

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

[Back to Form](#)

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

Date	Location	User	Value	Reason
Oct-30-2020 18:40:28 (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: 12101026

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

[Back to Form](#)

1. Date:

Date	Location	User	Value	Reason
Oct-30-2020 18:41:15 (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 18:55:40 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 86.0	Transcription Error
Oct-30-2020 18:41:15 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 71.0	Initial Entry

3. Unit:

Date	Location	User	Value	Reason
Oct-30-2020 18:41:15 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: kg	Initial Entry

4. Height:

Date	Location	User	Value	Reason
Oct-30-2020 18:55:55 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 183.0	Transcription Error
Oct-30-2020 18:41:15 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 176.0	Initial Entry

5. Unit:

Date	Location	User	Value	Reason
Oct-30-2020 18:41:15 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (6)	Data Entry: cm	Initial Entry

090177e196ae2fe1\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: 12101026

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

		(b) (4)		
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6. Body Mass Index:

Date	Location	User	Value	Reason
Oct-30-2020 18:55:55 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> 25.7	Transcription Error
Oct-30-2020 18:55:40 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> 27.8	Transcription Error
Oct-30-2020 18:41:15 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> 22.9	Initial Entry

7.a

Date	Location	User	Value	Reason
Oct-30-2020 18:56:09 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Record Identifier:: 1 Temperature: 36.3 Temperature Unit: C Temperature Location:: FOREHE AD	Transcription Error
Oct-30-2020 18:41:15 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Record Identifier:: 1 Temperature: 36.5 Temperature Unit: C Temperature Location:: FOREHE AD	Initial Entry

7.a Record Identifier:

Date	Location	User	Value	Reason
Oct-30-2020 18:41:15 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> 1	Initial Entry

7.a Temperature:

Date	Location	User	Value	Reason
Oct-30-2020 18:56:09 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (6)	<u>Data Entry:</u> 36.3	Transcription Error

090177e196ae2fe1\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: 12101026

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

		(b) (4)		
Oct-30-2020 18:41:15 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 36.5	Initial Entry

7.a Unit:

Date	Location	User	Value	Reason
Oct-30-2020 18:41:15 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: C	Initial Entry

7.a Temperature Location:

Date	Location	User	Value	Reason
Oct-30-2020 18:41:15 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: FOREHEAD	Initial Entry

090177e196ae2fe1\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: 12101026

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 18:41:34 (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 18:57:09 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 114315	Transcription Error
Oct-30-2020 18:41:34 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 114309	Initial Entry

090177e196ae2fe1\Final\Final On: 01-Apr-2021 03:54 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1210

Site Name: (1210) Medipol University Medical Faculty

Subject No: 12101026

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
Oct-30-2020 18:41:48 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Oct-30-2020 18:41:48 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SERUM	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Oct-30-2020 18:42:39 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Oct-30-2020 18:41:48 (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 18:41:48 (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 18:58:03 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BRCXND	Transcription Error
Oct-30-2020 18:42:39 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BRCXN8	Initial Entry

090177e196ae2fe1\Final\Final On: 01-Apr-2021 03:54 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1210

Site Name: (1210) Medipol University Medical Faculty

Subject No: 12101026

Subject Initials: ---

Generated By: (b) (4)

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

5.a Sample ID

Date	Location	User	Value	Reason
Oct-30-2020 18:58:03 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BRCXND	Transcription Error
Oct-30-2020 18:42:39 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BRCXN8	Initial Entry

5.b

Date	Location	User	Value	Reason
Oct-30-2020 18:59:09 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BRCXNC	Transcription Error
Oct-30-2020 18:42:52 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BRCXN9	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Oct-30-2020 18:59:09 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BRCXNC	Transcription Error
Oct-30-2020 18:42:52 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BRCXN9	Initial Entry

5.c

Date	Location	User	Value	Reason
Oct-30-2020 18:59:35 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BSHB2S	Transcription Error
Oct-30-2020 18:43:16 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BSHB2P	Initial Entry

090177e196ae2fe1\Final\Final On: 01-Apr-2021 03:54 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1210

Site Name: (1210) Medipol University Medical Faculty

Subject No: 12101026

Subject Initials: ---

Generated By: (b) (4)

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

5.c Sample ID

Date	Location	User	Value	Reason
Oct-30-2020 18:59:35 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BSHB2S	Transcription Error
Oct-30-2020 18:43:16 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BSHB2P	Initial Entry

5.d

Date	Location	User	Value	Reason
Oct-30-2020 18:59:49 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BSHB2T	Transcription Error
Oct-30-2020 18:43:29 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BSHB2R	Initial Entry

5.d Sample ID

Date	Location	User	Value	Reason
Oct-30-2020 18:59:49 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BSHB2T	Transcription Error
Oct-30-2020 18:43:29 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BSHB2R	Initial Entry

090177e196ae2fe1\Final\Final On: 01-Apr-2021 03:54 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1210

Site Name: (1210) Medipol University Medical Faculty

Subject No: 12101026

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
Oct-30-2020 18:44:15 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Oct-30-2020 18:44:15 (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 18:45:33 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Oct-30-2020 18:44:15 (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 18:44:15 (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 19:00:09 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BRCXNF	Transcription Error
Oct-30-2020 18:45:33 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BRCXNB	Initial Entry

090177e196ae2fe1\Final\Final On: 01-Apr-2021 03:54 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1210

Site Name: (1210) Medipol University Medical Faculty

Subject No: 12101026

Subject Initials: ---

Generated By: (b) (4)

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

5.a Sample ID

Date	Location	User	Value	Reason
Oct-30-2020 19:00:09 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BRCXNF	Transcription Error
Oct-30-2020 18:45:33 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BRCXNB	Initial Entry

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:04

Site No: 1210

Subject No: 12101026

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 18:47:24 (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 18:47:24 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: BLINDED THERAPY	Initial Entry

3. Formulation:

Date	Location	User	Value	Reason
Oct-30-2020 18:47:24 (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 19:00:36 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Oct/30/2020 10:50	Transcription Error
Oct-30-2020 18:47:24 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Oct/30/2020 10:35	Initial Entry

5. Anatomical Location:

Date	Location	User	Value	Reason
Oct-30-2020 18:47:24 (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 18:47:24	ACV0PFEINFP6000	(b) (6)	Data Entry:	Initial Entry

090177e196ae2fe1\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: 12101026

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

(UTC+03:00) Istanbul		(b) (4), (b) (6)	LEFT	
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7. Route:

Date	Location	User	Value	Reason
Oct-30-2020 18:47:24 (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 18:47:24 (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 18:47:24 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

090177e196ae2fe1\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: 12101026

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 18:47:39 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES - REACTOGENICITY E-DI ARY COLLECTED FOR THIS S UBJECT	Initial Entry

Header Text: C4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:02

Site No: 1210

Subject No: 12101026

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-16-2020 09:20:35 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Closed as per site response, updated PD tracker for clinical review
Dec-15-2020 11:09:52 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Because of adverse event this subject's V2 carried out late.
Dec-15-2020 08:27:12 (UTC+03:00) Istanbul	ACV0PFEINFP6000.InFormAdapter.Discrepancy	PFE SDQ PROD (b) (4)	Query 1: Opened	PDQ: Date of visit at V2_VAX2_L is out of window for 19 days from V1_DAY1_VAX1_L Dose Date. Please verify and update. Else, confirm in query response appropriately. (b) (4)
Dec-14-2020 10:04:40 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry : Dec/11/2020	Initial Entry

090177e196ae2fe1\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: 12101026

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
Dec-14-2020 10:13:45 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2.a

Date	Location	User	Value	Reason
Dec-14-2020 10:13:45 (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-14-2020 10:13:45 (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-14-2020 10:13:45 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2.b

Date	Location	User	Value	Reason
Dec-14-2020 10:13:45 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom:: FA TI	Initial Entry

090177e196ae2fe1\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: 12101026

Subject Initials: ---

Generated By: (b) (4)

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

			GU E 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-14-2020 10:13:45 (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-14-2020 10:13:45 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NO	Initial Entry

2.c

Date	Location	User	Value	Reason
Dec-14-2020 10:13:45 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> <u>Symptom::</u> HE AD AC HE Were fever or systemic symptoms present on the last day the Subject Diary was completed?: NO	Initial Entry

090177e196ae2fe1\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: 12101026

Subject Initials: ---

Generated By: (b) (4)

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

2.c Symptom:

Date	Location	User	Value	Reason
Dec-14-2020 10:13:45 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> HEADACHE	Initial Entry

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

Date	Location	User	Value	Reason
Dec-14-2020 10:13:45 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NO	Initial Entry

2.d

Date	Location	User	Value	Reason
Dec-14-2020 10:13:45 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Symptom:: CH IL LS Were fever or systemic sy NO mptoms present on the last day the Subject Diary was completed?:	Initial Entry

2.d Symptom:

Date	Location	User	Value	Reason
Dec-14-2020 10:13:45 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> CHILLS	Initial Entry

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

Date	Location	User	Value	Reason
Dec-14-2020 10:13:45 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NO	Initial Entry

2.e

090177e196ae2fe1\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: 12101026

Subject Initials: ---

Generated By: (b) (4)

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

Date	Location	User	Value	Reason
Dec-14-2020 10:13:45 (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

2.e Symptom:

Date	Location	User	Value	Reason
Dec-14-2020 10:13:45 (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-14-2020 10:13:45 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2.f

Date	Location	User	Value	Reason
Dec-14-2020 10:13:45 (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

090177e196ae2fe1\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: 12101026

Subject Initials: ---

Generated By: (b) (4)

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

2.f Symptom:

Date	Location	User	Value	Reason
Dec-14-2020 10:13:45 (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-14-2020 10:13:45 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2.g

Date	Location	User	Value	Reason
Dec-14-2020 10:13:45 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom:: NEW OR WORSE NED MU SCLE PA IN Were fever or syste mic symptoms prese nt on the last day the Subject Diary was co mpleted?: NO	Initial Entry

2.g Symptom:

Date	Location	User	Value	Reason
Dec-14-2020 10:13:45 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NEW OR WORSE NED MUSCLE 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-14-2020 10:13:45 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

090177e196ae2fe1\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: 12101026

Subject Initials: ---

Generated By: (b) (4)

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

2.h

Date	Location	User	Value	Reason
Dec-14-2020 10:13:45 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom:: NEW OR WORSE NED JOI NT PAIN Were fever or system NO ic symptoms present on the last day the Su bject Diary was com pleted?:	Initial Entry

2.h Symptom:

Date	Location	User	Value	Reason
Dec-14-2020 10:13:45 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NEW OR WORSE NEDED JOINT P AIN	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-14-2020 10:13:45 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

3. Injection Site Location:

Date	Location	User	Value	Reason
Dec-14-2020 10:13:45 (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-14-2020 10:13:45 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: LEFT	Initial Entry

5.a

090177e196ae2fe1\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: 12101026

Subject Initials: ---

Generated By: (b) (4)

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

Date	Location	User	Value	Reason
Dec-14-2020 10:13:45 (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-14-2020 10:13:45 (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-14-2020 10:13:45 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

5.b

Date	Location	User	Value	Reason
Dec-14-2020 10:13:45 (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

090177e196ae2fe1\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: 12101026

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-14-2020 10:13:45 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> SWELLING	Initial Entry

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

Date	Location	User	Value	Reason
Dec-14-2020 10:13:45 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NO	Initial Entry

5.c

Date	Location	User	Value	Reason
Dec-14-2020 10:13:45 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> 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-14-2020 10:13:45 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> 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-14-2020 10:13:45 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NO	Initial Entry

090177e196ae2fe1\Final\Final On: 01-Apr-2021 03:54 (GMT)

Header Text: C4591001

Visit: V2_VAX2_L

Form Version: 10-Dec-2020 02:27

Site No: 1210

Subject No: 12101026

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
Dec-14-2020 10:15:07 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Dec/11/2020	Initial Entry

2.a

Date	Location	User	Value	Reason
Dec-14-2020 10:15:07 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Record Identifier:: 1 Temperature: 36.4 Temperature Unit: C Temperature Location: FOREHE AD	Initial Entry

2.a Record Identifier:

Date	Location	User	Value	Reason
Dec-14-2020 10:15:07 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 1	Initial Entry

2.a Temperature:

Date	Location	User	Value	Reason
Dec-14-2020 10:15:07 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 36.4	Initial Entry

2.a Unit:

Date	Location	User	Value	Reason
Dec-14-2020 10:15:07 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: C	Initial Entry

2.a Temperature Location:

090177e196ae2fe1\Final\Final On: 01-Apr-2021 03:54 (GMT)

Header Text: C4591001

Visit: V2_VAX2_L

Form Version: 10-Dec-2020 02:27

Site No: 1210

Subject No: 12101026

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
Dec-14-2020 10:15:07 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> 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: 12101026

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-14-2020 10:15:17 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Dec-14-2020 10:15:17 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: NASAL_SWAB	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Dec-14-2020 10:16:23 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Deleted	Close Auto Query
Dec-14-2020 10:15:45 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Dec-14-2020 10:15:45 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Date of Collection: Dec/11/2020	Transcription Error
Dec-14-2020 10:15:17 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Dec-14-2020 10:15:17 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	Date of Collection 14/Dec/2020 is greater than Date of Visit 11/Dec/2020. Please review and update as appropriate, else clarify.

090177e196ae2fe1\Final\Final On: 01-Apr-2021 03:54 (GMT)

Header Text: C4591001

Visit: V2_VAX2_L

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1210

Site Name: (1210) Medipol University Medical Faculty

Subject No: 12101026

Subject Initials: ---

Generated By: (b) (4)

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

Dec-14-2020 10:15:17 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Date of Collection: Dec/14/2020	Initial Entry
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5.a

Date	Location	User	Value	Reason
Dec-14-2020 10:16:23 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BRCXVM	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Dec-14-2020 10:16:23 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BRCXVM	Initial Entry

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Header Text: C4591001

Visit: V2_VAX2_L

Form Version: 10-Dec-2020 02:26

Site No: 1210

Subject No: 12101026

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-14-2020 10:17:09 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2. Treatment Name

Date	Location	User	Value	Reason
Dec-14-2020 10:17:09 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: BLINDED THERAPY	Initial Entry

3. Formulation:

Date	Location	User	Value	Reason
Dec-14-2020 10:17:09 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: INJECTION	Initial Entry

4. Dose Date Time:

Date	Location	User	Value	Reason
Dec-14-2020 10:17:09 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Dec/11/2020 10:20	Initial Entry

5. Anatomical Location:

Date	Location	User	Value	Reason
Dec-14-2020 10:17:09 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: DELTOID MUSCLE	Initial Entry

6. Body Side:

Date	Location	User	Value	Reason
Dec-14-2020 10:17:09 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: LEFT	Initial Entry

7. Route:

090177e196ae2fe1\Final\Final On: 01-Apr-2021 03:54 (GMT)

Header Text: C4591001

Visit: V2_VAX2_L

Form Version: 10-Dec-2020 02:26

Site No: 1210

Subject No: 12101026

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-14-2020 10:17:09 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: INTRAMUSCULAR	Initial Entry

10. Timeframe Subject Was Observed

Date	Location	User	Value	Reason
Dec-14-2020 10:17:09 (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
Dec-14-2020 10:17:09 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

090177e196ae2fe1\Final\Final On: 01-Apr-2021 03:54 (GMT)

Header Text: C4591001

Visit: V3_MONTH1_POSTVAX2_L

Form: DATE OF VISIT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen, Verified

Site No: 1210

Site Name: (1210) Medipol University Medical Faculty

Subject No: 12101026

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
Jan-15-2021 13:22:19 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Closed	Close Auto Query
Jan-15-2021 09:15:26 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Opened	DM: Erroneous visit is marked. Please confirm if this visit occurred. If yes, kindly untick erroneous visit button. If not occurred, kindly erase data from rest of forms and mark the forms as Not Done/Not Applicable at form level comment or else clarify.
Jan-13-2021 09:50:41 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Candidate	Erroneous Visit is marked, but date of visit is entered. Please check whether other assessments are performed at this visit.
Jan-13-2021 09:50:41 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Jan/13/2021	New Information
Dec-24-2020 08:13:51 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Dec-23-2020 11:57:48 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	not applicable selected.
Dec-23-2020 10:17:29 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reissued:Opened	DM2: Thank you for the response, however please consider adding form level comment

090177e196ae2fe1\Final\Final On: 01-Apr-2021 03:54 (GMT)

Header Text: C4591001

Visit: V3_MONTH1_POSTVAX2_L

Form: DATE OF VISIT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen, Verified

Site No: 1210

Site Name: (1210) Medipol University Medical Faculty

Subject No: 12101026

Subject Initials: ---

Generated By: (b) (4)

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

				by selecting Not Done/Not Applicable on Electronic Sample Tracking of this visit.
Dec-22-2020 11:50:22 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Not applicable option was selected.
Dec-22-2020 11:32:08 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reissued:Opened	DM1: Thank you for your response. Kindly add form level comment by selecting Not Done/Not Applicable option on rest of forms of this visit or else clarify.
Dec-22-2020 11:04:35 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	The datas were corrected.
Dec-22-2020 08:54:41 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reissued:Opened	DM : Thanks for response. However, data is still present on SYMPRIDATE CRF. Please review and update. Else, clarify.
Dec-21-2020 10:03:05 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Could you please delete 18Dec2020 date on this form. It was entered by mistake.
Dec-21-2020 09:32:46 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	DM: Visit is marked ERRONEOUS VISIT, however data is present on rest of forms. If visit is ERRONEOUS then consider to clear data from rest of forms and add form level comment by

090177e196ae2fe1\Final\Final On: 01-Apr-2021 03:54 (GMT)

Header Text: C4591001

Visit: V3_MONTH1_POSTVAX2_L

Form: DATE OF VISIT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen, Verified

Site No: 1210

Site Name: (1210) Medipol University Medical Faculty

Subject No: 12101026

Subject Initials: ---

Generated By: (b) (4)

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

				selecting Not Applicable option at form level on rest of forms else, clarify.
Dec-18-2020 15:43:46 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Dec/18/2020	Could you please delete 11/Dec/2020 date which is entered by mistake.
Dec-18-2020 12:26:49 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	Erroneous Visit is marked, but date of visit is entered. Please check whether other assessments are performed at this visit.
Dec-18-2020 12:23:29 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Dec/11/2020	Initial Entry

2. Erroneous Visit

Date	Location	User	Value	Reason
Jan-15-2021 13:22:19 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Transcription Error
Dec-18-2020 12:26:49 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: ERRONEOUS VISIT	Initial Entry

090177e196ae2fe1\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: 12101026

Subject Initials: ---

Generated By: (b) (4)

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

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

Date	Location	User	Value	Reason
Jan-13-2021 09:54:04 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry
Jan-13-2021 09:53:25 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Initial Entry
Dec-22-2020 11:48:27 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry
Dec-18-2020 12:29:02 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Transcription Error
Dec-18-2020 12:23:53 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2.a

Date	Location	User	Value	Reason
Jan-13-2021 09:54:04 (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
Jan-13-2021 09:53:25 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom:: FE VE R	Initial Entry

090177e196ae2fe1\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: 12101026
Subject Initials: ---
Generated By: (b) (4)
Generated Time (GMT): 29-Mar-2021 13:11

			Were fever or systemic symptoms present on the last day the Subject Diary was completed?:	
Dec-22-2020 11:48:27 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom:: FEVER Were fever or systemic symptoms present on the last day the Subject Diary was completed?:	Initial Entry
Dec-22-2020 10:59:03 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom:: FEVER Were fever or systemic symptoms present on the last day the Subject Diary was completed?:	Transcription Error
Dec-18-2020 12:23:53 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom:: FEVER Were fever or systemic symptoms present on the last day the Subject Diary was completed?:	Initial Entry

2.a Symptom:

Date	Location	User	Value	Reason
Dec-18-2020 12:23:53 (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
Jan-13-2021 09:54:04 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (6)	Data Entry: NO	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: 12101026

Subject Initials: ---

Generated By: (b) (4)

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

		(b) (4)		
Jan-13-2021 09:53:25 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Initial Entry
Dec-22-2020 11:48:27 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry
Dec-22-2020 10:59:03 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Transcription Error
Dec-18-2020 12:23:53 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2.b

Date	Location	User	Value	Reason
Jan-13-2021 09:54:04 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom:: FA TI GU E Were fever or systemic sy mptoms present on the las t day the Subject Diary w as completed?: NO	Initial Entry
Jan-13-2021 09:53:25 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom:: FA TI GU E Were fever or systemic sy mptoms present on the las t day the Subject Diary w as completed?:	Initial Entry
Dec-22-2020 11:48:27 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom:: FATI GUE	Initial Entry

090177e196ae2fe1\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: 12101026

Subject Initials: ---

Generated By: (b) (4)

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

			Were fever or systemic symptoms present on the last day the Subject Diary was completed?:	Not applicable
Dec-22-2020 10:59:18 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom::	Transcription Error
			Were fever or systemic symptoms present on the last day the Subject Diary was completed?:	FA TI GU E
Dec-18-2020 12:23:53 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom::	Initial Entry
			Were fever or systemic symptoms present on the last day the Subject Diary was completed?:	NO

090177e196ae2fe1\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: 12101026

Subject Initials: ---

Generated By: (b) (4)

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

2.b Symptom:

Date	Location	User	Value	Reason
Dec-18-2020 12:23:53 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: FATIGUE	Initial Entry

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

Date	Location	User	Value	Reason
Jan-13-2021 09:54:04 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry
Jan-13-2021 09:53:25 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Initial Entry
Dec-22-2020 11:48:27 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry
Dec-22-2020 10:59:18 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Transcription Error
Dec-18-2020 12:23:53 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2.c

Date	Location	User	Value	Reason
Jan-13-2021 09:54:04 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom:: HE AD AC HE Were fever or systemic symptoms present on the last day the Subject Diary was completed?: NO	Initial Entry
Jan-13-2021 09:53:25 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (6)	Data Entry:	Initial Entry

090177e196ae2fe1\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: 12101026

Subject Initials: ---

Generated By: (b) (4)

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

		(b) (4)	Symptom:: HE AD AC HE Were fever or systemic symptoms present on the last day the Subject Diary was completed?:	
Dec-22-2020 11:48:27 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom:: HEA DAC HE Were fever or systemic symptoms present on the last day the Subject Diary was completed?:	Initial Entry
Dec-22-2020 10:59:28 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom:: HE AD AC HE Were fever or systemic symptoms present on the last day the Subject Diary was completed?:	Transcription Error
Dec-18-2020 12:23:53 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom:: HE AD AC HE Were fever or systemic symptoms present on the last day the Subject Diary was completed?:	Initial Entry

090177e196ae2fe1\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: 12101026

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 12:23:53 (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
Jan-13-2021 09:54:04 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry
Jan-13-2021 09:53:25 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Initial Entry
Dec-22-2020 11:48:27 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry
Dec-22-2020 10:59:28 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Transcription Error
Dec-18-2020 12:23:53 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2.d

Date	Location	User	Value	Reason
Jan-13-2021 09:54:04 (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
Jan-13-2021 09:53:25 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom:: CH	Initial Entry

090177e196ae2fe1\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: 12101026

Subject Initials: ---

Generated By: (b) (4)

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

			IL LS Were fever or systemic symptoms present on the last day the Subject Diary was completed?:	
Dec-22-2020 11:48:27 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Symptom:: CHI LLS Were fever or systemic symptoms present on the last day the Subject Diary was completed?: Not applicable	Initial Entry
Dec-22-2020 10:59:41 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Symptom:: CH IL LS Were fever or systemic symptoms present on the last day the Subject Diary was completed?:	Transcription Error
Dec-18-2020 12:23:53 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Symptom:: CH IL LS Were fever or systemic symptoms present on the last day the Subject Diary was completed?: NO	Initial Entry

090177e196ae2fe1\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: 12101026

Subject Initials: ---

Generated By: (b) (4)

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

2.d Symptom:

Date	Location	User	Value	Reason
Dec-18-2020 12:23:53 (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
Jan-13-2021 09:54:04 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry
Jan-13-2021 09:53:25 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Initial Entry
Dec-22-2020 11:48:27 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry
Dec-22-2020 10:59:41 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Transcription Error
Dec-18-2020 12:23:53 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2.e

Date	Location	User	Value	Reason
Jan-13-2021 09:54:04 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom:: VO MIT ING Were fever or systemic sy NO mptoms present on the la st day the Subject Diary was completed?:	Initial Entry
Jan-13-2021 09:53:25 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom:: VO	Initial Entry

090177e196ae2fe1\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: 12101026

Subject Initials: ---

Generated By: (b) (4)

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

			MIT ING Were fever or systemic symptoms present on the last day the Subject Diary was completed?:	
Dec-22-2020 11:48:27 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Symptom:: VO MIT ING Were fever or systemic symptoms present on the last day the Subject Diary was completed?: Not Applicable	Initial Entry
Dec-22-2020 10:59:53 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Symptom:: VO MIT ING Were fever or systemic symptoms present on the last day the Subject Diary was completed?:	Transcription Error
Dec-18-2020 12:23:53 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Symptom:: VO MIT ING Were fever or systemic symptoms present on the last day the Subject Diary was completed?: NO	Initial Entry

090177e196ae2fe1\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: 12101026

Subject Initials: ---

Generated By: (b) (4)

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

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2.e Symptom:

Date	Location	User	Value	Reason
Dec-18-2020 12:23:53 (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
Jan-13-2021 09:54:04 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry
Jan-13-2021 09:53:25 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Initial Entry
Dec-22-2020 11:48:27 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry
Dec-22-2020 10:59:53 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Transcription Error
Dec-18-2020 12:23:53 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2.f

Date	Location	User	Value	Reason
Jan-13-2021 09:54:04 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom:: DIA RR HE A Were fever or systemic sy NO mptoms present on the la st day the Subject Diary was completed?:	Initial Entry

090177e196ae2fe1\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: 12101026

Subject Initials: ---

Generated By: (b) (4)

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

Jan-13-2021 09:53:25 (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?:	Initial Entry
Dec-22-2020 11:48:27 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom:: DIA RRH EA Were fever or systemic symptoms present on the last day the Subject Diary was completed?: Not applicable	Initial Entry
Dec-22-2020 11:00:04 (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?:	Transcription Error
Dec-18-2020 12:23:53 (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

090177e196ae2fe1\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: 12101026

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 12:23:53 (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
Jan-13-2021 09:54:04 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry
Jan-13-2021 09:53:25 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Initial Entry
Dec-22-2020 11:48:27 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry
Dec-22-2020 11:00:04 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Transcription Error
Dec-18-2020 12:23:53 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2.g

Date	Location	User	Value	Reason
Jan-13-2021 09:54:04 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom:: NEW OR WORSE NED MU SCLE PA IN Were fever or systemic symptoms present on the last day the Subject Diary was completed?: NO	Initial Entry

090177e196ae2fe1\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: 12101026

Subject Initials: ---

Generated By: (b) (4)

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

Jan-13-2021 09:53:25 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom:: NEW OR WORSE NED MU SCLE PA IN Were fever or systemic symptoms present on the last day the Subject Diary was completed?:	Initial Entry
Dec-22-2020 11:48:27 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom:: NEW OR WORSE NED MU SCLE PA IN Were fever or systemic symptoms present on the last day the Subject Diary was completed?: Not Applicable	Initial Entry
Dec-22-2020 11:00:38 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom:: NEW OR WORSE NED MU SCLE PA IN Were fever or systemic symptoms present on the last day the Subject Diary was completed?:	Transcription Error
Dec-18-2020 12:23:53 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom:: NEW OR WORSE NED MU SCLE PA IN	Initial Entry

090177e196ae2fe1\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: 12101026

Subject Initials: ---

Generated By: (b) (4)

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

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

Date	Location	User	Value	Reason
Dec-18-2020 12:23:53 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NEW OR WORSENE D MUSCLE 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
Jan-13-2021 09:54:04 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry
Jan-13-2021 09:53:25 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Initial Entry
Dec-22-2020 11:48:27 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry
Dec-22-2020 11:00:38 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Transcription Error
Dec-18-2020 12:23:53 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2.h

Date	Location	User	Value	Reason
Jan-13-2021 09:54:04 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom:: NEW OR WORSE NEE JOI NT PAIN	Initial Entry

090177e196ae2fe1\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: 12101026

Subject Initials: ---

Generated By: (b) (4)

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

			Were fever or systemic symptoms present on the last day the Subject Diary was completed?: NO	
Jan-13-2021 09:53:25 (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?:	Initial Entry
Dec-22-2020 11:48:27 (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?: Not Applicable	Initial Entry
Dec-22-2020 11:01:10 (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?:	Transcription Error
Dec-18-2020 12:23:53 (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?:	Initial Entry

090177e196ae2fe1\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

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Site No: 1210

Site Name: (1210) Medipol University Medical Faculty

Subject No: 12101026

Subject Initials: ---

Generated By: (b) (4)

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

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

Date	Location	User	Value	Reason
Dec-18-2020 12:23:53 (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
Jan-13-2021 09:54:04 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry
Jan-13-2021 09:53:25 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Initial Entry
Dec-22-2020 11:48:27 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry
Dec-22-2020 11:01:10 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Transcription Error
Dec-18-2020 12:23:53 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

3. Injection Site Location:

Date	Location	User	Value	Reason
Jan-13-2021 09:54:04 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: DELTOID MUSCLE	Initial Entry
Jan-13-2021 09:53:25 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry:	Initial Entry

090177e196ae2fe1\Final\Final On: 01-Apr-2021 03:54 (GMT)

Header Text: C4591001

Visit: V3_MONTH1_POSTVAX2_L

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Form Status: Data Complete, Frozen, Verified

Site No: 1210

Site Name: (1210) Medipol University Medical Faculty

Subject No: 12101026

Subject Initials: ---

Generated By: (b) (4)

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

Dec-22-2020 11:48:27 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Not Applicable	Initial Entry
Dec-18-2020 12:29:02 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry:	Transcription Error
Dec-18-2020 12:23:53 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: DELTOID MUSCLE	Initial Entry

4. Injection Site Body Side:

Date	Location	User	Value	Reason
Jan-13-2021 09:54:04 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: LEFT	Initial Entry
Jan-13-2021 09:53:25 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Initial Entry
Dec-22-2020 11:48:27 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry
Dec-18-2020 12:29:42 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Transcription Error
Dec-18-2020 12:23:53 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: LEFT	Initial Entry

5.a

Date	Location	User	Value	Reason
Jan-13-2021 09:54:04 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Injection Site Reaction:: RE DN ESS Were injection site reactio NO ns present on the last day the Subject Diary was co mpleted?:	Initial Entry
Jan-13-2021 09:53:25 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (6)	Data Entry:	Initial Entry

090177e196ae2fe1\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: 12101026

Subject Initials: ---

Generated By: (b) (4)

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

		(b) (4)	Injection Site Reaction:: RE DN ESS Were injection site reactions present on the last day the Subject Diary was completed?:	
Dec-22-2020 11:48:27 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Injection Site Reaction:: RED NES S Were injection site reactions present on the last day the Subject Diary was completed?: Not Applicable	Initial Entry
Dec-22-2020 11:01:26 (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?:	Transcription Error
Dec-18-2020 12:23:53 (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 12:23:53 (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?

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: 12101026

Subject Initials: ---

Generated By: (b) (4)

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

Date	Location	User	Value	Reason
Jan-13-2021 09:54:04 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry
Jan-13-2021 09:53:25 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Initial Entry
Dec-22-2020 11:48:27 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry
Dec-22-2020 11:01:26 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Transcription Error
Dec-18-2020 12:23:53 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

5.b

Date	Location	User	Value	Reason
Jan-13-2021 09:54:04 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Injection Site Reaction:: SW ELL ING Were injection site reactions present on the last day the Subject Diary was completed?: NO	Initial Entry
Jan-13-2021 09:53:25 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Injection Site Reaction:: SW ELL ING Were injection site reactions present on the last day the Subject Diary was completed?:	Initial Entry
Dec-22-2020 11:48:27 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Injection Site Reaction:: SWE LLIN	Initial Entry

090177e196ae2fe1\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: 12101026

Subject Initials: ---

Generated By: (b) (4)

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

			<p style="text-align: right;">G</p> <p>Were injection site reactions present on the last day the Subject Diary was completed?: Not Applicable</p>	
Dec-22-2020 11:01:39 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<p>Data Entry:</p> <p>Injection Site Reaction:: SW ELL ING</p> <p>Were injection site reactions present on the last day the Subject Diary was completed?:</p>	Transcription Error
Dec-18-2020 12:23:53 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<p>Data Entry:</p> <p>Injection Site Reaction:: SW ELL ING</p> <p>Were injection site reactions present on the last day the Subject Diary was completed?: NO</p>	Initial Entry

090177e196ae2fe1\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: 12101026

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 12:23:53 (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
Jan-13-2021 09:54:04 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry
Jan-13-2021 09:53:25 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Initial Entry
Dec-22-2020 11:48:27 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry
Dec-22-2020 11:01:39 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Transcription Error
Dec-18-2020 12:23:53 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

5.c

Date	Location	User	Value	Reason
Jan-13-2021 09:54:04 (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
Jan-13-2021 09:53:25 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (6)	Data Entry:	Initial Entry

090177e196ae2fe1\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: 12101026

Subject Initials: ---

Generated By: (b) (4)

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

		(b) (4)	Injection Site Reaction: PAIN AT INJECTION SITE Were injection site reactions present on the last day the Subject Diary was completed?:	
Dec-22-2020 11:48:27 (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?: Not Applicable	Initial Entry
Dec-22-2020 11:01:50 (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?:	Transcription Error
Dec-18-2020 12:23:53 (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

090177e196ae2fe1\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: 12101026

Subject Initials: ---

Generated By: (b) (4)

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

5.c Injection Site Reaction:

Date	Location	User	Value	Reason
Dec-18-2020 12:23:53 (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
Jan-13-2021 09:54:04 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry
Jan-13-2021 09:53:25 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Initial Entry
Dec-22-2020 11:48:27 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry
Dec-22-2020 11:01:50 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Transcription Error
Dec-18-2020 12:23:53 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

090177e196ae2fe1\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: 12101026

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-13-2021 09:54:46 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry
Jan-13-2021 09:54:23 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry:	Initial Entry
Dec-23-2020 11:15:05 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Not Applicable	Initial Entry
Dec-18-2020 12:30:30 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry:	Transcription Error
Dec-18-2020 12:24:07 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Jan-13-2021 09:54:46 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SERUM	Initial Entry
Jan-13-2021 09:54:23 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry:	Initial Entry
Dec-23-2020 11:15:05 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Not Applicable	Initial Entry
Dec-18-2020 12:30:30 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry:	Transcription Error
Dec-18-2020 12:24:07 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SERUM	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Jan-13-2021 09:55:38 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Deleted	Close Auto Query
Jan-13-2021 09:54:46 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Candidate	'Sample Collected?' is Yes, however no

090177e196ae2fe1\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:** 12101026**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 13:11

				barcodes are entered. Please review and correct as appropriate.
Jan-13-2021 09:54:46 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Date of Collection: Jan/13/2021	Initial Entry
Jan-13-2021 09:54:23 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Initial Entry
Dec-23-2020 11:15:05 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry
Dec-18-2020 12:30:30 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Dec-18-2020 12:30:30 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Transcription Error
Dec-18-2020 12:24:07 (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 12:24:07 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Date of Collection: Dec/11/2020	Initial Entry

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

Date	Location	User	Value	Reason
Jan-13-2021 09:54:23 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Initial Entry
Dec-23-2020 11:15:05	ACV0PFEINFP6000	(b) (6)	Data Entry:	Initial Entry

Header Text: C4591001

Visit: V3_MONTH1_POSTVAX2_L

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1210

Site Name: (1210) Medipol University Medical Faculty

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Generated By: (b) (4)

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

(UTC+03:00) Istanbul		(b) (4), (b) (6)	Not Applicable	
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5.a

Date	Location	User	Value	Reason
Jan-13-2021 09:55:38 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BNLLLB	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Jan-13-2021 09:55:38 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BNLLLB	Initial Entry

5.b

Date	Location	User	Value	Reason
Jan-13-2021 09:55:54 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BNLLLC	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Jan-13-2021 09:55:54 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BNLLLC	Initial Entry

5.c

Date	Location	User	Value	Reason
Jan-13-2021 09:56:18 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BR0YZL	Initial Entry

090177e196ae2fe1\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: 12101026

Subject Initials: ---

Generated By: (b) (4)

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

5.c Sample ID

Date	Location	User	Value	Reason
Jan-13-2021 09:56:18 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BR0YZL	Initial Entry

5.d

Date	Location	User	Value	Reason
Jan-13-2021 09:56:30 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BR0YZM	Initial Entry

5.d Sample ID

Date	Location	User	Value	Reason
Jan-13-2021 09:56:30 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BR0YZM	Initial Entry

090177e196ae2fe1\Final\Final On: 01-Apr-2021 03:54 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** DATE OF VISIT - ILLNESS ONSET - eCRF Audit Trail History on Nov/10/2020

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: 12101026

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-18-2020 09:20:18 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Closed	Response satisfies query
Nov-17-2020 15:38:58 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Answered	completed
Nov-17-2020 08:49:20 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Reissued:Opened	DM 1 : Please review and complete ILL POTEN form. Else,clarify.
Nov-16-2020 10:37:36 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Answered	Self swab result is pending there is no local positive test
Nov-14-2020 15:58:17 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Opened	DM: Kindly review and complete 'Illness Details form' at this visit. Thank you.
Nov-10-2020 14:03:02 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Nov-10-2020 09:36:22 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Deleted	Close Auto Query
Nov-10-2020 09:31:04 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Candidate	Date of Visit is completed but Date of Assessment in the Signs and Symptoms form is missing. Please review and update as appropriate.
Nov-10-2020 09:31:04 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	Date of Visit is completed but Date of Collection in

090177e196ae2fe1\Final\Final On: 01-Apr-2021 03:54 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** DATE OF VISIT - ILLNESS ONSET - eCRF Audit Trail History on Nov/10/2020

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: 12101026

Subject Initials: ---

Generated By: (b) (4)

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

				both Nasal Swab Self and Nasal Swab are missing. Please review and update as appropriate.
Nov-10-2020 09:31:04 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Nov/10/2020	Initial Entry

3. COVID-19 Illness Visit:

Date	Location	User	Value	Reason
Nov-10-2020 09:31:04 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: COVID_A	Initial Entry

090177e196ae2fe1\Final\Final On: 01-Apr-2021 03:54 (GMT)

Header Text: C4591001**Visit:** POT_COVID_ILL 1 - Unscheduled Visit on Nov/10/2020**Form:** SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - eCRF Audit Trail History**Form Version:** 10-Oct-2020 16:02**Form Status:** Data Complete, Frozen, Verified**Site No:** 1210**Site Name:** (1210) Medipol University Medical Faculty**Subject No:** 12101026**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 13:11[Back to Form](#)**1. Date of Assessment:**

Date	Location	User	Value	Reason
Nov-10-2020 09:37:41 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Nov-10-2020 09:37:41 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Nov/10/2020	Transcription Error
Nov-10-2020 09:36:22 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	Date of assessment is not same as Date Visit. Please check and correct.
Nov-10-2020 09:36:22 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Nov/9/2020	Initial Entry

2. Date of First Symptom Started:

Date	Location	User	Value	Reason
Nov-10-2020 09:36:22 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Nov/7/2020	Initial Entry

3. Symptoms Ongoing?

Date	Location	User	Value	Reason
Feb-09-2021 10:57:21 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Feb-09-2021 09:56:02 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Transcription Error
Feb-09-2021 09:56:02 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO Date of Last Symptom Resolved: Dec/7/2020	Transcription Error

Header Text: C4591001**Visit:** POT_COVID_ILL 1 - Unscheduled Visit on Nov/10/2020**Form:** SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - eCRF Audit Trail History**Form Version:** 10-Oct-2020 16:02**Form Status:** Data Complete, Frozen, Verified**Site No:** 1210**Site Name:** (1210) Medipol University Medical Faculty**Subject No:** 12101026**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 13:11

Feb-05-2021 13:23:17 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reissued:Opened	clinical query: based on your response please change yes to no and add a stop date. thanks
Feb-05-2021 12:12:45 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Sypmtoms do not continue.
Feb-04-2021 16:35:28 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	clinical query: can you please confirm if symptoms are still ongoing? Thanks
Nov-10-2020 09:36:22 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

4.a

Date	Location	User	Value	Reason
Nov-10-2020 09:37:04 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptoms: FEVER Symptom Present: NO	Initial Entry
Nov-10-2020 09:36:22 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptoms: FEVER Symptom Present:	Initial Entry

4.a Symptoms:

Date	Location	User	Value	Reason
Nov-10-2020 09:36:22 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: FEVER	Initial Entry

4.a Was symptom present?

Date	Location	User	Value	Reason
Nov-10-2020 09:37:04 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/10/2020

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

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Site No: 1210

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Subject Initials: ---

Generated By: (b) (4)

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4.b

Date	Location	User	Value	Reason
Nov-10-2020 09:37:04 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptoms: NEW OR INCREASED COUGH Symptom Present: NO	Initial Entry
Nov-10-2020 09:36:22 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptoms: NEW OR INCREASED COUGH Symptom Present:	Initial Entry

4.b Symptoms:

Date	Location	User	Value	Reason
Nov-10-2020 09:36:22 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NEW OR INCREASED COUGH	Initial Entry

4.b Was symptom present?

Date	Location	User	Value	Reason
Nov-10-2020 09:37:04 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

4.c

Date	Location	User	Value	Reason
Nov-10-2020 09:37:04 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptoms: NEW OR INCREASED SHORTNESS OF BREATH Symptom Present: NO	Initial Entry
Nov-10-2020 09:36:22 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (6)	Data Entry: Symptoms: NEW OR INCREASED SHORTNESS OF BREATH	Initial Entry

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Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/10/2020

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

Form Version: 10-Oct-2020 16:02

Form Status: Data Complete, Frozen, Verified

Site No: 1210

Site Name: (1210) Medipol University Medical Faculty

Subject No: 12101026

Subject Initials: ---

Generated By: (b) (4)

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

		(b) (4)	ms: D SHORTNESS OF BREATH	
			Symptom Present:	

4.c Symptoms:

Date	Location	User	Value	Reason
Nov-10-2020 09:36:22 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NEW OR INCREASED SHORTNESS OF BREATH	Initial Entry

4.c Was symptom present?

Date	Location	User	Value	Reason
Nov-10-2020 09:37:04 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

4.d

Date	Location	User	Value	Reason
Nov-10-2020 09:37:04 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptoms: CHILLS Symptom Present: NO	Initial Entry
Nov-10-2020 09:36:22 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptoms: CHILLS Symptom Present:	Initial Entry

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Header Text: C4591001**Visit:** POT_COVID_ILL 1 - Unscheduled Visit on Nov/10/2020**Form Version:** 10-Oct-2020 16:02**Site No:** 1210**Subject No:** 12101026**Generated By:** (b) (4)**Form:** SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - 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**4.d Symptoms:**

Date	Location	User	Value	Reason
Nov-10-2020 09:36:22 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: CHILLS	Initial Entry

4.d Was symptom present?

Date	Location	User	Value	Reason
Nov-10-2020 09:37:04 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

4.e

Date	Location	User	Value	Reason
Nov-10-2020 09:36:22 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom NEW OR INCREASED MUSCLE PAIN Symptom Present: YES	Initial Entry

4.e Symptoms:

Date	Location	User	Value	Reason
Nov-10-2020 09:36:22 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NEW OR INCREASED MUSCLE PAIN	Initial Entry

4.e Was symptom present?

Date	Location	User	Value	Reason
Nov-10-2020 09:36:22 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

4.f

Date	Location	User	Value	Reason
Nov-10-2020 09:37:04	ACV0PFEINFP6000	(b) (6)	Data Entry:	Initial Entry

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/10/2020

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

Form Version: 10-Oct-2020 16:02

Form Status: Data Complete, Frozen, Verified

Site No: 1210

Site Name: (1210) Medipol University Medical Faculty

Subject No: 12101026

Subject Initials: ---

Generated By: (b) (4)

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(UTC+03:00) Istanbul		(b) (4), (b) (6)	Symptoms NEW LOSS OF TASTE OR SMELL Symptom Present: NO	
Nov-10-2020 09:36:22 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptoms NEW LOSS OF TASTE OR SMELL Symptom Present:	Initial Entry

4.f Symptoms:

Date	Location	User	Value	Reason
Nov-10-2020 09:36:22 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NEW LOSS OF TASTE OR SMELL	Initial Entry

4.f Was symptom present?

Date	Location	User	Value	Reason
Nov-10-2020 09:37:04 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

4.g

Date	Location	User	Value	Reason
Nov-10-2020 09:37:04 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom NEW OR INCREASED SORE THROAT Symptom Present: NO	Initial Entry
Nov-10-2020 09:36:22 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom NEW OR INCREASED SORE THROAT Symptom Present:	Initial Entry

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Header Text: C4591001**Visit:** POT_COVID_ILL 1 - Unscheduled Visit on Nov/10/2020**Form Version:** 10-Oct-2020 16:02**Site No:** 1210**Subject No:** 12101026**Generated By:** (b) (4)**Form:** SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - 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**4.g Symptoms:**

Date	Location	User	Value	Reason
Nov-10-2020 09:36:22 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NEW OR INCREASED SORE T HROAT	Initial Entry

4.g Was symptom present?

Date	Location	User	Value	Reason
Nov-10-2020 09:37:04 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

4.h

Date	Location	User	Value	Reason
Nov-10-2020 09:37:04 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptoms: DIARRHEA Symptom Present: NO	Initial Entry
Nov-10-2020 09:36:22 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptoms: DIARRHEA Symptom Present:	Initial Entry

4.h Symptoms:

Date	Location	User	Value	Reason
Nov-10-2020 09:36:22 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: DIARRHEA	Initial Entry

4.h Was symptom present?

Date	Location	User	Value	Reason
Nov-10-2020 09:37:04 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

4.i

Date	Location	User	Value	Reason
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Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/10/2020

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

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Site Name: (1210) Medipol University Medical Faculty

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Generated By: (b) (4)

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Nov-10-2020 09:37:04 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptoms: VOMITING Symptom Present: NO	Initial Entry
Nov-10-2020 09:36:22 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptoms: VOMITING Symptom Present:	Initial Entry

4.i Symptoms:

Date	Location	User	Value	Reason
Nov-10-2020 09:36:22 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: VOMITING	Initial Entry

4.i Was symptom present?

Date	Location	User	Value	Reason
Nov-10-2020 09:37:04 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

5.a

Date	Location	User	Value	Reason
Nov-10-2020 09:36:43 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptoms - Other: fatigue	Initial Entry

5.a Symptoms - Other Text:

Date	Location	User	Value	Reason
Nov-10-2020 09:36:43 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: fatigue	Initial Entry

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Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** MICROBIOLOGY SPECIMEN - Audit Trail
on Nov/10/2020

Form Version: 06-Jul-2020 21:54

Form Status:

Site No: 1210

Site Name: (1210) Medipol University Medical Faculty

Subject No: 12101026

Subject Initials: ---

Generated By: (b) (4)

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

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Date	Location	User	Value	Reason
Nov-10-2020 09:39:13 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Created	

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** MICROBIOLOGY SPECIMEN - Audit Trail
on Nov/10/2020

Form Version: 06-Jul-2020 21:54

Form Status:

Site No: 1210

Site Name: (1210) Medipol University Medical Faculty

Subject No: 12101026

Subject Initials: ---

Generated By: (b) (4)

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

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Date	Location	User	Value	Reason
Nov-10-2020 15:14:51 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Created	

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit Form: MICROBIOLOGY SPECIMEN - eCRF Audit Trail History on Nov/10/2020

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen, Verified

Site No: 1210

Site Name: (1210) Medipol University Medical Faculty

Subject No: 12101026

Subject Initials: ---

Generated By: (b) (4)

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

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1. Actual Date of Collection:

Date	Location	User	Value	Reason
Nov-10-2020 09:39:13 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Nov/7/2020	Initial Entry

2. Specimen Type:

Date	Location	User	Value	Reason
Nov-10-2020 09:39:13 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: SWABBED MATERIAL	Initial Entry

3. Specimen Collection Location:

Date	Location	User	Value	Reason
Nov-10-2020 09:39:13 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NASOPHARYNX	Initial Entry

4. Assay Code and Description:

Date	Location	User	Value	Reason
Nov-10-2020 09:39:13 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SEVERE ACUTE RESP SYNDR OME CORONAVIRUS 2	Initial Entry

5. Device Type:

Date	Location	User	Value	Reason
Nov-10-2020 09:39:13 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SARS-COV-2 DIAGNOSTIC TES T	Initial Entry

6. Trade Name:

Date	Location	User	Value	Reason
Nov-12-2020 12:08:30 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query

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Header Text: C4591001**Visit:** POT_COVID_ILL 1 - Unscheduled Visit **Form:** MICROBIOLOGY SPECIMEN - eCRF Audit Trail History on Nov/10/2020**Form Version:** 06-Jul-2020 21:54**Form Status:** Data Complete, Frozen, Verified**Site No:** 1210**Site Name:** (1210) Medipol University Medical Faculty**Subject No:** 12101026**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 13:11

Nov-11-2020 15:50:49 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	other specify entered.
Nov-11-2020 13:02:40 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reissued:Opened	Response does not satisfy query. Kindly enter the data onto the CRF at Field 6 'Trade Name Other, Specify' and not only in the query response.
Nov-10-2020 14:01:22 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Bioeksen Ar-Ge Teknolojileri Ltd.Şti.
Nov-10-2020 09:39:13 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	Trade Name is Other, however Trade Name Other, Specify is not completed. Please update.
Nov-10-2020 09:39:13 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: OTHER	Initial Entry

7. Test Result:

Date	Location	User	Value	Reason
Nov-10-2020 09:39:13 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NEGATIVE	Initial Entry

9. Trade Name Other, Specify:

Date	Location	User	Value	Reason
Nov-13-2020 12:05:08 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Nov-12-2020 15:46:36 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Transcription Error
Nov-12-2020 15:46:36 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Bioeksen Bio-Speedy Direct RT	Transcription Error

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** MICROBIOLOGY SPECIMEN - eCRF Audit Trail History on Nov/10/2020

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen, Verified

Site No: 1210

Site Name: (1210) Medipol University Medical Faculty

Subject No: 12101026

Subject Initials: ---

Generated By: (b) (4)

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			-qPCR SARS-CoV-2	
Nov-12-2020 14:42:08 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	As per FDA List of Trade names and CRF CR, data should be updated as "Bioeksen Bio-Speedy Direct RT-qPCR SARS-CoV-2", Kindly confirm and update data as requested, else clarify, Thank you.
Nov-10-2020 15:13:14 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Bioeksen	Initial Entry

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Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit Form: MICROBIOLOGY SPECIMEN - eCRF Audit Trail History on Nov/10/2020

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Form Status: Data Complete, Frozen, Verified

Site No: 1210

Site Name: (1210) Medipol University Medical Faculty

Subject No: 12101026

Subject Initials: ---

Generated By: (b) (4)

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

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1. Actual Date of Collection:

Date	Location	User	Value	Reason
Nov-10-2020 15:14:51 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Nov/9/2020	Initial Entry

2. Specimen Type:

Date	Location	User	Value	Reason
Nov-10-2020 15:14:51 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: SWABBED MATERIAL	Initial Entry

3. Specimen Collection Location:

Date	Location	User	Value	Reason
Nov-10-2020 15:14:51 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NASOPHARYNX	Initial Entry

4. Assay Code and Description:

Date	Location	User	Value	Reason
Nov-10-2020 15:14:51 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SEVERE ACUTE RESP SYNDR OME CORONAVIRUS 2	Initial Entry

5. Device Type:

Date	Location	User	Value	Reason
Nov-10-2020 15:14:51 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SARS-COV-2 DIAGNOSTIC TES T	Initial Entry

6. Trade Name:

Date	Location	User	Value	Reason
Nov-10-2020 15:14:51	ACV0PFEINFP6000	(b) (6)	Data Entry:	Initial Entry

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Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit Form: MICROBIOLOGY SPECIMEN - eCRF Audit Trail History on Nov/10/2020

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen, Verified

Site No: 1210

Site Name: (1210) Medipol University Medical Faculty

Subject No: 12101026

Subject Initials: ---

Generated By: (b) (4)

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

(UTC+03:00) Istanbul		(b) (4), (b) (6)	OTHER	
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7. Test Result:

Date	Location	User	Value	Reason
Nov-10-2020 15:14:51 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (4), (b) (6)	Data Entry: NEGATIVE	Initial Entry

9. Trade Name Other, Specify:

Date	Location	User	Value	Reason
Nov-13-2020 14:44:02 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Nov-13-2020 12:51:09 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Transcription Error
Nov-13-2020 12:51:09 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Bioeksen Bio-Speedy Direct RT-qPCR SARS-CoV-2	Transcription Error
Nov-12-2020 14:42:23 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	As per FDA List of Trade names and CRF CR, data should be updated as "Bioeksen Bio-Speedy Direct RT-qPCR SARS-CoV-2", Kindly confirm and update data as requested, else clarify, Thank you.
Nov-10-2020 15:14:51 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Bioeksen	Initial Entry

090177e196ae2fe1\Final\Final On: 01-Apr-2021 03:54 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/10/2020

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1210

Site Name: (1210) Medipol University Medical Faculty

Subject No: 12101026

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
Nov-10-2020 09:40:07 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Nov-10-2020 09:40:07 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: NASAL_SWAB_SELF	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Nov-17-2020 16:44:12 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Closed	Response satisfies query
Nov-17-2020 15:39:15 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Answered	completed
Nov-12-2020 11:48:42 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Reissued:Opened	clinical query: please leave the query open till illness potential page will be completed.Thanks
Nov-12-2020 09:56:55 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Answered	central lab result is pending. patient had no locally covid-19 diagnosis.
Nov-11-2020 18:10:38 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Opened	clinical query: please complete the page ILLness POTential specifying the grade and if a diagnosis was made. Thanks
Nov-10-2020 14:13:50	ACV0PFEINFP6000	auto query	Query 2: Deleted	Close Auto Query

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090177e196ae2fe1\Final\Final On: 01-Apr-2021 03:54 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/10/2020

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1210

Site Name: (1210) Medipol University Medical Faculty

Subject No: 12101026

Subject Initials: ---

Generated By: (b) (4)

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

(UTC+03:00) Istanbul		(autoquery)		
Nov-10-2020 14:13:38 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Date of Collection: Nov/10/2020	Transcription Error
Nov-10-2020 14:13:23 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Nov-10-2020 14:13:23 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Nov-10-2020 14:13:23 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Date of Collection: Nov/7/2020	Transcription Error
Nov-10-2020 09:40:07 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	'Sample Collected?' is marked as No and 'If no sample was collected or sample was not collected according to protocol, please provide reason' is missing. Please review and update as appropriate.
Nov-10-2020 09:40:07 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

5.a

Date	Location	User	Value	Reason
Nov-14-2020 00:10:32 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BRCXT1	Transcription Error

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/10/2020

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1210

Site Name: (1210) Medipol University Medical Faculty

Subject No: 12101026

Subject Initials: ---

Generated By: (b) (4)

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

Nov-13-2020 23:43:30 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BRCXT1R	Transcription Error
Nov-13-2020 23:43:14 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BRCXT1	Transcription Error
Nov-13-2020 23:42:53 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BRCXT1	Transcription Error
Nov-10-2020 14:22:08 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BRCXT1R	Transcription Error
Nov-10-2020 14:13:50 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BRCXT1	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Nov-17-2020 06:39:14 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 4: Closed	Response satisfies query
Nov-16-2020 10:36:52 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 4: Answered	site label was used instead of self swab label by mistake
Nov-14-2020 00:10:32 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto query (autoquery)	Query 4: Opened	Barcode is not 7 characters in length. Please review and correct as appropriate.
Nov-14-2020 00:10:32 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BRCXT1	Transcription Error
Nov-13-2020 23:43:30 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto query (autoquery)	Query 3: Closed	Close Auto Query
Nov-13-2020 23:43:30 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BRCXT1R	Transcription Error
Nov-13-2020 23:43:14 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto query (autoquery)	Query 3: Opened	Barcode is not 7 characters in length.

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Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/10/2020

Form Version: 22-Apr-2020 21:03

Site No: 1210

Subject No: 12101026

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB SELF - 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

				Please review and correct as appropriate.
Nov-13-2020 23:43:14 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Closed	Close Auto Query
Nov-13-2020 23:43:14 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BRCXT1	Transcription Error
Nov-13-2020 23:42:53 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Opened	Entered text has either a carriage return (line break) or extra spaces at the end of the text or between words. Please correct by removing all data in the field and re-enter without adding extra spaces or using enter or tab keys.
Nov-13-2020 23:42:53 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BRCXT1	Transcription Error
Nov-10-2020 14:22:08 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Nov-10-2020 14:22:08 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BRCXT1R	Transcription Error
Nov-10-2020 14:13:50 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	Barcode is not 7 characters in length. Please review and correct as appropriate.
Nov-10-2020 14:13:50 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BRCXT1	Initial Entry

090177e196ae2fe1\Final\Final On: 01-Apr-2021 03:54 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/10/2020

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

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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
Nov-10-2020 14:03:02 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Nov-10-2020 14:03:02 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: NASAL_SWAB	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Nov-10-2020 14:16:02 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto query (autoquery)	Query 3: Closed	Close Auto Query
Nov-10-2020 14:14:39 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Closed	Close Auto Query
Nov-10-2020 14:14:08 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto query (autoquery)	Query 3: Opened	'Sample Collected?' is marked as No and 'If no sample was collected or sample was not collected according to protocol, please provide reason' is missing. Please review and update as appropriate.
Nov-10-2020 14:14:08 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Opened	Response to "Sample Collected?" is No, but Barcodes are present on the page.
Nov-10-2020 14:14:08 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Transcription Error

090177e196ae2fe1\Final\Final On: 01-Apr-2021 03:54 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/10/2020

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: 12101026

Subject Initials: ---

Generated By: (b) (4)

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

Nov-10-2020 14:07:20 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Nov-10-2020 14:03:02 (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-10-2020 14:03:02 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Date of Collection: Nov/10/2020	Initial Entry

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

Date	Location	User	Value	Reason
Nov-10-2020 14:16:02 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: collected self swab	Initial Entry

5.a

Date	Location	User	Value	Reason
Nov-10-2020 14:14:39 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BRCXT1	Transcription Error (DELETED)
Nov-10-2020 14:07:20 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BRCXT1	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Nov-10-2020 14:14:39 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BRCXT1	Transcription Error (DELETED)
Nov-10-2020 14:07:20 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BRCXT1	Initial Entry

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Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit Form: HEALTH CARE UTILIZATION - eCRF Audit Trail History on Nov/10/2020

Form Version: 10-Oct-2020 15:59

Form Status: Data Complete, Frozen, Verified

Site No: 1210

Site Name: (1210) Medipol University Medical Faculty

Subject No: 12101026

Subject Initials: ---

Generated By: (b) (4)

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I.a

Date	Location	User	Value	Reason
Nov-10-2020 09:53:39 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Type of Practitioner: SPECIALIST Occurrence of Visits or Contacts: NO	Initial Entry

I.a Physician or Healthcare Professional:

Date	Location	User	Value	Reason
Nov-10-2020 09:53:39 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: SPECIALIST	Initial Entry

I.a Occurrence of Visits or Contacts:

Date	Location	User	Value	Reason
Nov-10-2020 09:53:39 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

I.b

Date	Location	User	Value	Reason
Nov-10-2020 09:53:39 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Type of Practitioner: EMERGENCY ROOM Occurrence of Visits or Contacts: YES <i>Number of Visits or Contacts:</i> 2	Initial Entry

090177e196ae2fe1\Final\Final On: 01-Apr-2021 03:54 (GMT)

Header Text: C4591001**Visit:** POT_COVID_ILL 1 - Unscheduled Visit **Form:** HEALTH CARE UTILIZATION - eCRF Audit Trail History on Nov/10/2020**Form Version:** 10-Oct-2020 15:59**Form Status:** Data Complete, Frozen, Verified**Site No:** 1210**Site Name:** (1210) Medipol University Medical Faculty**Subject No:** 12101026**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 13:11***1.b Physician or Healthcare Professional:***

Date	Location	User	Value	Reason
Nov-10-2020 09:53:39 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: EMERGENCY ROOM	Initial Entry

1.b Occurrence of Visits or Contacts:

Date	Location	User	Value	Reason
Nov-10-2020 09:53:39 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES <i>Number of Visits or Contacts:</i> 2	Initial Entry

1.c

Date	Location	User	Value	Reason
Nov-10-2020 09:53:39 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Type of Practitioner: PRIMARY CARE PHYSICIAN Occurrence of Visits or Contacts: NO	Initial Entry

1.c Physician or Healthcare Professional:

Date	Location	User	Value	Reason
Nov-10-2020 09:53:39 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: PRIMARY CARE PHYSICIAN	Initial Entry

1.c Occurrence of Visits or Contacts:

Date	Location	User	Value	Reason
Nov-10-2020 09:53:39 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

1.d

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit Form: HEALTH CARE UTILIZATION - eCRF Audit Trail History on Nov/10/2020

Form Version: 10-Oct-2020 15:59

Form Status: Data Complete, Frozen, Verified

Site No: 1210

Site Name: (1210) Medipol University Medical Faculty

Subject No: 12101026

Subject Initials: ---

Generated By: (b) (4)

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

Date	Location	User	Value	Reason
Nov-10-2020 09:53:39 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Type of Practitioner URGENT : CARE Occurrence of Visits NO or Contacts:	Initial Entry

1.d Physician or Healthcare Professional:

Date	Location	User	Value	Reason
Nov-10-2020 09:53:39 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: URGENT CARE	Initial Entry

1.d Occurrence of Visits or Contacts:

Date	Location	User	Value	Reason
Nov-10-2020 09:53:39 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

1.e

Date	Location	User	Value	Reason
Nov-10-2020 09:53:39 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Type of Practitioner: TELEPHONE CONSULTATION Occurrence of Visits or Contacts: NO	Initial Entry

090177e196ae2fe1\Final\Final On: 01-Apr-2021 03:54 (GMT)

Header Text: C4591001**Visit:** POT_COVID_ILL 1 - Unscheduled Visit **Form:** HEALTH CARE UTILIZATION - eCRF Audit Trail History
on Nov/10/2020**Form Version:** 10-Oct-2020 15:59**Form Status:** Data Complete, Frozen, Verified**Site No:** 1210**Site Name:** (1210) Medipol University Medical Faculty**Subject No:** 12101026**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 13:11***1.e Physician or Healthcare Professional:***

Date	Location	User	Value	Reason
Nov-10-2020 09:53:39 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: TELEPHONE CONSULTATION	Initial Entry

1.e Occurrence of Visits or Contacts:

Date	Location	User	Value	Reason
Nov-10-2020 09:53:39 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

1.f

Date	Location	User	Value	Reason
Nov-10-2020 09:53:39 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Type of Practitioner: OTH ER Occurrence of Visits or Contacts: NO	Initial Entry

1.f Physician or Healthcare Professional:

Date	Location	User	Value	Reason
Nov-10-2020 09:53:39 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: OTHER	Initial Entry

1.f Occurrence of Visits or Contacts:

Date	Location	User	Value	Reason
Nov-10-2020 09:53:39 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

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

Date	Location	User	Value	Reason
Dec-14-2020 15:49:56	ACV0PFEINFP6000	(b) (6)	Query 1: Closed	Response satisfies

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit Form: HEALTH CARE UTILIZATION - eCRF Audit Trail History on Nov/10/2020

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Site No: 1210

Site Name: (1210) Medipol University Medical Faculty

Subject No: 12101026

Subject Initials: ---

Generated By: (b) (4)

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

(UTC+03:00) Istanbul		(b) (4), (b) (6)		query
Dec-14-2020 10:22:45 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	This is looking for SAE, not for Covid illness.
Dec-07-2020 20:08:24 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reissued:Opened	Clin: LAB CHEM and LAB HEM not updated.
Dec-07-2020 11:28:10 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Changed Information
Dec-07-2020 11:28:10 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Changed Information
Dec-02-2020 21:57:37 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reissued:Opened	Clin: Per CRF CRs Section 8.29, LAB CHEM, LAB HEM, and IMAGING should be recorded for potential illness.
Dec-02-2020 11:42:12 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	The event evaluated as SAE lab results,imaging provided via SAE form. Subject did not diagnosed with covid19.
Dec-02-2020 03:57:28 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	Clinical Query: As this subject was hospitalized, please enter on the CRF form any available information (vital signs, pulse oxymet, respiratory treatment, lab results, imaging...). Please make every effort to obtain these information.

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Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** HEALTH CARE UTILIZATION - eCRF Audit Trail History on Nov/10/2020

Form Version: 10-Oct-2020 15:59

Form Status: Data Complete, Frozen, Verified

Site No: 1210

Site Name: (1210) Medipol University Medical Faculty

Subject No: 12101026

Subject Initials: ---

Generated By: (b) (4)

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

Nov-17-2020 15:40:09 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Has the subject been in intensive care due to potential COVID-19 illness? NO	New Information
Nov-10-2020 09:53:39 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

090177e196ae2fe1\Final\Final On: 01-Apr-2021 03:54 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** HOSPITALIZATION DETAILS - Audit Trail
on Nov/10/2020

Form Version: 22-Apr-2020 21:02

Form Status:

Site No: 1210

Site Name: (1210) Medipol University Medical Faculty

Subject No: 12101026

Subject Initials: ---

Generated By: (b) (4)

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

*** THIS REPEATING FORM HAS BEEN DELETED ***

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Date	Location	User	Value	Reason
Dec-07-2020 11:27:17 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Deleted	Changed Information
Nov-17-2020 15:54:15 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Created	

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit Form: HOSPITALIZATION DETAILS - eCRF Audit Trail History on Nov/10/2020

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Deleted, Verified

Site No: 1210

Site Name: (1210) Medipol University Medical Faculty

Subject No: 12101026

Subject Initials: ---

Generated By: (b) (4)

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*** THIS REPEATING FORM HAS BEEN DELETED ***

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1. Hospitalization Category:

Date	Location	User	Value	Reason
Nov-17-2020 15:54:15 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: HOSPITALIZATION STATUS	Initial Entry

2. Hospitalization Term:

Date	Location	User	Value	Reason
Nov-17-2020 15:54:15 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: HOSPITAL	Initial Entry

3. Admission Date:

Date	Location	User	Value	Reason
Nov-17-2020 15:54:15 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Nov/16/2020	Initial Entry

4. Ongoing?

Date	Location	User	Value	Reason
Nov-23-2020 16:50:52 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO Discharge Date: Nov/23/2020	Transcription Error
Nov-17-2020 15:54:15 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

090177e196ae2fe1\Final\Final On: 01-Apr-2021 03:54 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit Form: RESPIRATORY TREATMENT - eCRF Audit Trail History on Nov/10/2020

Form Version: 06-Jul-2020 21:53

Form Status: Data Complete, Frozen, Verified

Site No: 1210

Site Name: (1210) Medipol University Medical Faculty

Subject No: 12101026

Subject Initials: ---

Generated By: (b) (4)

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

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1. What is the treatment Identifier?

Date	Location	User	Value	Reason
Nov-27-2020 18:18:56 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

2. Concomitant Non-drug Treatment Pre-specified:

Date	Location	User	Value	Reason
Nov-27-2020 18:18:56 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

3. Treatment:

Date	Location	User	Value	Reason
Nov-27-2020 18:18:56 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

4. Treatment:

Date	Location	User	Value	Reason
Nov-27-2020 18:18:56 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5. Start Date:

Date	Location	User	Value	Reason
Nov-27-2020 18:18:56 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

6. Ongoing?

Date	Location	User	Value	Reason
Nov-27-2020 18:18:56	ACV0PFEINFP6000	(b) (6)	Data Entry:	Initial Entry

090177e196ae2fe1\Final\Final On: 01-Apr-2021 03:54 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** RESPIRATORY TREATMENT - eCRF Audit Trail History on Nov/10/2020

Form Version: 06-Jul-2020 21:53

Form Status: Data Complete, Frozen, Verified

Site No: 1210

Site Name: (1210) Medipol University Medical Faculty

Subject No: 12101026

Subject Initials: ---

Generated By: (b) (4)

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

(UTC+03:00) Istanbul	(b) (4), (b) (6)	Not Applicable
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Header Text: C4591001**Visit:** POT_COVID_ILL 1 - Unscheduled Visit **Form:** ILLNESS DETAILS - eCRF Audit Trail History
on Nov/10/2020**Form Version:** 06-Jul-2020 21:52**Form Status:** Data Complete, Frozen, Verified**Site No:** 1210**Site Name:** (1210) Medipol University Medical Faculty**Subject No:** 12101026**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 13:11[Back to Form](#)**1. Category of Clinical Event:**

Date	Location	User	Value	Reason
Nov-17-2020 14:50:38 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: POTENTIAL COVID-19 ILLNES S	Initial Entry

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

Date	Location	User	Value	Reason
Nov-27-2020 10:03:46 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	New Information
Nov-17-2020 15:39:39 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Nov-17-2020 15:39:39 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES <i>Respiratory Illness Diagnosis:</i> COVID19 Date of Diagnosis: Nov/16/2020	Transcription Error
Nov-17-2020 14:50:38 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	Yes is selected, however, either the diagnosis details or date of diagnosis is missing. Please correct.
Nov-17-2020 14:50:38 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Date of Diagnosis: Nov/16/2020	Initial Entry

3. Toxicity Grade:

Date	Location	User	Value	Reason
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Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** ILLNESS DETAILS - eCRF Audit Trail History
on Nov/10/2020

Form Version: 06-Jul-2020 21:52

Form Status: Data Complete, Frozen, Verified

Site No: 1210

Site Name: (1210) Medipol University Medical Faculty

Subject No: 12101026

Subject Initials: ---

Generated By: (b) (4)

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

Nov-27-2020 10:04:23 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Nov-27-2020 10:04:23 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 2	New Information
Nov-27-2020 10:03:56 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	Per CRF CRs Section 8.33.5, please enter worst toxicity grade (1 to 5) as it relates to reported symptom(s) on SOD CRF. Please review and update as appropriate.
Nov-27-2020 10:03:56 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 0	New Information
Nov-17-2020 14:50:38 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 2	Initial Entry

090177e196ae2fe1\Final\Final On: 01-Apr-2021 03:54 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** ILLNESS DETAILS - SEVERE - eCRF Audit Trail History on Nov/10/2020

Form Version: 17-Jul-2020 21:55

Form Status: Data Complete, Frozen, Verified

Site No: 1210

Site Name: (1210) Medipol University Medical Faculty

Subject No: 12101026

Subject Initials: ---

Generated By: (b) (4)

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

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1. Category of Clinical Event:

Date	Location	User	Value	Reason
Nov-27-2020 18:19:29 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

2. Subcategory of Clinical Event:

Date	Location	User	Value	Reason
Nov-27-2020 18:19:29 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

3. Was a diagnosis obtained?

Date	Location	User	Value	Reason
Nov-27-2020 18:19:29 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

4. Toxicity Grade:

Date	Location	User	Value	Reason
Nov-27-2020 18:19:29 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

090177e196ae2fe1\Final\Final On: 01-Apr-2021 03:54 (GMT)

Header Text: C4591001**Visit:** POT_COVID_ILL 1 - Unscheduled Visit on Nov/10/2020**Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History**Form Version:** 10-Oct-2020 15:58**Form Status:** Data Complete, Frozen, Verified**Site No:** 1210**Site Name:** (1210) Medipol University Medical Faculty**Subject No:** 12101026**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 13:11[Back to Form](#)**1. Lab Panel:**

Date	Location	User	Value	Reason
Nov-27-2020 18:36:43 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

2. Laboratory Name and Address

Date	Location	User	Value	Reason
Nov-27-2020 18:36:43 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

3. Collection Date:

Date	Location	User	Value	Reason
Nov-27-2020 18:36:43 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

4. Specimen Type:

Date	Location	User	Value	Reason
Nov-27-2020 18:36:43 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.a

Date	Location	User	Value	Reason
Nov-27-2020 18:36:43 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sponsor-Defined Id Not Applicable Test:: Not Applicable Result:: Not Applicable	Initial Entry

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/10/2020

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History

Form Version: 10-Oct-2020 15:58

Form Status: Data Complete, Frozen, Verified

Site No: 1210

Site Name: (1210) Medipol University Medical Faculty

Subject No: 12101026

Subject Initials: ---

Generated By: (b) (4)

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

			Not Done:: Not Applicable	
			Lab Normal Range: Not Applicable	

5.a Sponsor ID:

Date	Location	User	Value	Reason
Nov-27-2020 18:36:43 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.a Test:

Date	Location	User	Value	Reason
Nov-27-2020 18:36:43 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.a Result:

Date	Location	User	Value	Reason
Nov-27-2020 18:36:43 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.a Not Done:

Date	Location	User	Value	Reason
Nov-27-2020 18:36:43 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.a LNMT

Date	Location	User	Value	Reason
Nov-27-2020 18:36:43 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.b

090177e196ae2fe1\Final\Final On: 01-Apr-2021 03:54 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/10/2020

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History

Form Version: 10-Oct-2020 15:58

Form Status: Data Complete, Frozen, Verified

Site No: 1210

Site Name: (1210) Medipol University Medical Faculty

Subject No: 12101026

Subject Initials: ---

Generated By: (b) (4)

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

Date	Location	User	Value	Reason
Nov-27-2020 18:36:43 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sponsor-Defined Identifier: Not Applicable Test:: Not Applicable Result:: Not Applicable Not Done:: Not Applicable Lab Normal Range: Not Applicable	Initial Entry

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/10/2020

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History

Form Version: 10-Oct-2020 15:58

Form Status: Data Complete, Frozen, Verified

Site No: 1210

Site Name: (1210) Medipol University Medical Faculty

Subject No: 12101026

Subject Initials: ---

Generated By: (b) (4)

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

5.b Sponsor ID:

Date	Location	User	Value	Reason
Nov-27-2020 18:36:43 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.b Test:

Date	Location	User	Value	Reason
Nov-27-2020 18:36:43 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.b Result:

Date	Location	User	Value	Reason
Nov-27-2020 18:36:43 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.b Not Done:

Date	Location	User	Value	Reason
Nov-27-2020 18:36:43 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.b LNMT

Date	Location	User	Value	Reason
Nov-27-2020 18:36:43 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.c

Date	Location	User	Value	Reason
Nov-27-2020 18:36:43 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sponsor-Defined Id Not Applicable entifier:	Initial Entry

090177e196ae2fe1\Final\Final On: 01-Apr-2021 03:54 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/10/2020

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History

Form Version: 10-Oct-2020 15:58

Form Status: Data Complete, Frozen, Verified

Site No: 1210

Site Name: (1210) Medipol University Medical Faculty

Subject No: 12101026

Subject Initials: ---

Generated By: (b) (4)

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

			Test::	Not Applicable	
			Result::	Not Applicable	
			Not Done::	Not Applicable	
			Lab Normal Range:	Not Applicable	

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/10/2020

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History

Form Version: 10-Oct-2020 15:58

Form Status: Data Complete, Frozen, Verified

Site No: 1210

Site Name: (1210) Medipol University Medical Faculty

Subject No: 12101026

Subject Initials: ---

Generated By: (b) (4)

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

5.c Sponsor ID:

Date	Location	User	Value	Reason
Nov-27-2020 18:36:43 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.c Test:

Date	Location	User	Value	Reason
Nov-27-2020 18:36:43 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.c Result:

Date	Location	User	Value	Reason
Nov-27-2020 18:36:43 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.c Not Done:

Date	Location	User	Value	Reason
Nov-27-2020 18:36:43 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.c LNMT

Date	Location	User	Value	Reason
Nov-27-2020 18:36:43 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.d

Date	Location	User	Value	Reason
Nov-27-2020 18:36:43 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sponsor-Defined Id Not Applicable entifier: able	Initial Entry

090177e196ae2fe1\Final\Final On: 01-Apr-2021 03:54 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/10/2020

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History

Form Version: 10-Oct-2020 15:58

Form Status: Data Complete, Frozen, Verified

Site No: 1210

Site Name: (1210) Medipol University Medical Faculty

Subject No: 12101026

Subject Initials: ---

Generated By: (b) (4)

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

			Test::	Not Applicable	
			Result::	Not Applicable	
			Not Done::	Not Applicable	
			Lab Normal Range:	Not Applicable	

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/10/2020

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History

Form Version: 10-Oct-2020 15:58

Form Status: Data Complete, Frozen, Verified

Site No: 1210

Site Name: (1210) Medipol University Medical Faculty

Subject No: 12101026

Subject Initials: ---

Generated By: (b) (4)

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

5.d Sponsor ID:

Date	Location	User	Value	Reason
Nov-27-2020 18:36:43 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.d Test:

Date	Location	User	Value	Reason
Nov-27-2020 18:36:43 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.d Result:

Date	Location	User	Value	Reason
Nov-27-2020 18:36:43 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.d Not Done:

Date	Location	User	Value	Reason
Nov-27-2020 18:36:43 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.d LNMT

Date	Location	User	Value	Reason
Nov-27-2020 18:36:43 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.e

Date	Location	User	Value	Reason
Nov-27-2020 18:36:43 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sponsor-Defined Id Not Applicable entifier:	Initial Entry

090177e196ae2fe1\Final\Final On: 01-Apr-2021 03:54 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/10/2020

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History

Form Version: 10-Oct-2020 15:58

Form Status: Data Complete, Frozen, Verified

Site No: 1210

Site Name: (1210) Medipol University Medical Faculty

Subject No: 12101026

Subject Initials: ---

Generated By: (b) (4)

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

			Test::	Not Applicable	
			Result::	Not Applicable	
			Not Done::	Not Applicable	
			Lab Normal Range:	Not Applicable	

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/10/2020

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History

Form Version: 10-Oct-2020 15:58

Form Status: Data Complete, Frozen, Verified

Site No: 1210

Site Name: (1210) Medipol University Medical Faculty

Subject No: 12101026

Subject Initials: ---

Generated By: (b) (4)

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

5.e Sponsor ID:

Date	Location	User	Value	Reason
Nov-27-2020 18:36:43 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.e Test:

Date	Location	User	Value	Reason
Nov-27-2020 18:36:43 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.e Result:

Date	Location	User	Value	Reason
Nov-27-2020 18:36:43 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.e Not Done:

Date	Location	User	Value	Reason
Nov-27-2020 18:36:43 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.e LNMT

Date	Location	User	Value	Reason
Nov-27-2020 18:36:43 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.f

Date	Location	User	Value	Reason
Nov-27-2020 18:36:43 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sponsor-Defined Id Not Applicable entifier:	Initial Entry

090177e196ae2fe1\Final\Final On: 01-Apr-2021 03:54 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/10/2020

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History

Form Version: 10-Oct-2020 15:58

Form Status: Data Complete, Frozen, Verified

Site No: 1210

Site Name: (1210) Medipol University Medical Faculty

Subject No: 12101026

Subject Initials: ---

Generated By: (b) (4)

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

			Test::	Not Applicable	
			Result::	Not Applicable	
			Not Done::	Not Applicable	
			Lab Normal Range:	Not Applicable	

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/10/2020

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History

Form Version: 10-Oct-2020 15:58

Form Status: Data Complete, Frozen, Verified

Site No: 1210

Site Name: (1210) Medipol University Medical Faculty

Subject No: 12101026

Subject Initials: ---

Generated By: (b) (4)

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

5.f Sponsor ID:

Date	Location	User	Value	Reason
Nov-27-2020 18:36:43 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.f Test:

Date	Location	User	Value	Reason
Nov-27-2020 18:36:43 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.f Result:

Date	Location	User	Value	Reason
Nov-27-2020 18:36:43 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.f Not Done:

Date	Location	User	Value	Reason
Nov-27-2020 18:36:43 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.f LNMT

Date	Location	User	Value	Reason
Nov-27-2020 18:36:43 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.g

Date	Location	User	Value	Reason
Nov-27-2020 18:36:43 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sponsor-Defined Id Not Applicable entifier:	Initial Entry

090177e196ae2fe1\Final\Final On: 01-Apr-2021 03:54 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/10/2020

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History

Form Version: 10-Oct-2020 15:58

Form Status: Data Complete, Frozen, Verified

Site No: 1210

Site Name: (1210) Medipol University Medical Faculty

Subject No: 12101026

Subject Initials: ---

Generated By: (b) (4)

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

			Test::	Not Applicable	
			Result::	Not Applicable	
			Not Done::	Not Applicable	
			Lab Normal Range:	Not Applicable	

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/10/2020

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History

Form Version: 10-Oct-2020 15:58

Form Status: Data Complete, Frozen, Verified

Site No: 1210

Site Name: (1210) Medipol University Medical Faculty

Subject No: 12101026

Subject Initials: ---

Generated By: (b) (4)

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

5.g Sponsor ID:

Date	Location	User	Value	Reason
Nov-27-2020 18:36:43 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.g Test:

Date	Location	User	Value	Reason
Nov-27-2020 18:36:43 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.g Result:

Date	Location	User	Value	Reason
Nov-27-2020 18:36:43 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.g Not Done:

Date	Location	User	Value	Reason
Nov-27-2020 18:36:43 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.g LNMT

Date	Location	User	Value	Reason
Nov-27-2020 18:36:43 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

090177e196ae2fe1\Final\Final On: 01-Apr-2021 03:54 (GMT)

Header Text: C4591001**Visit:** POT_COVID_ILL 1 - Unscheduled Visit on Nov/10/2020**Form:** LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History**Form Version:** 10-Oct-2020 16:02**Form Status:** Data Complete, Frozen, Verified**Site No:** 1210**Site Name:** (1210) Medipol University Medical Faculty**Subject No:** 12101026**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 13:11[Back to Form](#)**1. Lab Panel:**

Date	Location	User	Value	Reason
Nov-27-2020 18:37:32 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

2. Laboratory Name and Address

Date	Location	User	Value	Reason
Nov-27-2020 18:37:32 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

3. Collection Date:

Date	Location	User	Value	Reason
Nov-27-2020 18:37:32 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

4. Specimen Type:

Date	Location	User	Value	Reason
Nov-27-2020 18:37:32 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.a

Date	Location	User	Value	Reason
Nov-27-2020 18:37:32 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sponsor-Defined Id Not Applicable Test:: Not Applicable Result:: Not Applicable	Initial Entry

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/10/2020

Form: LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

Form Version: 10-Oct-2020 16:02

Form Status: Data Complete, Frozen, Verified

Site No: 1210

Site Name: (1210) Medipol University Medical Faculty

Subject No: 12101026

Subject Initials: ---

Generated By: (b) (4)

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

			Not Done:: Not Applicable Lab Normal Range: Not Applicable	
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5.a Sponsor ID:

Date	Location	User	Value	Reason
Nov-27-2020 18:37:32 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.a Test:

Date	Location	User	Value	Reason
Nov-27-2020 18:37:32 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.a Result:

Date	Location	User	Value	Reason
Nov-27-2020 18:37:32 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.a Not Done:

Date	Location	User	Value	Reason
Nov-27-2020 18:37:32 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.a LNMT

Date	Location	User	Value	Reason
Nov-27-2020 18:37:32 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.b

090177e196ae2fe1\Final\Final On: 01-Apr-2021 03:54 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/10/2020

Form: LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

Form Version: 10-Oct-2020 16:02

Form Status: Data Complete, Frozen, Verified

Site No: 1210

Site Name: (1210) Medipol University Medical Faculty

Subject No: 12101026

Subject Initials: ---

Generated By: (b) (4)

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

Date	Location	User	Value	Reason
Nov-27-2020 18:37:32 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sponsor-Defined Identifier: Not Applicable Test:: Not Applicable Result:: Not Applicable Not Done:: Not Applicable Lab Normal Range: Not Applicable	Initial Entry

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/10/2020

Form: LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

Form Version: 10-Oct-2020 16:02

Form Status: Data Complete, Frozen, Verified

Site No: 1210

Site Name: (1210) Medipol University Medical Faculty

Subject No: 12101026

Subject Initials: ---

Generated By: (b) (4)

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

5.b Sponsor ID:

Date	Location	User	Value	Reason
Nov-27-2020 18:37:32 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.b Test:

Date	Location	User	Value	Reason
Nov-27-2020 18:37:32 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.b Result:

Date	Location	User	Value	Reason
Nov-27-2020 18:37:32 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.b Not Done:

Date	Location	User	Value	Reason
Nov-27-2020 18:37:32 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.b LNMT

Date	Location	User	Value	Reason
Nov-27-2020 18:37:32 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.c

Date	Location	User	Value	Reason
Nov-27-2020 18:37:32 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sponsor-Defined Id Not Applicable entifier:	Initial Entry

090177e196ae2fe1\Final\Final On: 01-Apr-2021 03:54 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/10/2020

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Site No: 1210

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Subject No: 12101026

Subject Initials: ---

Generated By: (b) (4)

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

			Test::	Not Applicable	
			Result::	Not Applicable	
			Not Done::	Not Applicable	
			Lab Normal Range:	Not Applicable	

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/10/2020

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Site No: 1210

Site Name: (1210) Medipol University Medical Faculty

Subject No: 12101026

Subject Initials: ---

Generated By: (b) (4)

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

5.c Sponsor ID:

Date	Location	User	Value	Reason
Nov-27-2020 18:37:32 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.c Test:

Date	Location	User	Value	Reason
Nov-27-2020 18:37:32 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.c Result:

Date	Location	User	Value	Reason
Nov-27-2020 18:37:32 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.c Not Done:

Date	Location	User	Value	Reason
Nov-27-2020 18:37:32 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.c LNMT

Date	Location	User	Value	Reason
Nov-27-2020 18:37:32 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.d

Date	Location	User	Value	Reason
Nov-27-2020 18:37:32 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sponsor-Defined Id Not Applicable entifier:	Initial Entry

090177e196ae2fe1\Final\Final On: 01-Apr-2021 03:54 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/10/2020

Form: LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

Form Version: 10-Oct-2020 16:02

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Site No: 1210

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Generated By: (b) (4)

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

			Test::	Not Applicable	
			Result::	Not Applicable	
			Not Done::	Not Applicable	
			Lab Normal Range:	Not Applicable	

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Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/10/2020

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Subject No: 12101026

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Generated By: (b) (4)

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

5.d Sponsor ID:

Date	Location	User	Value	Reason
Nov-27-2020 18:37:32 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.d Test:

Date	Location	User	Value	Reason
Nov-27-2020 18:37:32 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.d Result:

Date	Location	User	Value	Reason
Nov-27-2020 18:37:32 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.d Not Done:

Date	Location	User	Value	Reason
Nov-27-2020 18:37:32 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.d LNMT

Date	Location	User	Value	Reason
Nov-27-2020 18:37:32 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.e

Date	Location	User	Value	Reason
Nov-27-2020 18:37:32 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sponsor-Defined Identifier: Not Applicable	Initial Entry

090177e196ae2fe1\Final\Final On: 01-Apr-2021 03:54 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/10/2020

Form: LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

Form Version: 10-Oct-2020 16:02

Form Status: Data Complete, Frozen, Verified

Site No: 1210

Site Name: (1210) Medipol University Medical Faculty

Subject No: 12101026

Subject Initials: ---

Generated By: (b) (4)

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

			Test::	Not Applicable	
			Result::	Not Applicable	
			Not Done::	Not Applicable	
			Lab Normal Range:	Not Applicable	

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/10/2020

Form: LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

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

5.e Sponsor ID:

Date	Location	User	Value	Reason
Nov-27-2020 18:37:32 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.e Test:

Date	Location	User	Value	Reason
Nov-27-2020 18:37:32 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.e Result:

Date	Location	User	Value	Reason
Nov-27-2020 18:37:32 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.e Not Done:

Date	Location	User	Value	Reason
Nov-27-2020 18:37:32 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.e LNMT

Date	Location	User	Value	Reason
Nov-27-2020 18:37:32 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.f

Date	Location	User	Value	Reason
Nov-27-2020 18:37:32 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sponsor-Defined Id Not Applicable entifier: able	Initial Entry

090177e196ae2fe1\Final\Final On: 01-Apr-2021 03:54 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/10/2020

Form: LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

Form Version: 10-Oct-2020 16:02

Form Status: Data Complete, Frozen, Verified

Site No: 1210

Site Name: (1210) Medipol University Medical Faculty

Subject No: 12101026

Subject Initials: ---

Generated By: (b) (4)

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

			Test::	Not Applicable	
			Result::	Not Applicable	
			Not Done::	Not Applicable	
			Lab Normal Range:	Not Applicable	

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/10/2020

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Subject No: 12101026

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Generated By: (b) (4)

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

5.f Sponsor ID:

Date	Location	User	Value	Reason
Nov-27-2020 18:37:32 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.f Test:

Date	Location	User	Value	Reason
Nov-27-2020 18:37:32 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.f Result:

Date	Location	User	Value	Reason
Nov-27-2020 18:37:32 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.f Not Done:

Date	Location	User	Value	Reason
Nov-27-2020 18:37:32 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.f LNMT

Date	Location	User	Value	Reason
Nov-27-2020 18:37:32 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.g

Date	Location	User	Value	Reason
Nov-27-2020 18:37:32 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sponsor-Defined Identifier: Not Applicable	Initial Entry

090177e196ae2fe1\Final\Final On: 01-Apr-2021 03:54 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/10/2020

Form: LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

Form Version: 10-Oct-2020 16:02

Form Status: Data Complete, Frozen, Verified

Site No: 1210

Site Name: (1210) Medipol University Medical Faculty

Subject No: 12101026

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Generated By: (b) (4)

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

			Test::	Not Applicable	
			Result::	Not Applicable	
			Not Done::	Not Applicable	
			Lab Normal Range:	Not Applicable	

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/10/2020

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5.g Sponsor ID:

Date	Location	User	Value	Reason
Nov-27-2020 18:37:32 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.g Test:

Date	Location	User	Value	Reason
Nov-27-2020 18:37:32 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.g Result:

Date	Location	User	Value	Reason
Nov-27-2020 18:37:32 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.g Not Done:

Date	Location	User	Value	Reason
Nov-27-2020 18:37:32 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.g LNMT

Date	Location	User	Value	Reason
Nov-27-2020 18:37:32 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.h

Date	Location	User	Value	Reason
Nov-27-2020 18:37:32 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sponsor-Defined Id Not Applicable entifier:	Initial Entry

090177e196ae2fe1\Final\Final On: 01-Apr-2021 03:54 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/10/2020

Form: LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

Form Version: 10-Oct-2020 16:02

Form Status: Data Complete, Frozen, Verified

Site No: 1210

Site Name: (1210) Medipol University Medical Faculty

Subject No: 12101026

Subject Initials: ---

Generated By: (b) (4)

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

			Test::	Not Applicable	
			Result::	Not Applicable	
			Not Done::	Not Applicable	
			Lab Normal Range:	Not Applicable	

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/10/2020

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

5.h Sponsor ID:

Date	Location	User	Value	Reason
Nov-27-2020 18:37:32 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.h Test:

Date	Location	User	Value	Reason
Nov-27-2020 18:37:32 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.h Result:

Date	Location	User	Value	Reason
Nov-27-2020 18:37:32 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.h Not Done:

Date	Location	User	Value	Reason
Nov-27-2020 18:37:32 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.h LNMT

Date	Location	User	Value	Reason
Nov-27-2020 18:37:32 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.i

Date	Location	User	Value	Reason
Nov-27-2020 18:37:32 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sponsor-Defined Identifier: Not Applicable	Initial Entry

090177e196ae2fe1\Final\Final On: 01-Apr-2021 03:54 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/10/2020

Form: LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

Form Version: 10-Oct-2020 16:02

Form Status: Data Complete, Frozen, Verified

Site No: 1210

Site Name: (1210) Medipol University Medical Faculty

Subject No: 12101026

Subject Initials: ---

Generated By: (b) (4)

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

			Test::	Not Applicable	
			Result::	Not Applicable	
			Not Done::	Not Applicable	
			Lab Normal Range:	Not Applicable	

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/10/2020

Form: LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

Form Version: 10-Oct-2020 16:02

Form Status: Data Complete, Frozen, Verified

Site No: 1210

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

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5.i Sponsor ID:

Date	Location	User	Value	Reason
Nov-27-2020 18:37:32 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.i Test:

Date	Location	User	Value	Reason
Nov-27-2020 18:37:32 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.i Result:

Date	Location	User	Value	Reason
Nov-27-2020 18:37:32 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.i Not Done:

Date	Location	User	Value	Reason
Nov-27-2020 18:37:32 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.i LNMT

Date	Location	User	Value	Reason
Nov-27-2020 18:37:32 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.j

Date	Location	User	Value	Reason
Nov-27-2020 18:37:32 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (6)	Data Entry: Sponsor-Defined Id Not Applicable	Initial Entry

090177e196ae2fe1\Final\Final On: 01-Apr-2021 03:54 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/10/2020

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Site Name: (1210) Medipol University Medical Faculty

Subject No: 12101026

Subject Initials: ---

Generated By: (b) (4)

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

		(b) (4)	entifier:	able	
			Test::	Not Applicable	
			Result::	Not Applicable	
			Not Done::	Not Applicable	
			Lab Normal Range:	Not Applicable	

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/10/2020

Form: LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

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Form Status: Data Complete, Frozen, Verified

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Site Name: (1210) Medipol University Medical Faculty

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

5.j Sponsor ID:

Date	Location	User	Value	Reason
Nov-27-2020 18:37:32 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.j Test:

Date	Location	User	Value	Reason
Nov-27-2020 18:37:32 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.j Result:

Date	Location	User	Value	Reason
Nov-27-2020 18:37:32 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.j Not Done:

Date	Location	User	Value	Reason
Nov-27-2020 18:37:32 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.j LNMT

Date	Location	User	Value	Reason
Nov-27-2020 18:37:32 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

090177e196ae2fe1\Final\Final On: 01-Apr-2021 03:54 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit Form: VITAL SIGNS - COVID - eCRF Audit Trail History on Nov/10/2020

Form Version: 10-Oct-2020 15:59

Form Status: Data Complete, Frozen, Verified

Site No: 1210

Site Name: (1210) Medipol University Medical Faculty

Subject No: 12101026

Subject Initials: ---

Generated By: (b) (4)

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

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I. Date:

Date	Location	User	Value	Reason
Nov-27-2020 18:38:14 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

2.a

Date	Location	User	Value	Reason
Nov-27-2020 18:38:14 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Record Identifier:: Not Applicable Systolic:: Not Applicable Diastolic:: Not Applicable Respiratory Rate in re Not App spirations/minute: licable Heart Rate in beats/mi Not App ute: licable	Initial Entry

2.a Record Identifier:

Date	Location	User	Value	Reason
Nov-27-2020 18:38:14 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

2.a Systolic:

Date	Location	User	Value	Reason
Nov-27-2020 18:38:14 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

2.a Diastolic:

Date	Location	User	Value	Reason
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090177e196ae2fe1\Final\Final On: 01-Apr-2021 03:54 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** VITAL SIGNS - COVID - eCRF Audit Trail History
on Nov/10/2020

Form Version: 10-Oct-2020 15:59

Form Status: Data Complete, Frozen, Verified

Site No: 1210

Site Name: (1210) Medipol University Medical Faculty

Subject No: 12101026

Subject Initials: ---

Generated By: (b) (4)

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

Nov-27-2020 18:38:14 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry
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2.a Respiratory Rate in respirations/minute:

Date	Location	User	Value	Reason
Nov-27-2020 18:38:14 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

2.a Heart Rate in beats/minute:

Date	Location	User	Value	Reason
Nov-27-2020 18:38:14 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

090177e196ae2fe1\Final\Final On: 01-Apr-2021 03:54 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** VITAL SIGNS - PULSE OX ROOM AIR - Audit Trail on Nov/10/2020

Form Version: 10-Oct-2020 16:04

Form Status:

Site No: 1210

Site Name: (1210) Medipol University Medical Faculty

Subject No: 12101026

Subject Initials: ---

Generated By: (b) (4)

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

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Date	Location	User	Value	Reason
Nov-17-2020 16:24:29 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Created	

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/10/2020

Form: VITAL SIGNS - PULSE OX ROOM AIR - eCRF Audit Trail History

Form Version: 10-Oct-2020 16:04

Form Status: Data Complete, Frozen, Verified

Site No: 1210

Site Name: (1210) Medipol University Medical Faculty

Subject No: 12101026

Subject Initials: ---

Generated By: (b) (4)

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

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1. Date:

Date	Location	User	Value	Reason
Nov-17-2020 16:24:29 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Nov/17/2020	Initial Entry

2.a

Date	Location	User	Value	Reason
Nov-17-2020 16:24:29 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Record Identifier:: 1 Oxygen Saturation: 92.0	Initial Entry

2.a Record Identifier:

Date	Location	User	Value	Reason
Nov-17-2020 16:24:29 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 1	Initial Entry

2.a SPO2 Pulse Oximetry %

Date	Location	User	Value	Reason
Nov-17-2020 16:24:29 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 92.0	Initial Entry

090177e196ae2fe1\Final\Final On: 01-Apr-2021 03:54 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** OXYGENATION PARAMETERS - eCRF Audit Trail History on Nov/10/2020

Form Version: 06-Jul-2020 21:52

Form Status: Data Complete, Frozen, Verified

Site No: 1210

Site Name: (1210) Medipol University Medical Faculty

Subject No: 12101026

Subject Initials: ---

Generated By: (b) (4)

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

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1. Date Time of Assessment:

Date	Location	User	Value	Reason
Nov-27-2020 18:38:37 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

2. Arterial Blood Gases PaO2 (mmHg):

Date	Location	User	Value	Reason
Nov-27-2020 18:38:37 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

3. FiO2 (Fraction of Inhaled Oxygen):

Date	Location	User	Value	Reason
Nov-27-2020 18:38:37 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

090177e196ae2fe1\Final\Final On: 01-Apr-2021 03:54 (GMT)

Header Text: C4591001**Visit:** POT_COVID_ILL 1 - Unscheduled Visit on Nov/10/2020**Form Version:** 06-Jul-2020 21:55**Site No:** 1210**Subject No:** 12101026**Generated By:** (b) (4)**Form:** CONCOMITANT MEDICATIONS - VASOPRESSORS - 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. What is the medication identifier?**

Date	Location	User	Value	Reason
Nov-27-2020 18:39:19 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

2. Category:

Date	Location	User	Value	Reason
Nov-27-2020 18:39:19 (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-27-2020 18:39:19 (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-27-2020 18:39:19 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5. Start Date:

Date	Location	User	Value	Reason
Nov-27-2020 18:39:19 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

6. Ongoing?

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/10/2020

Form: CONCOMITANT MEDICATIONS - VASOPRESSORS - eCRF Audit Trail History

Form Version: 06-Jul-2020 21:55

Form Status: Data Complete, Frozen, Verified

Site No: 1210

Site Name: (1210) Medipol University Medical Faculty

Subject No: 12101026

Subject Initials: ---

Generated By: (b) (4)

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

Date	Location	User	Value	Reason
Nov-27-2020 18:39:19 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** IMAGING - Audit Trail
on Nov/10/2020

Form Version: 06-Jul-2020 21:53

Form Status:

Site No: 1210

Site Name: (1210) Medipol University Medical Faculty

Subject No: 12101026

Subject Initials: ---

Generated By: (b) (4)

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

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Date	Location	User	Value	Reason
Nov-27-2020 18:35:52 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Created	

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit Form: IMAGING - eCRF Audit Trail History on Nov/10/2020

Form Version: 06-Jul-2020 21:53

Form Status: Data Complete, Frozen, Verified

Site No: 1210

Site Name: (1210) Medipol University Medical Faculty

Subject No: 12101026

Subject Initials: ---

Generated By: (b) (4)

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

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1. Date of Assessment:

Date	Location	User	Value	Reason
Nov-27-2020 18:35:52 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Nov/16/2020	Initial Entry

2. Location of Assessment:

Date	Location	User	Value	Reason
Nov-27-2020 18:35:52 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: CHEST	Initial Entry

3. Type of Imaging Exam:

Date	Location	User	Value	Reason
Nov-27-2020 18:35:52 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: CT SCAN	Initial Entry

4. Assessment:

Date	Location	User	Value	Reason
Dec-01-2020 08:48:42 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Nov-30-2020 13:36:20 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Transcription Error
Nov-30-2020 13:36:20 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: ABNORMAL <i>If abnormal, specify findings:</i> In both lungs, ground glass appearance and areas of increased density consistent with consolidation are observed.	Transcription Error
Nov-29-2020 18:32:52 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (6)	Query 1: Opened	DM: A carriage is identified. To avoid

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Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** IMAGING - eCRF Audit Trail History
on Nov/10/2020

Form Version: 06-Jul-2020 21:53

Form Status: Data Complete, Frozen, Verified

Site No: 1210

Site Name: (1210) Medipol University Medical Faculty

Subject No: 12101026

Subject Initials: ---

Generated By: (b) (4)

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

		(b) (4)		processing errors, please remove the identified character by deleting the entry and re-entering the data (without using copy and paste).
Nov-27-2020 18:35:52 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: ABNORMAL <i>If abnormal, specify findings:</i> Right lung lower lobe posterior, middle lobe, in the upper lobe anterior and left lung upper lobe anterior segment compatible with ground glass and consolidation Density increase areas are monitor-	Initial Entry

090177e196ae2fe1\Final\Final On: 01-Apr-2021 03:54 (GMT)

Header Text: C4591001

Visit: POT_COVID_CONVA 1 - Unscheduled
Visit on Dec/11/2020

Form: DATE OF VISIT - ILLNESS CONVALESCENT - 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: 12101026

Subject Initials: ---

Generated By: (b) (4)

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

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1. Date of Visit

Date	Location	User	Value	Reason
Dec-14-2020 11:38:49 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Dec/11/2020	Initial Entry

3. COVID-19 Illness Visit:

Date	Location	User	Value	Reason
Dec-14-2020 11:38:49 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: COVID_A1	Initial Entry

Header Text: C4591001**Visit:** POT_COVID_CONVA 1 - Unscheduled
Visit on Dec/11/2020**Form Version:** 22-Apr-2020 21:03**Site No:** 1210**Subject No:** 12101026**Generated By:** (b) (4)**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY -
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. Data Origin**

Date	Location	User	Value	Reason
Dec-14-2020 11:39:06 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Dec-14-2020 11:39:06 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SERUM	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Dec-14-2020 11:39:34 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Dec-14-2020 11:39:06 (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-14-2020 11:39:06 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Date of Collection: Dec/11/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Dec-14-2020 11:39:34 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BRCXVL	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
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Header Text: C4591001

Visit: POT_COVID_CONVA 1 - Unscheduled
Visit on Dec/11/2020

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1210

Site Name: (1210) Medipol University Medical Faculty

Subject No: 12101026

Subject Initials: ---

Generated By: (b) (4)

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

Dec-14-2020 11:39:34 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BRCXVL	Initial Entry
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5.b

Date	Location	User	Value	Reason
Dec-14-2020 11:39:48 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BRCXVK	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Dec-14-2020 11:39:48 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BRCXVK	Initial Entry

5.c

Date	Location	User	Value	Reason
Dec-14-2020 11:40:03 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BSHB5L	Initial Entry

5.c Sample ID

Date	Location	User	Value	Reason
Dec-14-2020 11:40:03 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BSHB5L	Initial Entry

5.d

Date	Location	User	Value	Reason
Dec-14-2020 11:40:14 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BSHB5K	Initial Entry

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Header Text: C4591001

Visit: POT_COVID_CONVA 1 - Unscheduled
Visit on Dec/11/2020

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1210

Site Name: (1210) Medipol University Medical Faculty

Subject No: 12101026

Subject Initials: ---

Generated By: (b) (4)

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

5.d Sample ID

Date	Location	User	Value	Reason
Dec-14-2020 11:40:14 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BSHB5K	Initial Entry

Header Text: C4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1210

Subject No: 12101026

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-26-2020 12:23:47 (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: 12101026

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
Dec-02-2020 11:37:02 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Created	

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Header Text: C4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1210

Subject No: 12101026

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
Nov-26-2020 12:23:47 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: ADVERSE EVENT	Initial Entry

2. AE ID:

Date	Location	User	Value	Reason
Nov-26-2020 12:23:47 (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
Dec-14-2020 17:15:08 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Acute upper respiratory tract infections	Transcription Error
Nov-26-2020 12:23:47 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Pneumonia	Initial Entry

4. Start Date Time:

Date	Location	User	Value	Reason
Jan-15-2021 19:39:48 (UTC+03:00) Istanbul	ACV0PFEINFP6000	Giselle Castillo (b) (4)	Query 3: Closed	Response satisfies query
Jan-15-2021 17:08:00 (UTC+03:00) Istanbul	ACV0PFEINFP6000	Giselle Castillo (b) (4)	Query 3: Reissued:Opened	Kindly clarify how the events recorded are two separate events? Please review CRF CG 8.50.2. Adverse Event Term.
Jan-07-2021 10:14:57 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Answered	My symptom started 7 Nov. This situation has been entered in the non-serious part. The SAE part has

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Header Text: C4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1210

Subject No: 12101026

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

				been entered in AE1. SAE form was corrected and sent on 17/12/2020.
Jan-06-2021 17:54:58 (UTC+03:00) Istanbul	ACV0PFEINFP6000	Giselle Castillo (b) (4)	Query 3: Opened	CLIN_Safety report records: "subject reported first complaint on 07Nov2020". Per protocol section 8.1. "the onset date of the case will be the date that symptoms were first experienced". Please review/update onset date and submit a FU SAE form. Thanks
Dec-09-2020 13:45:21 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Closed	Response satisfies query
Dec-07-2020 15:38:34 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Answered	Correct SAE Form is send on 07Dec2020.
Dec-07-2020 13:14:14 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Opened	SAE RECON: AER#2020470537 ,onset date was uptdaed to 17Nov2020 in Safety database however, recorded as 16Nov2020 on AE CRF. Please confirm correct Onset Date. If safety update is required, please submit a follow-up SAE form
Dec-02-2020 15:38:58 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Dec-02-2020 11:34:26 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Transcription Error

090177e196ae2fe1\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:** 12101026**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

Dec-02-2020 11:34:26 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Nov/16/2020 UNK:UNK	Transcription Error
Dec-01-2020 15:18:43 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	SAE RECON: AER#2020470537 ,onset date was recorded as 16Nov2020 in Safety database however, recorded as 07Nov2020 on AE CRF. Please confirm correct Onset Date. If safety update is required, please submit a follow-up SAE form
Nov-26-2020 12:33:39 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Nov/7/2020 UNK:UNK	Transcription Error
Nov-26-2020 12:25:44 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Nov/16/2020 UNK:UNK	Transcription Error
Nov-26-2020 12:23:47 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Nov/7/2020 UNK:UNK	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Dec-14-2020 13:50:50 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO End Date Time: Dec/7/2020 UNK:UNK	New Information
Nov-26-2020 12:23:47 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

6. Toxicity Grade:

Date	Location	User	Value	Reason
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Header Text: C4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1210

Subject No: 12101026

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

Nov-26-2020 12:23:47 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 3	Initial Entry
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7. Is the adverse event serious?

If Yes, NOTIFY PFIZER IMMEDIATELY.

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

Date	Location	User	Value	Reason
Dec-01-2020 15:14:05 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Closed	Response satisfies query
Nov-30-2020 13:48:07 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Answered	Symptoms were started on 07Nov20. Subject had local negative COVID19 PCR results on 7/9 Nov20. Subject diagnosed with Covid19 with CT scan on 16Nov20. Subject discharged on 23Nov20. On 25Nov20, central COVID19 test resulted as negative. Event evaluated as SAE
Nov-27-2020 13:20:24 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Opened	SAE RECON:Pnuemonia(Onset date:07Nov2020) is not reported to Safety database but marked serious on AE CRF. Confirm seriousness and report to Pfizer immediately. If this event is not serious, downgrade the event on AE CRF
Nov-27-2020 13:19:46 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	missing in sdb
Nov-27-2020 12:25:18	ACV0PFEINFP6000	(b) (6)	Query 1: Opened	For AE Pnuemonia:

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Header Text: C4591001

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Site No: 1210

Subject No: 12101026

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

(UTC+03:00) Istanbul		(b) (4), (b) (6)		Response to "Is the adverse event serious?" is 'Yes' but "Serious Adverse Event Number" is blank.
Nov-26-2020 12:25:16 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	For AE Pnuemonia: Response to "Is the adverse event serious?" is 'Yes' but "Serious Adverse Event Number" is blank.
Nov-26-2020 12:25:16 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<p>Data Entry:</p> <p>YES</p> <p>Is this serious event associated with congenital anomaly or birth defect?</p> <p>NO</p> <p>Did this serious event result in death?</p> <p>NO</p> <p>Did this serious event require or prolong hospitalization?</p> <p>YES</p> <p>Did this serious event result in persistent or significant disability/incapacity?</p> <p>NO</p> <p>Is this serious event life threatening?</p> <p>NO</p> <p>Other medically important serious event</p> <p>NO</p>	Transcription Error
Nov-26-2020 12:23:47	ACV0PFEINFP6000	(b) (6)	Data Entry:	Initial Entry

090177e196ae2fe1\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: 12101026

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

(UTC+03:00) Istanbul		(b) (4), (b) (6)	NO	
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8. Is this adverse event the result of a study Medication Error?

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

Date	Location	User	Value	Reason
Nov-26-2020 12:23:47 (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-26-2020 12:24:12 (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: Suspected COVID19	Transcription Error
Nov-26-2020 12:23:47 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NOT RELATED	Initial Entry

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Nov-26-2020 12:23:47 (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-26-2020 12:23:47 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

12. Was a Non-Drug Treatment given?

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090177e196ae2fe1\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: 12101026

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

Date	Location	User	Value	Reason
Nov-26-2020 12:23:47 (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
Dec-14-2020 13:51:18 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Dec-14-2020 13:51:18 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: RECOVERED/RESOLVED	New Information
Dec-14-2020 13:50:50 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	For AE Pnuemonia: Response to "What was the outcome of this adverse event?" is 'Recovering/Resolving' but AE End Date/Time is present.
Nov-26-2020 12:23:47 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: RECOVERING/RESOLVING	Initial Entry

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

Date	Location	User	Value	Reason
Nov-26-2020 12:23:47 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

15. Serious Adverse Event Number: For Pfizer Use Only

Date	Location	User	Value	Reason
Dec-01-2020 15:17:27 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 2020470537	Initial Entry

090177e196ae2fe1\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: 12101026

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
Dec-02-2020 11:37:02 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: ADVERSE EVENT	Initial Entry

2. AE ID:

Date	Location	User	Value	Reason
Dec-02-2020 11:37:02 (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
Dec-23-2020 10:05:22 (UTC+03:00) Istanbul	ACV0PFEINFP6000	Salim Bouguermouh (b) (4)	Query 1: Closed	Response satisfies query
Dec-21-2020 14:12:18 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	According to Safety team, the SAE onset date should be the date when the first signs/symptoms started, even if they were non-serious. The symptoms started on 07 Nov 2020 as non serious and the AE should be remain.
Dec-16-2020 18:37:31 (UTC+03:00) Istanbul	ACV0PFEINFP6000	Salim Bouguermouh (b) (4)	Query 1: Reissued:Opened	Medical monitor: This is no correct. ACUTE UPPER RESPIRATORY TRACT INFECTIONS should be documented ONLY on the ILLNESS DETAILS CRF form

090177e196ae2fe1\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: 12101026

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

				irrespective of any SARS-CoV-2 test result and should not be captured on the AE CRF page
Dec-15-2020 11:12:38 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Patient had no covid-19 positive PCR test. So AE need to be recorded.
Dec-15-2020 09:46:13 (UTC+03:00) Istanbul	ACV0PFEINFP6000	Salim Bouguermouh (b) (4)	Query 1: Reissued:Opened	Clin: Per Prot Section 8.3.7., ACUTE UPPER RESPIRATORY TRACT INFECTIONS does not qualify as AE and please should be documented ONLY on the ILLNESS DETAILS CRF form irrespective of any SARS-CoV-2 test result and should not be captured on the AE CRF page
Dec-14-2020 17:15:36 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Acute upper respiratory tract infections	Transcription Error
Dec-14-2020 11:11:19 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Patient had no covid-19 positive PCR test. So AE need to be recorded.
Dec-14-2020 09:51:14 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	Clin: Per protocol section 8.3.7., potential COVID-19 relate PNEUMONIA does not qualify as AE and please should be documented ONLY on the ILLNESS DETAILS CRF form and should not be

090177e196ae2fe1\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: 12101026

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: ---

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				captured on the AE CRF page
Dec-14-2020 00:56:52 (UTC+03:00) Istanbul	ACV0PFEINFP6000	Salim Bouguermouh (b) (4)	Query 1: Candidate	Clin: Per protocol section 8.3.7., potential COVID-19 relate PNEUMONIA does not qualify as AE and please should be documented ONLY on the ILLNESS DETAILS CRF form and should not be captured on the AE CRF page.
Dec-02-2020 11:37:02 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: pneumonia	Initial Entry

4. Start Date Time:

Date	Location	User	Value	Reason
Dec-02-2020 11:37:02 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Nov/7/2020 UNK:UNK	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Dec-02-2020 11:37:02 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO End Date Time: Nov/16/2020 UNK:UNK	Initial Entry

6. Toxicity Grade:

Date	Location	User	Value	Reason
Dec-02-2020 11:37:02 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 1	Initial Entry

7. Is the adverse event serious?

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Header Text: C4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1210

Subject No: 12101026

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

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
Dec-02-2020 11:37:02 (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
Dec-02-2020 11:37:02 (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
Dec-02-2020 11:37:02 (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: suspected covid 19	Initial Entry

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Dec-02-2020 11:37:02 (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
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Header Text: C4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1210

Subject No: 12101026

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

Dec-02-2020 11:37:02 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry
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12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Dec-02-2020 11:37:02 (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
Dec-02-2020 11:37:02 (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
Dec-02-2020 11:37:02 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

090177e196ae2fe1\Final\Final On: 01-Apr-2021 03:54 (GMT)

Header Text: C4591001

Visit: End of Treatment - Unscheduled

Form: DISPOSITION - TREATMENT - eCRF Audit Trail History

Form Version: 15-Sep-2020 21:55

Form Status: Data Complete, Frozen, Verified

Site No: 1210

Site Name: (1210) Medipol University Medical Faculty

Subject No: 12101026

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
Jan-13-2021 10:28:14 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Jan/13/2021	Initial Entry
Jan-13-2021 10:28:00 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Initial Entry
Dec-01-2020 11:52:51 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry
Nov-27-2020 10:06:41 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	New Information
Nov-24-2020 16:47:19 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Nov/16/2020	Initial Entry

2. Phase of Disposition:

Date	Location	User	Value	Reason
Jan-13-2021 10:28:14 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: VACCINATION	Initial Entry
Jan-13-2021 10:28:00 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry:	Initial Entry
Dec-01-2020 11:52:51 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Not Done	Initial Entry
Nov-27-2020 10:06:41 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry:	New Information
Nov-24-2020 16:47:19 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: VACCINATION	Initial Entry

3. Status:

Date	Location	User	Value	Reason
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090177e196ae2fe1\Final\Final On: 01-Apr-2021 03:54 (GMT)

Header Text: C4591001

Visit: End of Treatment - Unscheduled

Form: DISPOSITION - TREATMENT - eCRF Audit Trail History

Form Version: 15-Sep-2020 21:55

Form Status: Data Complete, Frozen, Verified

Site No: 1210

Site Name: (1210) Medipol University Medical Faculty

Subject No: 12101026

Subject Initials: ---

Generated By: (b) (4)

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

Jan-13-2021 10:28:14 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: COMPLETED	Initial Entry
Jan-13-2021 10:28:00 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Initial Entry
Dec-01-2020 11:52:51 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry
Nov-27-2020 10:06:15 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	New Information
Nov-24-2020 16:47:19 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO LONGER MEETS ELIGIBILITY CRITERIA	Initial Entry

4. Specify Status:

Date	Location	User	Value	Reason
Jan-13-2021 10:28:00 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Initial Entry
Dec-01-2020 11:52:51 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry
Nov-27-2020 10:06:30 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	New Information
Nov-24-2020 16:47:19 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: subject is diagnosed with symptomatic COVID-19	Initial Entry

090177e196ae2fe1\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: 12101026

Subject Initials: ---

Generated By: (b) (4)

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

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1. Date of Visit

Date	Location	User	Value	Reason
Jan-19-2021 15:21:37 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Jan/19/2021	Initial Entry

Header Text: C4591001

Visit: Potential ReVax Initial Contact -
Unscheduled

Form Version: 10-Dec-2020 02:25

Site No: 1210

Subject No: 12101026

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
Jan-19-2021 15:36:27 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Jan-19-2021 15:22:00 (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.
Jan-19-2021 15:22:00 (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	Initial Entry

090177e196ae2fe1\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: 12101026

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
Jan-19-2021 15:36:27 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Jan/19/2021	Initial Entry

2. Primary Reason for Unblinding:

Date	Location	User	Value	Reason
Jan-19-2021 15:36:27 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: ASSESS ELIGIBILITY FOR AD DITIONAL VACCINATION	Initial Entry

Header Text: C4591001

Visit: Disposition - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1210

Subject No: 12101026

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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I. Withdrawal of Consent Date :

Date	Location	User	Value	Reason
Jan-19-2021 15:36:38 (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: 12101026

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-19-2021 15:36:52 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

Header Text: C4591001

Visit: V101_VAX3

Form Version: 22-Apr-2020 21:02

Site No: 1210

Subject No: 12101026

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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1. Date of Visit

Date	Location	User	Value	Reason
Jan-20-2021 13:04:59 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Jan/20/2021	Initial Entry

Header Text: C4591001

Visit: V101_VAX3

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

Form Version: 10-Dec-2020 02:31

Form Status: Data Complete, Frozen, Verified

Site No: 1210

Site Name: (1210) Medipol University Medical Faculty

Subject No: 12101026

Subject Initials: ---

Generated By: (b) (4)

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

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I. Consent Was:

Date	Location	User	Value	Reason
Jan-20-2021 13:05:14 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: OBTAINED Date Written Consent Obtained Jan/20/2021	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: 12101026

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
Jan-20-2021 13:06:09 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Jan/20/2021	Initial Entry

2. Phase of Disposition:

Date	Location	User	Value	Reason
Jan-20-2021 13:06:09 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: REPEAT SCREENING 1	Initial Entry

3. Status:

Date	Location	User	Value	Reason
Jan-20-2021 13:06:09 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: COMPLETED	Initial Entry

090177e196ae2fe1\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: 12101026

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-20-2021 13:06:22 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Jan-20-2021 13:06:22 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SERUM	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Jan-20-2021 13:54:11 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Jan-20-2021 13:06:22 (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-20-2021 13:06:22 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Date of Collection: Jan/20/2021	Initial Entry

5.a

Date	Location	User	Value	Reason
Jan-20-2021 13:54:11 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BR0Z0F	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
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090177e196ae2fe1\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: 12101026

Subject Initials: ---

Generated By: (b) (4)

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

Jan-20-2021 13:54:11 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BR0Z0F	Initial Entry
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5.b

Date	Location	User	Value	Reason
Jan-20-2021 13:54:27 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BR0Z0G	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Jan-20-2021 13:54:27 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BR0Z0G	Initial Entry

5.c

Date	Location	User	Value	Reason
Jan-20-2021 13:54:48 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BNLLLP	Initial Entry

5.c Sample ID

Date	Location	User	Value	Reason
Jan-20-2021 13:54:48 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BNLLLP	Initial Entry

5.d

Date	Location	User	Value	Reason
Jan-20-2021 13:54:57 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BNLLLR	Initial Entry

090177e196ae2fe1\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: 12101026

Subject Initials: ---

Generated By: (b) (4)

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

5.d Sample ID

Date	Location	User	Value	Reason
Jan-20-2021 13:54:57 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BNLLLR	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: 12101026

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-20-2021 13:06:35 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Jan-20-2021 13:06:35 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: NASAL_SWAB	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Jan-20-2021 13:55:30 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Jan-20-2021 13:06:35 (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-20-2021 13:06:35 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Date of Collection: Jan/20/2021	Initial Entry

5.a

Date	Location	User	Value	Reason
Jan-20-2021 13:55:30 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BR0Z0D	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
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090177e196ae2fe1\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: 12101026

Subject Initials: ---

Generated By: (b) (4)

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

Jan-20-2021 13:55:30 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BR0Z0D	Initial Entry
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Header Text: C4591001

Visit: V101_VAX3

Form Version: 10-Dec-2020 02:26

Site No: 1210

Subject No: 12101026

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-20-2021 13:57:46 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2. Treatment Name

Date	Location	User	Value	Reason
Jan-20-2021 13:57:46 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: BNT162b2	Initial Entry

3. Formulation:

Date	Location	User	Value	Reason
Jan-20-2021 13:57:46 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: INJECTION	Initial Entry

4. Dose Date Time:

Date	Location	User	Value	Reason
Jan-20-2021 13:57:46 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Jan/20/2021 09:50	Initial Entry

5. Anatomical Location:

Date	Location	User	Value	Reason
Jan-20-2021 13:57:46 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: DELTOID MUSCLE	Initial Entry

6. Body Side:

Date	Location	User	Value	Reason
Jan-20-2021 13:57:46 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: LEFT	Initial Entry

7. Route:

090177e196ae2fe1\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: 12101026

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-20-2021 13:57:46 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> INTRAMUSCULAR	Initial Entry

8. Actual Dose:

Date	Location	User	Value	Reason
Jan-20-2021 13:57:46 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> 30.0	Initial Entry

9. Unit:

Date	Location	User	Value	Reason
Jan-20-2021 13:57:46 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> ug	Initial Entry

10. Timeframe Subject Was Observed

Date	Location	User	Value	Reason
Jan-20-2021 13:57:46 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> 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-20-2021 13:57:46 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> YES	Initial Entry

090177e196ae2fe1\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: 12101026

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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1. Date of Visit

Date	Location	User	Value	Reason
Feb-12-2021 16:23:37 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Feb/12/2021	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:** 12101026**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
Feb-12-2021 16:23:50 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Feb-12-2021 16:23:50 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: NASAL_SWAB	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Feb-12-2021 16:24:17 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Feb-12-2021 16:23:50 (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.
Feb-12-2021 16:23:50 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Date of Collection: Feb/12/2021	Initial Entry

5.a

Date	Location	User	Value	Reason
Feb-12-2021 16:24:17 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BR0Z1B	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
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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: 12101026

Subject Initials: ---

Generated By: (b) (4)

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

Feb-12-2021 16:24:17 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BR0Z1B	Initial Entry
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090177e196ae2fe1\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: 12101026

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
Feb-12-2021 16:25:09 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2. Treatment Name

Date	Location	User	Value	Reason
Feb-12-2021 16:25:09 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: BNT162b2	Initial Entry

3. Formulation:

Date	Location	User	Value	Reason
Feb-12-2021 16:25:09 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: INJECTION	Initial Entry

4. Dose Date Time:

Date	Location	User	Value	Reason
Feb-12-2021 16:25:09 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Feb/12/2021 11:00	Initial Entry

5. Anatomical Location:

Date	Location	User	Value	Reason
Feb-12-2021 16:25:09 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: DELTOID MUSCLE	Initial Entry

6. Body Side:

Date	Location	User	Value	Reason
Feb-12-2021 16:25:09 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: LEFT	Initial Entry

7. Route:

090177e196ae2fe1\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: 12101026

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
Feb-12-2021 16:25:09 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> INTRAMUSCULAR	Initial Entry

8. Actual Dose:

Date	Location	User	Value	Reason
Feb-12-2021 16:25:09 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> 30.0	Initial Entry

9. Unit:

Date	Location	User	Value	Reason
Feb-12-2021 16:25:09 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> ug	Initial Entry

10. Timeframe Subject Was Observed

Date	Location	User	Value	Reason
Feb-12-2021 16:25:09 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> 30 MINUTES	Initial Entry

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

Date	Location	User	Value	Reason
Feb-12-2021 16:25:09 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> YES	Initial Entry

090177e196ae2fe1\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: 12101026

Generated By: (b) (4)

Form: DATE OF VISIT - 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 Visit

Date	Location	User	Value	Reason
Mar-12-2021 13:11:39 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Mar/12/2021	Initial Entry

Header Text: C4591001

Visit: V103_MONTH1

Form Version: 22-Apr-2020 21:04

Site No: 1210

Subject No: 12101026

Generated By: (b) (4)

Form: CONTACT OUTCOME - 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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I. Contact Type:

Date	Location	User	Value	Reason
Mar-12-2021 13:11:53 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: TELEPHONE VISIT	Initial Entry

2. Was contact made?

Date	Location	User	Value	Reason
Mar-12-2021 13:11:53 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Date of Contact: Mar/12/2021	Initial Entry

090177e196ae2fe1\Final\Final On: 01-Apr-2021 03:54 (GMT)

Header Text: C4591001

Visit: FURTHER_VACCINATION_EOT -
Unscheduled

Form: DISPOSITION - TREATMENT - eCRF Audit Trail History

Form Version: 20-Feb-2021 02:26

Form Status: Data Complete, Verified

Site No: 1210

Site Name: (1210) Medipol University Medical Faculty

Subject No: 12101026

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
Mar-12-2021 13:12:07 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Mar/12/2021	Initial Entry

2. Phase of Disposition:

Date	Location	User	Value	Reason
Mar-12-2021 13:12:07 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: OPEN LABEL TREATMENT	Initial Entry

3. Status:

Date	Location	User	Value	Reason
Mar-12-2021 13:12:07 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: COMPLETED	Initial Entry

090177e196ae2fe1\Final\Final On: 01-Apr-2021 03:54 (GMT)

Header Text: C4591001

Visit: Subject Status - Unscheduled

Form: SUBJECT STATUS - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Verified

Site No: 1210

Site Name: (1210) Medipol University Medical Faculty

Subject No: 12101026

Subject Initials: ---

Generated By: (b) (4)

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

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1. Subject Status

Date	Location	User	Value	Reason
Jan-13-2021 10:28:14 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: FOLLOW-UP	Initial Entry
Nov-27-2020 10:06:15 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: ENROLLED/RANDOMIZED	New Information
Nov-24-2020 16:47:19 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: DISCONTINUED	Initial Entry
Oct-30-2020 18:41:34 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: ENROLLED/RANDOMIZED	Initial Entry
Oct-30-2020 18:38:46 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SCREENED	Initial Entry

2. Subject Status Date

Date	Location	User	Value	Reason
Jan-13-2021 10:28:14 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Jan/13/2021	Initial Entry
Nov-27-2020 10:06:41 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Oct/30/2020	New Information
Nov-27-2020 10:06:15 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Oct/30/2020	New Information
Nov-24-2020 16:47:19 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Nov/16/2020	Initial Entry
Oct-30-2020 18:41:34 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Oct/30/2020	Initial Entry
Oct-30-2020 18:38:46 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Oct/30/2020	Initial Entry

090177e196ae2fe1\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, Verified

Site No: 1210

Site Name: (1210) Medipol University Medical Faculty

Subject No: 12101026

Subject Initials: ---

Generated By: (b) (4)

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

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1. Casebook Signature

Date	Location	User	Value	Reason
Nov-03-2020 17:12:35 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Click Here to Enable	Initial Entry