

Header Text: C4591001

Visit: COHORT_SELECTION

Form: COHORT_SELECTION

Form Version: 10-Oct-2020 16:01

Form Status: Data Complete, Frozen, Verified

Site No: 1214

Site Name: (1214) ISTANBUL UNIVERSITY MEDICAL FACULTY
CARDIOLOGY INSTITUTE

Subject No: 12141018

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: 1214

Subject No: 12141018

Generated By: (b) (4)

Form: MAIN INFORMED CONSENT

Form Status: Data Complete, Frozen, Verified

Site Name: (1214) ISTANBUL UNIVERSITY MEDICAL FACULTY
CARDIOLOGY INSTITUTE

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Informed Consent

1.	Consent Was:	OBTAINED Date Written Consent Obtained Nov/2/2020
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090177e196ae3d5d\Final\Final On: 01-Apr-2021 04:32 (GMT)

Header Text: C4591001

Visit: COHORT_SELECTION

Form Version: 15-Sep-2020 21:54

Site No: 1214

Subject No: 12141018

Generated By: (b) (4)

Form: DEMOGRAPHY

Form Status: Data Complete, Frozen, Verified

Site Name: (1214) ISTANBUL UNIVERSITY MEDICAL FACULTY
CARDIOLOGY INSTITUTE

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Demography

1.	Subject ID	[12141018]
2.	Birth Date:	(b) (6)/1990
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: 1214

Subject No: 12141018

Generated By: (b) (4)

Form: DATE OF VISIT

Form Status: Data Complete, Frozen, Verified

Site Name: (1214) ISTANBUL UNIVERSITY MEDICAL FACULTY
CARDIOLOGY INSTITUTE

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Date of Visit

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

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 10-Oct-2020 16:00

Site No: 1214

Subject No: 12141018

Generated By: (b) (4)

Form: INCLUSION/EXCLUSION CRITERIA

Form Status: Data Complete, Frozen, Verified

Site Name: (1214) ISTANBUL UNIVERSITY MEDICAL FACULTY
CARDIOLOGY INSTITUTE

Subject Initials: ---

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

Form Comments

Inclusion Criteria Not Met

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

2.	Description of Exclusion Criterion Met	Not Applicable
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Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 15-Sep-2020 21:52

Site No: 1214

Subject No: 12141018

Generated By: (b) (4)

Form: DISPOSITION - SCREENING

Form Status: Data Complete, Frozen, Verified

Site Name: (1214) ISTANBUL UNIVERSITY MEDICAL FACULTY
CARDIOLOGY INSTITUTE

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Disposition - Screening

1.	Date of Completion/Discontinuation/Death	Nov/2/2020
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: 1214

Subject No: 12141018

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY

Form Status: Data Complete, Frozen, Verified

Site Name: (1214) ISTANBUL UNIVERSITY MEDICAL FACULTY
CARDIOLOGY INSTITUTE

Subject Initials: ---

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

[Form Comments](#)

[eCRF Audit Trail History](#)

Medical History Details

1.a	Line/MH Number:	[1]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[vertebral disk herniation surgery]
	Start Date:	UNK/UNK/2010
	Ongoing:	NO End Date: UNK/UNK/2010

090177e196ae3d5d\Final\Final On: 01-Apr-2021 04:32 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 15-Sep-2020 21:57

Site No: 1214

Subject No: 12141018

Generated By: (b) (4)

Form: HIV STATUS

Form Status: Data Complete, Frozen, Verified

Site Name: (1214) ISTANBUL UNIVERSITY MEDICAL FACULTY
CARDIOLOGY INSTITUTE

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
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Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 10-Oct-2020 16:04

Site No: 1214

Subject No: 12141018

Generated By: (b) (4)

Form: VITAL SIGNS - BASELINE

Form Status: Data Complete, Frozen, Verified

Site Name: (1214) ISTANBUL UNIVERSITY MEDICAL FACULTY
CARDIOLOGY INSTITUTE

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Vital Signs

1.	Date:	Nov/2/2020
2.	Weight:	[88.2]
3.	Unit:	kg
4.	Height:	[186.0]
5.	Unit:	cm
6.	Body Mass Index:	[25.5]

Vital Signs Details

7.a	Record Identifier:	1
	Temperature:	[37.0]
	Unit:	C
	Temperature Location:	FOREHEAD

090177e196ae3d5d\Final\Final On: 01-Apr-2021 04:32 (GMT)

Header Text: C4591001
Visit: V1_DAY1_VAX1_L
Form Version: 22-Apr-2020 21:03
Site No: 1214
Subject No: 12141018
Generated By: (b) (4)

Form: RANDOMIZATION
Form Status: Data Complete, Frozen, Verified
Site Name: (1214) ISTANBUL UNIVERSITY MEDICAL FACULTY
 CARDIOLOGY INSTITUTE
Subject Initials: ---
Generated Time (GMT): 29-Mar-2021 13:11

[eCRF Audit Trail History](#)

Disposition

1.	Randomization Date :	Nov/2/2020
2.	Randomization Number:	[115208]
3.	Randomization Group:	[]

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1214

Subject No: 12141018

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Status: Data Complete, Frozen, Verified

Site Name: (1214) ISTANBUL UNIVERSITY MEDICAL FACULTY
CARDIOLOGY INSTITUTE

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: Nov/2/2020
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	[BPZD2S]
5.b	Sample ID	[BPZD2T]
5.c	Sample ID	[BSHCW8]
5.d	Sample ID	[BSHCW9]

090177e196ae3d5d\Final\Final On: 01-Apr-2021 04:32 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1214

Subject No: 12141018

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB

Form Status: Data Complete, Frozen, Verified

Site Name: (1214) ISTANBUL UNIVERSITY MEDICAL FACULTY
CARDIOLOGY INSTITUTE

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Electronic Sample Tracking

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB
3.	Sample Collected?	YES Date of Collection: Nov/2/2020
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	[BPZD2J]
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090177e196ae3d5d\Final\Final On: 01-Apr-2021 04:32 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:04

Site No: 1214

Subject No: 12141018

Generated By: (b) (4)

Form: VACCINATION

Form Status: Data Complete, Frozen, Verified

Site Name: (1214) ISTANBUL UNIVERSITY MEDICAL FACULTY
CARDIOLOGY INSTITUTE

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Vaccination

1.	Was there a temporary delay of vaccination?	NO
2.	Treatment Name	[BLINDED THERAPY]
3.	Formulation:	INJECTION
4.	Dose Date Time:	Nov/2/2020 12:36
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

090177e196ae3d5d\Final\Final On: 01-Apr-2021 04:32 (GMT)

Header Text: C4591001	Form: REACTOGENICITY DIARY
Visit: V1_DAY1_VAX1_L	Form Status: Data Complete, Frozen, Verified
Form Version: 06-Jul-2020 21:53	Site Name: (1214) ISTANBUL UNIVERSITY MEDICAL FACULTY CARDIOLOGY INSTITUTE
Site No: 1214	Subject Initials: ---
Subject No: 12141018	Generated Time (GMT): 29-Mar-2021 13:11
Generated By: (b) (4)	

[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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090177e196ae3d5d\Final\Final On: 01-Apr-2021 04:32 (GMT)

Header Text: C4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:02

Site No: 1214

Subject No: 12141018

Generated By: (b) (4)

Form: DATE OF VISIT

Form Status: Data Complete, Frozen, Verified

Site Name: (1214) ISTANBUL UNIVERSITY MEDICAL FACULTY
CARDIOLOGY INSTITUTE

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Date of Visit

1.	Date of Visit	Nov/23/2020
2.	Erroneous Visit	

Header Text: C4591001

Visit: V2_VAX2_L

Form Version: 10-Oct-2020 16:03

Site No: 1214

Subject No: 12141018

Generated By: (b) (4)

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES

Form Status: Data Complete, Frozen, Verified

Site Name: (1214) ISTANBUL UNIVERSITY MEDICAL FACULTY CARDIOLOGY INSTITUTE

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

090177e196ae3d5d\Final\Final On: 01-Apr-2021 04:32 (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: 1214

Site Name: (1214) ISTANBUL UNIVERSITY MEDICAL FACULTY CARDIOLOGY INSTITUTE

Subject No: 12141018

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

090177e196ae3d5d\Final\Final On: 01-Apr-2021 04:32 (GMT)

Header Text: C4591001

Visit: V2_VAX2_L

Form Version: 10-Oct-2020 16:01

Site No: 1214

Subject No: 12141018

Generated By: (b) (4)

Form: VITAL SIGNS - TEMP

Form Status: Data Complete, Frozen, Verified

Site Name: (1214) ISTANBUL UNIVERSITY MEDICAL FACULTY
CARDIOLOGY INSTITUTE

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Vital Signs

1.	Date:	Nov/23/2020
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Vital Signs Details

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

Header Text: C4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:03

Site No: 1214

Subject No: 12141018

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB

Form Status: Data Complete, Frozen, Verified

Site Name: (1214) ISTANBUL UNIVERSITY MEDICAL FACULTY
CARDIOLOGY INSTITUTE

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Electronic Sample Tracking

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB
3.	Sample Collected?	YES Date of Collection: Nov/23/2020
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	[BPZD72]
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090177e196ae3d5d\Final\Final On: 01-Apr-2021 04:32 (GMT)

Header Text: C4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:04

Site No: 1214

Subject No: 12141018

Generated By: (b) (4)

Form: VACCINATION

Form Status: Data Complete, Frozen, Verified

Site Name: (1214) ISTANBUL UNIVERSITY MEDICAL FACULTY
CARDIOLOGY INSTITUTE

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Vaccination

1.	Was there a temporary delay of vaccination?	NO
2.	Treatment Name	[BLINDED THERAPY]
3.	Formulation:	INJECTION
4.	Dose Date Time:	Nov/23/2020 09:43
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

090177e196ae3d5d\Final\Final On: 01-Apr-2021 04:32 (GMT)

Header Text: C4591001

Visit: V3_MONTH1_POSTVAX2_L

Form Version: 22-Apr-2020 21:02

Site No: 1214

Subject No: 12141018

Generated By: (b) (4)

Form: DATE OF VISIT

Form Status: Data Complete, Frozen, Verified

Site Name: (1214) ISTANBUL UNIVERSITY MEDICAL FACULTY
CARDIOLOGY INSTITUTE

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Date of Visit

1.	Date of Visit	Dec/21/2020
2.	Erroneous Visit	

Header Text: C4591001

Visit: V3_MONTH1_POSTVAX2_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES

Form Version: 10-Oct-2020 16:03

Form Status: Data Complete, Frozen, Verified

Site No: 1214

Site Name: (1214) ISTANBUL UNIVERSITY MEDICAL FACULTY CARDIOLOGY INSTITUTE

Subject No: 12141018

Subject Initials: ---

Generated By: (b) (4)

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

[eCRF Audit Trail History](#)

Vaccination Symptoms Diary - Symptom Resolved Dates

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

090177e196ae3d5d\Final\Final On: 01-Apr-2021 04:32 (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: 1214

Site Name: (1214) ISTANBUL UNIVERSITY MEDICAL FACULTY CARDIOLOGY INSTITUTE

Subject No: 12141018

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

090177e196ae3d5d\Final\Final On: 01-Apr-2021 04:32 (GMT)

Header Text: C4591001

Visit: V3_MONTH1_POSTVAX2_L

Form Version: 22-Apr-2020 21:03

Site No: 1214

Subject No: 12141018

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Status: Data Complete, Frozen, Verified

Site Name: (1214) ISTANBUL UNIVERSITY MEDICAL FACULTY
CARDIOLOGY INSTITUTE

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Electronic Sample Tracking

1.	Data Origin	SITE
2.	Sample Type	SERUM
3.	Sample Collected?	YES Date of Collection: Dec/21/2020
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	[BPZD9H]
5.b	Sample ID	[BPZD9J]
5.c	Sample ID	[BSHD4S]
5.d	Sample ID	[BSHD4T]

090177e196ae3d5d\Final\Final On: 01-Apr-2021 04:32 (GMT)

Header Text: C4591001

Visit: V4_MONTH6_L

Form Version: 22-Apr-2020 21:02

Site No: 1214

Subject No: 12141018

Generated By: (b) (4)

Form: DATE OF VISIT

Form Status: Not Started

Site Name: (1214) ISTANBUL UNIVERSITY MEDICAL FACULTY
CARDIOLOGY INSTITUTE

Subject Initials: ---

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

Date of Visit

1.	Date of Visit	//
2.	Erroneous Visit	

Header Text: C4591001

Visit: V4_MONTH6_L

Form Version: 22-Apr-2020 21:03

Site No: 1214

Subject No: 12141018

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Status: Not Started

Site Name: (1214) ISTANBUL UNIVERSITY MEDICAL FACULTY
CARDIOLOGY INSTITUTE

Subject Initials: ---

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

Electronic Sample Tracking

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

Aliquot

Please enter barcode for each aliquot.

5.	Sample ID	[]
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Header Text: C4591001

Visit: V5_MONTH12_L

Form Version: 22-Apr-2020 21:02

Site No: 1214

Subject No: 12141018

Generated By: (b) (4)

Form: DATE OF VISIT

Form Status: Not Started

Site Name: (1214) ISTANBUL UNIVERSITY MEDICAL FACULTY
CARDIOLOGY INSTITUTE

Subject Initials: ---

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

Date of Visit

1.	Date of Visit	//
2.	Erroneous Visit	

Header Text: C4591001

Visit: V5_MONTH12_L

Form Version: 22-Apr-2020 21:03

Site No: 1214

Subject No: 12141018

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Status: Not Started

Site Name: (1214) ISTANBUL UNIVERSITY MEDICAL FACULTY
CARDIOLOGY INSTITUTE

Subject Initials: ---

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

Electronic Sample Tracking

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

Aliquot

Please enter barcode for each aliquot.

5.	Sample ID	[]
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Header Text: C4591001

Visit: V6_MONTH24_L

Form Version: 22-Apr-2020 21:02

Site No: 1214

Subject No: 12141018

Generated By: (b) (4)

Form: DATE OF VISIT

Form Status: Not Started

Site Name: (1214) ISTANBUL UNIVERSITY MEDICAL FACULTY
CARDIOLOGY INSTITUTE

Subject Initials: ---

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

Date of Visit

1.	Date of Visit	//
2.	Erroneous Visit	

Header Text: C4591001

Visit: V6_MONTH24_L

Form Version: 22-Apr-2020 21:03

Site No: 1214

Subject No: 12141018

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Status: Not Started

Site Name: (1214) ISTANBUL UNIVERSITY MEDICAL FACULTY
CARDIOLOGY INSTITUTE

Subject Initials: ---

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

Electronic Sample Tracking

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

Aliquot

Please enter barcode for each aliquot.

5.	Sample ID	[]
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Header Text: C4591001

Visit: POT_COVID_ILL - New Unscheduled Visit

Form: DATE OF VISIT - ILLNESS ONSET

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1214

Site Name: (1214) ISTANBUL UNIVERSITY MEDICAL FACULTY
CARDIOLOGY INSTITUTE

Subject No: 12141018

Subject Initials: ---

Generated By: (b) (4)

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

Date of Visit

1.	Date of Visit	//
2.	Erroneous Visit	

COVID-19 Illness Visit

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

Header Text: C4591001

Visit: POT_COVID_ILL - New Unscheduled Visit

Form: SIGNS AND SYMPTOMS OF POTENTIAL COVID-19

Form Version: 20-Feb-2021 02:17

Form Status: Not Started

Site No: 1214

Site Name: (1214) ISTANBUL UNIVERSITY MEDICAL FACULTY
CARDIOLOGY INSTITUTE

Subject No: 12141018

Subject Initials: ---

Generated By: (b) (4)

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

Signs and Symptoms

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

Symptoms

4.	Symptoms:	
	Was symptom present?	

Symptoms - Other

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

Header Text: C4591001

Visit: POT_COVID_ILL - New Unscheduled Visit

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB SELF

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1214

Site Name: (1214) ISTANBUL UNIVERSITY MEDICAL FACULTY
CARDIOLOGY INSTITUTE

Subject No: 12141018

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

090177e196ae3d5d\Final\Final On: 01-Apr-2021 04:32 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL - New Unscheduled Visit

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1214

Site Name: (1214) ISTANBUL UNIVERSITY MEDICAL FACULTY CARDIOLOGY INSTITUTE

Subject No: 12141018

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: POT_COVID_ILL - New Unscheduled Visit

Form: HEALTH CARE UTILIZATION

Form Version: 20-Feb-2021 02:19

Form Status: Not Started

Site No: 1214

Site Name: (1214) ISTANBUL UNIVERSITY MEDICAL FACULTY
CARDIOLOGY INSTITUTE

Subject No: 12141018

Subject Initials: ---

Generated By: (b) (4)

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

Health Care Utilization

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

Health Care Utilization Other

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

Health Care Utilization

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

090177e196ae3d5d\Final\Final On: 01-Apr-2021 04:32 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL - New Unscheduled Visit

Form: ILLNESS DETAILS

Form Version: 06-Jul-2020 21:52

Form Status: Not Started

Site No: 1214

Site Name: (1214) ISTANBUL UNIVERSITY MEDICAL FACULTY
CARDIOLOGY INSTITUTE

Subject No: 12141018

Subject Initials: ---

Generated By: (b) (4)

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

Illness Details

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

Header Text: C4591001

Visit: POT_COVID_CONVA - New
Unscheduled Visit

Form Version: 22-Apr-2020 21:04

Site No: 1214

Subject No: 12141018

Generated By: (b) (4)

Form: DATE OF VISIT - ILLNESS CONVALESCENT

Form Status: Not Started

Site Name: (1214) ISTANBUL UNIVERSITY MEDICAL FACULTY
CARDIOLOGY INSTITUTE

Subject Initials: ---

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

Date of Visit

1.	Date of Visit	//
2.	Erroneous Visit	

COVID-19 Illness Visit

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

Header Text: C4591001

Visit: POT_COVID_CONVA - New
Unscheduled Visit

Form Version: 22-Apr-2020 21:03

Site No: 1214

Subject No: 12141018

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Status: Not Started

Site Name: (1214) ISTANBUL UNIVERSITY MEDICAL FACULTY
CARDIOLOGY INSTITUTE

Subject Initials: ---

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: 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: 1214

Site Name: (1214) ISTANBUL UNIVERSITY MEDICAL FACULTY
CARDIOLOGY INSTITUTE

Subject No: 12141018

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: 1214

Site Name: (1214) ISTANBUL UNIVERSITY MEDICAL FACULTY
CARDIOLOGY INSTITUTE

Subject No: 12141018

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: 1214

Site Name: (1214) ISTANBUL UNIVERSITY MEDICAL FACULTY
CARDIOLOGY INSTITUTE

Subject No: 12141018

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	recurrence vertebral disc herniation	Nov/18/2020 UNK:UNK	NO End Date Time: Dec/2/2020 UNK:UNK	Repeating Pages
2. DELETED	ADVERSE EVENT	2	spinal fusion surgery	Dec/2/2020 UNK:UNK	NO End Date Time: Dec/2/2020 UNK:UNK	Repeating Pages
3.	ADVERSE EVENT	3	pulmonary embolism	Dec/5/2020 UNK:UNK	NO End Date Time: Dec/5/2020 UNK:UNK	Repeating Pages
4. DELETED	ADVERSE EVENT	4	Worsening of vertebral disc herniation	Dec/2/2020 UNK:UNK	NO End Date Time: Dec/2/2020 UNK:UNK	Repeating Pages

090177e196ae3d5d\Final\Final On: 01-Apr-2021 04:32 (GMT)

Header Text: C4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1214

Subject No: 12141018

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Frozen, Not Complete

Site Name: (1214) ISTANBUL UNIVERSITY MEDICAL FACULTY
CARDIOLOGY INSTITUTE

Subject Initials: ---

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

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

Adverse Event Report

1.	Category:	ADVERSE EVENT
2.	AE ID:	[1]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[recurrence vertebral disc herniation]
4.	Start Date Time:	Nov/18/2020 UNK:UNK
5.	Is the adverse event still ongoing?	NO End Date Time: Dec/2/2020 UNK:UNK
6.	Toxicity Grade:	2
7.	Is the adverse event serious? If Yes, NOTIFY PFIZER IMMEDIATELY. Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).	YES Is this serious event associated with congenital anomaly or birth defect? NO Did this serious event result in death? NO Did this serious event require or prolong hospitalization? YES Did this serious event result in persistent or significant disability/incapacity? NO Is this serious event life threatening? NO Other medically important serious event NO
8.	Is this adverse event the result of a study Medication Error? If Yes, record the type of medication error on the Medication Error Log.	NO

090177e196ae3d5d\Final\Final On: 01-Apr-2021 04:32 (GMT)

Header Text: C4591001
Visit: Logs - Unscheduled
Form Version: 22-Apr-2020 21:02
Site No: 1214
Subject No: 12141018
Generated By: (b) (4)

Form: ADVERSE EVENT REPORT
Form Status: Data Complete, Frozen, Not Complete
Site Name: (1214) ISTANBUL UNIVERSITY MEDICAL FACULTY
 CARDIOLOGY INSTITUTE
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: [disk herniation]
10.	Latest Action Taken with Study Treatment:	NOT APPLICABLE
11.	Was a Concomitant Medication given?	YES
12.	Was a Non-Drug Treatment given?	YES
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	[2020505098]

090177e196ae3d5d\Final\Final On: 01-Apr-2021 04:32 (GMT)

Header Text: C4591001		
Visit: Logs - Unscheduled		Form: ADVERSE EVENT REPORT
Form Version: 22-Apr-2020 21:02		Form Status: Data Complete, Deleted
Site No: 1214		Site Name: (1214) ISTANBUL UNIVERSITY MEDICAL FACULTY CARDIOLOGY INSTITUTE
Subject No: 12141018		Subject Initials: ---
Generated By: (b) (4) [REDACTED]		Generated Time (GMT): 29-Mar-2021 13:11
*** THIS REPEATING FORM HAS BEEN DELETED ***		
Back to Form eCRF Audit Trail History Form Audit Trail		
Adverse Event Report		
1.	Category:	ADVERSE EVENT
2.	AE ID:	[2]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[spinal fusion surgery]
4.	Start Date Time:	Dec/2/2020 UNK:UNK
5.	Is the adverse event still ongoing?	NO End Date Time: Dec/2/2020 UNK:UNK
6.	Toxicity Grade:	2
7.	Is the adverse event serious? If Yes, NOTIFY PFIZER IMMEDIATELY. Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).	YES Is this serious event associated with congenital anomaly or birth defect? NO Did this serious event result in death? NO Did this serious event require or prolong hospitalization? YES Did this serious event result in persistent or significant disability/incapacity? NO Is this serious event life threatening? NO Other medically important serious event NO
8.	Is this adverse event the result of a study Medication Error? If Yes, record the type of medication error on the Medication Error Log.	NO

Header Text: C4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1214

Subject No: 12141018

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Deleted

Site Name: (1214) ISTANBUL UNIVERSITY MEDICAL FACULTY
CARDIOLOGY INSTITUTE

Subject Initials: ---

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

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

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: [vertebral disc herniation]
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	[2020505098]

090177e196ae3d5d\Final\Final On: 01-Apr-2021 04:32 (GMT)

Header Text: C4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1214

Subject No: 12141018

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Frozen

Site Name: (1214) ISTANBUL UNIVERSITY MEDICAL FACULTY
CARDIOLOGY INSTITUTE

Subject Initials: ---

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

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

Adverse Event Report

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

090177e196ae3d5d\Final\Final On: 01-Apr-2021 04:32 (GMT)

Header Text: C4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1214

Subject No: 12141018

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Frozen

Site Name: (1214) ISTANBUL UNIVERSITY MEDICAL FACULTY
CARDIOLOGY INSTITUTE

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: [immobility and surgery]
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	[2020505098]

090177e196ae3d5d\Final\Final On: 01-Apr-2021 04:32 (GMT)

Header Text: C4591001		Form: ADVERSE EVENT REPORT
Visit: Logs - Unscheduled		Form Status: Data Complete, Deleted
Form Version: 22-Apr-2020 21:02		Site Name: (1214) ISTANBUL UNIVERSITY MEDICAL FACULTY CARDIOLOGY INSTITUTE
Site No: 1214		Subject Initials: ---
Subject No: 12141018		Generated Time (GMT): 29-Mar-2021 13:11
Generated By: (b) (4) [REDACTED]		
*** THIS REPEATING FORM HAS BEEN DELETED ***		
Back to Form eCRF Audit Trail History Form Audit Trail		
Adverse Event Report		
1.	Category:	ADVERSE EVENT
2.	AE ID:	[4]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[Worsening of vertebral disc herniation]
4.	Start Date Time:	Dec/2/2020 UNK:UNK
5.	Is the adverse event still ongoing?	NO End Date Time: Dec/2/2020 UNK:UNK
6.	Toxicity Grade:	2
7.	Is the adverse event serious? If Yes, NOTIFY PFIZER IMMEDIATELY. Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).	<p>YES</p> <p>Is this serious event associated with congenital anomaly or birth defect? NO</p> <p>Did this serious event result in death? NO</p> <p>Did this serious event require or prolong hospitalization? YES</p> <p>Did this serious event result in persistent or significant disability/incapacity? NO</p> <p>Is this serious event life threatening? NO</p> <p>Other medically important serious event NO</p>
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

Header Text: C4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1214

Subject No: 12141018

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Deleted

Site Name: (1214) ISTANBUL UNIVERSITY MEDICAL FACULTY
CARDIOLOGY INSTITUTE

Subject Initials: ---

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

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

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: [vertebral disc herniation]
10.	Latest Action Taken with Study Treatment:	NOT APPLICABLE
11.	Was a Concomitant Medication given?	YES
12.	Was a Non-Drug Treatment given?	YES
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	[2020505098]

090177e196ae3d5d\Final\Final On: 01-Apr-2021 04:32 (GMT)

Header Text: C4591001

Visit: Logs

Form: MEDICATION ERROR

Form Version: 17-Jul-2020 21:54

Site No: 1214

Site Name: (1214) ISTANBUL UNIVERSITY MEDICAL FACULTY
CARDIOLOGY INSTITUTE

Subject No: 12141018

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 Error's Action	Form Instance
1.	Not Applicable	Not Applicable	Not Applicable	Not Applicable	Not Applicable	Repeating Pages

Header Text: C4591001

Visit: Logs - Unscheduled

Form Version: 17-Jul-2020 21:54

Site No: 1214

Subject No: 12141018

Generated By: (b) (4)

Form: MEDICATION ERROR

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1214) ISTANBUL UNIVERSITY MEDICAL FACULTY
CARDIOLOGY INSTITUTE

Subject Initials: ---

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

[Back to Form](#)

[Form Comments](#)

[eCRF Audit Trail History](#)

Medication Error

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

090177e196ae3d5d\Final\Final On: 01-Apr-2021 04:32 (GMT)

Header Text: C4591001

Visit: Logs

Form: CONCOMITANT MEDICATIONS - NON STUDY
VACCINATIONS

Form Version: 22-Apr-2020 21:03

Site No: 1214

Site Name: (1214) ISTANBUL UNIVERSITY MEDICAL FACULTY
CARDIOLOGY INSTITUTE

Subject No: 12141018

Subject Initials: ---

Generated By: (b) (4)

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

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

Header Text: C4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1214

Subject No: 12141018

Generated By: (b) (4)

Form: CONCOMITANT MEDICATIONS - NON STUDY
VACCINATIONS

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1214) ISTANBUL UNIVERSITY MEDICAL FACULTY
CARDIOLOGY INSTITUTE

Subject Initials: ---

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

[Back to Form](#)

[Form Comments](#)

[eCRF Audit Trail History](#)

Concomitant Medications

1.	What is the medication identifier?	Not Applicable _____ []	Comments
2.	Category:	Not Applicable _____	Comments
3.	Concomitant Medications Pre-specified:	Not Applicable _____	Comments
4.	Medication: Provide the complete generic drug name (including salt form, where applicable). Where generic name is unknown, enter the full trade or proprietary name. Include clarifying information in the Medication text (e.g., Ingredient(s), route, use, formulation).	Not Applicable _____ []	Comments
5.	Date:	Not Applicable _____ //	Comments

090177e196ae3d5d\Final\Final On: 01-Apr-2021 04:32 (GMT)

Header Text: C4591001

Visit: Logs

Form: CONCOMITANT MEDICATIONS - PROHIBITED

Form Version: 22-Apr-2020 21:03

Site No: 1214

Site Name: (1214) ISTANBUL UNIVERSITY MEDICAL FACULTY
CARDIOLOGY INSTITUTE

Subject No: 12141018

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. DELETED						Repeating Pages

090177e196ae3d5d\Final\Final On: 01-Apr-2021 04:32 (GMT)

Header Text: C4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1214

Subject No: 12141018

Generated By: (b) (4)

Form: CONCOMITANT MEDICATIONS - PROHIBITED

Form Status: Incomplete, Data Complete, Deleted, Verified

Site Name: (1214) ISTANBUL UNIVERSITY MEDICAL FACULTY
CARDIOLOGY INSTITUTE

Subject Initials: ---

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

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

[Back to Form](#)

[Form Comments](#)

[eCRF Audit Trail History](#)

[Form Audit Trail](#)

Concomitant Medications

1.	What is the medication identifier?	[]	Comments
2.	Category:		Comments
3.	Concomitant Medications Pre-specified:		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).	[]	Comments
5.	Dose:	[]	Comments
6.	Dose Unit:		Comments
7.	Dose Frequency:		Comments
8.	Route:		Comments
9.	Start Date:	//	Comments
10.	Ongoing?		Comments

090177e196ae3d5d\Final\Final On: 01-Apr-2021 04:32 (GMT)

Header Text: C4591001

Visit: Logs

Form: RADIATION TREATMENT

Form Version: 22-Apr-2020 21:02

Site No: 1214

Site Name: (1214) ISTANBUL UNIVERSITY MEDICAL FACULTY
CARDIOLOGY INSTITUTE

Subject No: 12141018

Subject Initials: ---

Generated By: (b) (4)

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

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

Header Text: C4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1214

Subject No: 12141018

Generated By: (b) (4)

Form: RADIATION TREATMENT

Form Status: Data Complete, Verified

Site Name: (1214) ISTANBUL UNIVERSITY MEDICAL FACULTY
CARDIOLOGY INSTITUTE

Subject Initials: ---

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

[Back to Form](#)

[Form Comments](#)

[eCRF Audit Trail History](#)

Radiation Treatment

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

090177e196ae3d5d\Final\Final On: 01-Apr-2021 04:32 (GMT)

Header Text: C4591001

Visit: Logs

Form: TRANSFUSIONS

Form Version: 22-Apr-2020 21:03

Site No: 1214

Site Name: (1214) ISTANBUL UNIVERSITY MEDICAL FACULTY
CARDIOLOGY INSTITUTE

Subject No: 12141018

Subject Initials: ---

Generated By: (b) (4)

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

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

Header Text: C4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1214

Subject No: 12141018

Generated By: (b) (4)

Form: TRANSFUSIONS

Form Status: Data Complete, Verified

Site Name: (1214) ISTANBUL UNIVERSITY MEDICAL FACULTY
CARDIOLOGY INSTITUTE

Subject Initials: ---

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

[Back to Form](#)

[Form Comments](#)

[eCRF Audit Trail History](#)

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

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: 1214

Site Name: (1214) ISTANBUL UNIVERSITY MEDICAL FACULTY
CARDIOLOGY INSTITUTE

Subject No: 12141018

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: 1214

Site Name: (1214) ISTANBUL UNIVERSITY MEDICAL FACULTY
CARDIOLOGY INSTITUTE

Subject No: 12141018

Subject Initials: ---

Generated By: (b) (4)

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

Unplanned Assessments

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

090177e196ae3d5d\Final\Final On: 01-Apr-2021 04:32 (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: 1214

Site Name: (1214) ISTANBUL UNIVERSITY MEDICAL FACULTY
CARDIOLOGY INSTITUTE

Subject No: 12141018

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: 1214

Site Name: (1214) ISTANBUL UNIVERSITY MEDICAL FACULTY
CARDIOLOGY INSTITUTE

Subject No: 12141018

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: 1214

Site Name: (1214) ISTANBUL UNIVERSITY MEDICAL FACULTY
CARDIOLOGY INSTITUTE

Subject No: 12141018

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?	

090177e196ae3d5d\Final\Final On: 01-Apr-2021 04:32 (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: 1214

Site Name: (1214) ISTANBUL UNIVERSITY MEDICAL FACULTY
CARDIOLOGY INSTITUTE

Subject No: 12141018

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: 1214

Site Name: (1214) ISTANBUL UNIVERSITY MEDICAL FACULTY
CARDIOLOGY INSTITUTE

Subject No: 12141018

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: V201_SURVEIL_CONSENT -
Unscheduled

Form: DATE OF VISIT

Form Version: 22-Apr-2020 21:02

Form Status: Not Started

Site No: 1214

Site Name: (1214) ISTANBUL UNIVERSITY MEDICAL FACULTY
CARDIOLOGY INSTITUTE

Subject No: 12141018

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: V201_SURVEIL_CONSENT -
Unscheduled

Form: INFORMED CONSENT - ASYMPTOMATIC SURVEILLANCE

Form Version: 14-Jan-2021 02:29

Form Status: Not Started

Site No: 1214

Site Name: (1214) ISTANBUL UNIVERSITY MEDICAL FACULTY
CARDIOLOGY INSTITUTE

Subject No: 12141018

Subject Initials: ---

Generated By: (b) (4)

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

Informed Consent - Asymptomatic Surveillance

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

Header Text: C4591001

Visit: V201_SURVEIL_CONSENT -
Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1214

Subject No: 12141018

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Status: Not Started

Site Name: (1214) ISTANBUL UNIVERSITY MEDICAL FACULTY
CARDIOLOGY INSTITUTE

Subject Initials: ---

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: V201_SURVEIL_CONSENT -
Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1214

Subject No: 12141018

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB

Form Status: Not Started

Site Name: (1214) ISTANBUL UNIVERSITY MEDICAL FACULTY
CARDIOLOGY INSTITUTE

Subject Initials: ---

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: End of Treatment - Unscheduled

Form Version: 10-Dec-2020 02:29

Site No: 1214

Subject No: 12141018

Generated By: (b) (4)

Form: DISPOSITION - TREATMENT

Form Status: Data Complete, Frozen, Verified

Site Name: (1214) ISTANBUL UNIVERSITY MEDICAL FACULTY
CARDIOLOGY INSTITUTE

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Disposition - Treatment

1.	Date of Completion/Discontinuation/Death :	Dec/21/2020
2.	Phase of Disposition:	VACCINATION
3.	Status:	COMPLETED
4.	Specify Status:	[]

Header Text: C4591001

Visit: Potential ReVax Initial Contact -
Unscheduled

Form: DATE OF VISIT

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen, Verified

Site No: 1214

Site Name: (1214) ISTANBUL UNIVERSITY MEDICAL FACULTY
CARDIOLOGY INSTITUTE

Subject No: 12141018

Subject Initials: ---

Generated By: (b) (4)

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

[eCRF Audit Trail History](#)

Date of Visit

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

Header Text: C4591001

Visit: Potential ReVax Initial Contact -
Unscheduled

Form Version: 10-Dec-2020 02:25

Site No: 1214

Subject No: 12141018

Generated By: (b) (4)

Form: FURTHER VACCINATION CONFIRMATION

Form Status: Data Complete, Frozen, Verified

Site Name: (1214) ISTANBUL UNIVERSITY MEDICAL FACULTY
CARDIOLOGY INSTITUTE

Subject Initials: ---

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 and NOT 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: 1214

Subject No: 12141018

Generated By: (b) (4)

Form: DISPOSITION - FOLLOW-UP

Form Status: Not Started

Site Name: (1214) ISTANBUL UNIVERSITY MEDICAL FACULTY
CARDIOLOGY INSTITUTE

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: 1214

Subject No: 12141018

Generated By: (b) (4)

Form: TREATMENT UNBLINDED

Form Status: Data Complete, Frozen, Verified

Site Name: (1214) ISTANBUL UNIVERSITY MEDICAL FACULTY
CARDIOLOGY INSTITUTE

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Treatment Unblinded

1.	Date Treatment Unblinded :	Dec/30/2020
2.	Primary Reason for Unblinding:	ASSESS ELIGIBILITY FOR ADDITIONAL VACCINATION

Header Text: C4591001

Visit: Disposition - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1214

Subject No: 12141018

Generated By: (b) (4)

Form: WITHDRAWAL OF CONSENT

Form Status: Data Complete, Verified

Site Name: (1214) ISTANBUL UNIVERSITY MEDICAL FACULTY
CARDIOLOGY INSTITUTE

Subject Initials: ---

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

[Form Comments](#)

[eCRF Audit Trail History](#)

Withdrawal Of Consent

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

Header Text: C4591001

Visit: Disposition - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1214

Subject No: 12141018

Generated By: (b) (4)

Form: DEATH DETAILS CODED

Form Status: Data Complete, Verified

Site Name: (1214) ISTANBUL UNIVERSITY MEDICAL FACULTY
CARDIOLOGY INSTITUTE

Subject Initials: ---

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

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

Death Details

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

Cause of Death

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

090177e196ae3d5d\Final\Final On: 01-Apr-2021 04:32 (GMT)

Header Text: C4591001

Visit: Subject Status - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1214

Subject No: 12141018

Generated By: (b) (4)

Form: SUBJECT STATUS

Form Status: Data Complete, Verified

Site Name: (1214) ISTANBUL UNIVERSITY MEDICAL FACULTY
CARDIOLOGY INSTITUTE

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Subject Status

1.	Subject Status	FOLLOW-UP
2.	Subject Status Date	Dec/21/2020

Header Text: C4591001

Visit: Investigator Signature - Unscheduled

Form Version: 22-Apr-2020 21:04

Site No: 1214

Subject No: 12141018

Generated By: (b) (4)

Form: CASEBOOK SIGNATURE FORM

Form Status: Data Complete, Signed, Verified

Site Name: (1214) ISTANBUL UNIVERSITY MEDICAL FACULTY
CARDIOLOGY INSTITUTE

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Casebook Signature Form

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

Header Text: C4591001

Visit: Investigator Signature - Unscheduled

Form: CASEBOOK SIGNATURE FORM

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Signed, Verified

Site No: 1214

Site Name: (1214) ISTANBUL UNIVERSITY MEDICAL FACULTY
CARDIOLOGY INSTITUTE

Subject No: 12141018

Subject Initials: ---

Generated By: (b) (4)

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

[Audit Trail](#)

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

- CRF_Sign

Name	Signature Meaning	Date	Type	Action
Serap Yavuz	Approved	Feb-02-2021 17:00:13 (UTC+03:00) Istanbul	BOOK	Signed

Affidavit:

By my dated signature below, I, SerapYavuz, 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.

090177e196ae3d5d\Final\Final On: 01-Apr-2021 04:32 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 10-Oct-2020 16:00

Site No: 1214

Subject No: 12141018

Generated By: (b) (4)

Form: INCLUSION/EXCLUSION CRITERIA - Comments

Form Status: Data Complete, Frozen, Verified

Site Name: (1214) ISTANBUL UNIVERSITY MEDICAL FACULTY
CARDIOLOGY INSTITUTE

Subject Initials: ---

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

[Back to Form](#)

Item	Date	User	Comment
Form	Nov-02-2020 19:58:23 (UTC+03:00) Istanbul	(b) (4), (b) (6)	Not Applicable

090177e196ae3d5d\Final\Final On: 01-Apr-2021 04:32 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1214

Subject No: 12141018

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - Comments

Form Status: Data Complete, Frozen, Verified

Site Name: (1214) ISTANBUL UNIVERSITY MEDICAL FACULTY
CARDIOLOGY INSTITUTE

Subject Initials: ---

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

[Back to Form](#)

Item	Date	User	Comment
Form	Nov-23-2020 11:54:24 (UTC+03:00) Istanbul	(b) (4), (b) (6)	
Form	Nov-02-2020 20:00:29 (UTC+03:00) Istanbul	(b) (4), (b) (6)	Not Applicable

Header Text: C4591001

Visit: Logs - Unscheduled

Form Version: 17-Jul-2020 21:54

Site No: 1214

Subject No: 12141018

Generated By: (b) (4)

Form: MEDICATION ERROR - Comments

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1214) ISTANBUL UNIVERSITY MEDICAL FACULTY
CARDIOLOGY INSTITUTE

Subject Initials: ---

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

[Back to Form](#)

Item	Date	User	Comment
Form	Nov-23-2020 11:22:48 (UTC+03:00) Istanbul	(b) (4), (b) (6)	Not Applicable

Header Text: C4591001

Visit: Logs - Unscheduled

Form Version: 17-Jul-2020 21:54

Site No: 1214

Subject No: 12141018

Generated By: (b) (4)

Form: MEDICATION ERROR - Comments

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1214) ISTANBUL UNIVERSITY MEDICAL FACULTY
CARDIOLOGY INSTITUTE

Subject Initials: ---

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

[Back to Form](#)

Item	Date	User	Comment
1	Nov-23-2020 11:22:48 (UTC+03:00) Istanbul	(b) (4), (b) (6)	Not Applicable

Header Text: C4591001

Visit: Logs - Unscheduled

Form Version: 17-Jul-2020 21:54

Site No: 1214

Subject No: 12141018

Generated By: (b) (4)

Form: MEDICATION ERROR - Comments

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1214) ISTANBUL UNIVERSITY MEDICAL FACULTY
CARDIOLOGY INSTITUTE

Subject Initials: ---

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

[Back to Form](#)

Item	Date	User	Comment
2	Nov-23-2020 11:22:48 (UTC+03:00) Istanbul	(b) (4), (b) (6)	Not Applicable

Header Text: C4591001

Visit: Logs - Unscheduled

Form Version: 17-Jul-2020 21:54

Site No: 1214

Subject No: 12141018

Generated By: (b) (4)

Form: MEDICATION ERROR - Comments

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1214) ISTANBUL UNIVERSITY MEDICAL FACULTY
CARDIOLOGY INSTITUTE

Subject Initials: ---

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

[Back to Form](#)

Item	Date	User	Comment
3	Nov-23-2020 11:22:48 (UTC+03:00) Istanbul	(b) (4), (b) (6)	Not Applicable

Header Text: C4591001

Visit: Logs - Unscheduled

Form Version: 17-Jul-2020 21:54

Site No: 1214

Subject No: 12141018

Generated By: (b) (4)

Form: MEDICATION ERROR - Comments

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1214) ISTANBUL UNIVERSITY MEDICAL FACULTY
CARDIOLOGY INSTITUTE

Subject Initials: ---

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

[Back to Form](#)

Item	Date	User	Comment
4	Nov-23-2020 11:22:48 (UTC+03:00) Istanbul	(b) (4), (b) (6)	Not Applicable

Header Text: C4591001

Visit: Logs - Unscheduled

Form Version: 17-Jul-2020 21:54

Site No: 1214

Subject No: 12141018

Generated By: (b) (4)

Form: MEDICATION ERROR - Comments

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1214) ISTANBUL UNIVERSITY MEDICAL FACULTY
CARDIOLOGY INSTITUTE

Subject Initials: ---

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

[Back to Form](#)

Item	Date	User	Comment
5	Nov-23-2020 11:22:48 (UTC+03:00) Istanbul	(b) (4), (b) (6)	Not Applicable

Header Text: C4591001

Visit: Logs - Unscheduled

Form Version: 17-Jul-2020 21:54

Site No: 1214

Subject No: 12141018

Generated By: (b) (4)

Form: MEDICATION ERROR - Comments

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1214) ISTANBUL UNIVERSITY MEDICAL FACULTY
CARDIOLOGY INSTITUTE

Subject Initials: ---

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

[Back to Form](#)

Item	Date	User	Comment
6	Nov-23-2020 11:22:48 (UTC+03:00) Istanbul	(b) (4), (b) (6)	Not Applicable

Header Text: C4591001

Visit: Logs - Unscheduled

Form Version: 17-Jul-2020 21:54

Site No: 1214

Subject No: 12141018

Generated By: (b) (4)

Form: MEDICATION ERROR - Comments

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1214) ISTANBUL UNIVERSITY MEDICAL FACULTY
CARDIOLOGY INSTITUTE

Subject Initials: ---

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

[Back to Form](#)

Item	Date	User	Comment
7	Nov-23-2020 11:22:48 (UTC+03:00) Istanbul	(b) (4), (b) (6)	Not Applicable

Header Text: C4591001

Visit: Logs - Unscheduled

Form Version: 17-Jul-2020 21:54

Site No: 1214

Subject No: 12141018

Generated By: (b) (4)

Form: MEDICATION ERROR - Comments

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1214) ISTANBUL UNIVERSITY MEDICAL FACULTY
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Subject Initials: ---

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

[Back to Form](#)

Item	Date	User	Comment
8	Nov-23-2020 11:22:48 (UTC+03:00) Istanbul	(b) (4), (b) (6)	Not Applicable

090177e196ae3d5d\Final\Final On: 01-Apr-2021 04:32 (GMT)

Header Text: C4591001

Visit: Logs - Unscheduled

Form Version: 17-Jul-2020 21:54

Site No: 1214

Subject No: 12141018

Generated By: (b) (4)

Form: MEDICATION ERROR - Comments

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1214) ISTANBUL UNIVERSITY MEDICAL FACULTY
CARDIOLOGY INSTITUTE

Subject Initials: ---

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

[Back to Form](#)

Item	Date	User	Comment
9	Nov-23-2020 11:22:48 (UTC+03:00) Istanbul	(b) (4), (b) (6)	Not Applicable

Header Text: C4591001

Visit: Logs - Unscheduled

Form Version: 17-Jul-2020 21:54

Site No: 1214

Subject No: 12141018

Generated By: (b) (4)

Form: MEDICATION ERROR - Comments

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1214) ISTANBUL UNIVERSITY MEDICAL FACULTY
CARDIOLOGY INSTITUTE

Subject Initials: ---

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

[Back to Form](#)

Item	Date	User	Comment
10	Nov-23-2020 11:22:48 (UTC+03:00) Istanbul	(b) (4), (b) (6)	Not Applicable

090177e196ae3d5d\Final\Final On: 01-Apr-2021 04:32 (GMT)

Header Text: C4591001

Visit: Logs - Unscheduled

Form: CONCOMITANT MEDICATIONS - NON STUDY
VACCINATIONS - Comments

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1214

Site Name: (1214) ISTANBUL UNIVERSITY MEDICAL FACULTY
CARDIOLOGY INSTITUTE

Subject No: 12141018

Subject Initials: ---

Generated By: (b) (4)

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

[Back to Form](#)

Item	Date	User	Comment
Form	Nov-23-2020 11:23:11 (UTC+03:00) Istanbul	(b) (4), (b) (6)	Not Applicable

Header Text: C4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1214

Subject No: 12141018

Generated By: (b) (4)

Form: CONCOMITANT MEDICATIONS - NON STUDY
VACCINATIONS - Comments

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1214) ISTANBUL UNIVERSITY MEDICAL FACULTY
CARDIOLOGY INSTITUTE

Subject Initials: ---

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

[Back to Form](#)

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

Header Text: C4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1214

Subject No: 12141018

Generated By: (b) (4)

Form: CONCOMITANT MEDICATIONS - NON STUDY
VACCINATIONS - Comments

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1214) ISTANBUL UNIVERSITY MEDICAL FACULTY
CARDIOLOGY INSTITUTE

Subject Initials: ---

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

[Back to Form](#)

Item	Date	User	Comment
2	Nov-23-2020 11:23:11 (UTC+03:00) Istanbul	(b) (4), (b) (6)	Not Applicable

Header Text: C4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1214

Subject No: 12141018

Generated By: (b) (4)

Form: CONCOMITANT MEDICATIONS - NON STUDY
VACCINATIONS - Comments

Form Status: Data Complete, Locked, Frozen, Verified

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CARDIOLOGY INSTITUTE

Subject Initials: ---

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

[Back to Form](#)

Item	Date	User	Comment
3	Nov-23-2020 11:23:11 (UTC+03:00) Istanbul	(b) (4), (b) (6)	Not Applicable

Header Text: C4591001

Visit: Logs - Unscheduled

Form: CONCOMITANT MEDICATIONS - NON STUDY
VACCINATIONS - Comments

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1214

Site Name: (1214) ISTANBUL UNIVERSITY MEDICAL FACULTY
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Subject No: 12141018

Subject Initials: ---

Generated By: (b) (4)

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

[Back to Form](#)

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

Header Text: C4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1214

Subject No: 12141018

Generated By: (b) (4)

Form: CONCOMITANT MEDICATIONS - NON STUDY
VACCINATIONS - Comments

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CARDIOLOGY INSTITUTE

Subject Initials: ---

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

[Back to Form](#)

Item	Date	User	Comment
5	Nov-23-2020 11:23:11 (UTC+03:00) Istanbul	(b) (4), (b) (6)	Not Applicable

Header Text: C4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1214

Subject No: 12141018

Generated By: (b) (4)

Form: CONCOMITANT MEDICATIONS - PROHIBITED - Comments

Form Status: Incomplete, Data Complete, Deleted, Verified

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

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

[Back to Form](#)

Item	Date	User	Comment
Form	Jan-11-2021 10:54:48 (UTC+03:00) Istanbul	(b) (4), (b) (6)	
Form	Nov-23-2020 11:23:30 (UTC+03:00) Istanbul	(b) (4), (b) (6)	Not Applicable

Header Text: C4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1214

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Form: CONCOMITANT MEDICATIONS - PROHIBITED - Comments

Form Status: Incomplete, Data Complete, Deleted, Verified

Site Name: (1214) ISTANBUL UNIVERSITY MEDICAL FACULTY
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Subject Initials: ---

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

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

[Back to Form](#)

Item	Date	User	Comment
1	Jan-11-2021 10:54:48 (UTC+03:00) Istanbul	(b) (4), (b) (6)	
1	Nov-23-2020 11:23:30 (UTC+03:00) Istanbul	(b) (4), (b) (6)	Not Applicable

090177e196ae3d5d\Final\Final On: 01-Apr-2021 04:32 (GMT)

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Form Version: 22-Apr-2020 21:03

Site No: 1214

Subject No: 12141018

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Form: CONCOMITANT MEDICATIONS - PROHIBITED - Comments

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

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

[Back to Form](#)

Item	Date	User	Comment
2	Jan-11-2021 10:54:48 (UTC+03:00) Istanbul	(b) (4), (b) (6)	
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Form Version: 22-Apr-2020 21:03

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

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[Back to Form](#)

Item	Date	User	Comment
3	Jan-11-2021 10:54:48 (UTC+03:00) Istanbul	(b) (4), (b) (6)	
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Site Name: (1214) ISTANBUL UNIVERSITY MEDICAL FACULTY
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Subject Initials: ---

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

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

[Back to Form](#)

Item	Date	User	Comment
4	Jan-11-2021 10:54:48 (UTC+03:00) Istanbul	(b) (4), (b) (6)	
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Generated Time (GMT): 29-Mar-2021 13:11

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

[Back to Form](#)

Item	Date	User	Comment
5	Jan-11-2021 10:54:48 (UTC+03:00) Istanbul	(b) (4), (b) (6)	
5	Nov-23-2020 11:23:30 (UTC+03:00) Istanbul	(b) (4), (b) (6)	Not Applicable

090177e196ae3d5d\Final\Final On: 01-Apr-2021 04:32 (GMT)

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Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:03

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Subject No: 12141018

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Form Status: Incomplete, Data Complete, Deleted, Verified

Site Name: (1214) ISTANBUL UNIVERSITY MEDICAL FACULTY
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Subject Initials: ---

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

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[Back to Form](#)

Item	Date	User	Comment
6	Jan-11-2021 10:54:48 (UTC+03:00) Istanbul	(b) (4), (b) (6)	
6	Nov-23-2020 11:23:30 (UTC+03:00) Istanbul	(b) (4), (b) (6)	Not Applicable

Header Text: C4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1214

Subject No: 12141018

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Form: CONCOMITANT MEDICATIONS - PROHIBITED - Comments

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Site Name: (1214) ISTANBUL UNIVERSITY MEDICAL FACULTY
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Generated Time (GMT): 29-Mar-2021 13:11

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[Back to Form](#)

Item	Date	User	Comment
7	Jan-11-2021 10:54:48 (UTC+03:00) Istanbul	(b) (4), (b) (6)	
7	Nov-23-2020 11:23:30 (UTC+03:00) Istanbul	(b) (4), (b) (6)	Not Applicable

090177e196ae3d5d\Final\Final On: 01-Apr-2021 04:32 (GMT)

Header Text: C4591001

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Form Version: 22-Apr-2020 21:03

Site No: 1214

Subject No: 12141018

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Form: CONCOMITANT MEDICATIONS - PROHIBITED - Comments

Form Status: Incomplete, Data Complete, Deleted, Verified

Site Name: (1214) ISTANBUL UNIVERSITY MEDICAL FACULTY
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Generated Time (GMT): 29-Mar-2021 13:11

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[Back to Form](#)

Item	Date	User	Comment
8	Jan-11-2021 10:54:48 (UTC+03:00) Istanbul	(b) (4), (b) (6)	
8	Nov-23-2020 11:23:30 (UTC+03:00) Istanbul	(b) (4), (b) (6)	Not Applicable

Header Text: C4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1214

Subject No: 12141018

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Subject Initials: ---

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

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[Back to Form](#)

Item	Date	User	Comment
9	Jan-11-2021 10:54:48 (UTC+03:00) Istanbul	(b) (4), (b) (6)	
9	Nov-23-2020 11:23:30 (UTC+03:00) Istanbul	(b) (4), (b) (6)	Not Applicable

090177e196ae3d5d\Final\Final On: 01-Apr-2021 04:32 (GMT)

Header Text: C4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1214

Subject No: 12141018

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Form Status: Incomplete, Data Complete, Deleted, Verified

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Subject Initials: ---

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

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[Back to Form](#)

Item	Date	User	Comment
10	Jan-11-2021 10:54:48 (UTC+03:00) Istanbul	(b) (4), (b) (6)	
10	Nov-23-2020 11:23:30 (UTC+03:00) Istanbul	(b) (4), (b) (6)	Not Applicable

Header Text: C4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1214

Subject No: 12141018

Generated By: (b) (4)

Form: RADIATION TREATMENT - Comments

Form Status: Data Complete, Verified

Site Name: (1214) ISTANBUL UNIVERSITY MEDICAL FACULTY
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Subject Initials: ---

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

[Back to Form](#)

Item	Date	User	Comment
Form	Nov-23-2020 11:23:50 (UTC+03:00) Istanbul	(b) (4), (b) (6)	Not Applicable

090177e196ae3d5d\Final\Final On: 01-Apr-2021 04:32 (GMT)

Header Text: C4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1214

Subject No: 12141018

Generated By: (b) (4)

Form: RADIATION TREATMENT - Comments

Form Status: Data Complete, Verified

Site Name: (1214) ISTANBUL UNIVERSITY MEDICAL FACULTY
CARDIOLOGY INSTITUTE

Subject Initials: ---

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

[Back to Form](#)

Item	Date	User	Comment
1	Nov-23-2020 11:23:50 (UTC+03:00) Istanbul	(b) (4), (b) (6)	Not Applicable

Header Text: C4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1214

Subject No: 12141018

Generated By: (b) (4)

Form: RADIATION TREATMENT - Comments

Form Status: Data Complete, Verified

Site Name: (1214) ISTANBUL UNIVERSITY MEDICAL FACULTY
CARDIOLOGY INSTITUTE

Subject Initials: ---

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

[Back to Form](#)

Item	Date	User	Comment
2	Nov-23-2020 11:23:50 (UTC+03:00) Istanbul	(b) (4), (b) (6)	Not Applicable

090177e196ae3d5d\Final\Final On: 01-Apr-2021 04:32 (GMT)

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Site Name: (1214) ISTANBUL UNIVERSITY MEDICAL FACULTY
CARDIOLOGY INSTITUTE

Subject Initials: ---

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

[Back to Form](#)

Item	Date	User	Comment
3	Nov-23-2020 11:23:50 (UTC+03:00) Istanbul	(b) (4), (b) (6)	Not Applicable

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Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

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Site Name: (1214) ISTANBUL UNIVERSITY MEDICAL FACULTY
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Subject Initials: ---

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

[Back to Form](#)

Item	Date	User	Comment
4	Nov-23-2020 11:23:50 (UTC+03:00) Istanbul	(b) (4), (b) (6)	Not Applicable

Header Text: C4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

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CARDIOLOGY INSTITUTE

Subject Initials: ---

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

[Back to Form](#)

Item	Date	User	Comment
5	Nov-23-2020 11:23:50 (UTC+03:00) Istanbul	(b) (4), (b) (6)	Not Applicable

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Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

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Site Name: (1214) ISTANBUL UNIVERSITY MEDICAL FACULTY
CARDIOLOGY INSTITUTE

Subject Initials: ---

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

[Back to Form](#)

Item	Date	User	Comment
6	Nov-23-2020 11:23:50 (UTC+03:00) Istanbul	(b) (4), (b) (6)	Not Applicable

090177e196ae3d5d\Final\Final On: 01-Apr-2021 04:32 (GMT)

Header Text: C4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1214

Subject No: 12141018

Generated By: (b) (4)

Form: TRANSFUSIONS - Comments

Form Status: Data Complete, Verified

Site Name: (1214) ISTANBUL UNIVERSITY MEDICAL FACULTY
CARDIOLOGY INSTITUTE

Subject Initials: ---

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

[Back to Form](#)

Item	Date	User	Comment
Form	Nov-23-2020 11:24:10 (UTC+03:00) Istanbul	(b) (4), (b) (6)	Not Applicable

Header Text: C4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1214

Subject No: 12141018

Generated By: (b) (4)

Form: TRANSFUSIONS - Comments

Form Status: Data Complete, Verified

Site Name: (1214) ISTANBUL UNIVERSITY MEDICAL FACULTY
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Subject Initials: ---

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

[Back to Form](#)

Item	Date	User	Comment
1	Nov-23-2020 11:24:10 (UTC+03:00) Istanbul	(b) (4), (b) (6)	Not Applicable

Header Text: C4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1214

Subject No: 12141018

Generated By: (b) (4)

Form: TRANSFUSIONS - Comments

Form Status: Data Complete, Verified

Site Name: (1214) ISTANBUL UNIVERSITY MEDICAL FACULTY
CARDIOLOGY INSTITUTE

Subject Initials: ---

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

[Back to Form](#)

Item	Date	User	Comment
2	Nov-23-2020 11:24:10 (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: 1214

Subject No: 12141018

Generated By: (b) (4)

Form: WITHDRAWAL OF CONSENT - Comments

Form Status: Data Complete, Verified

Site Name: (1214) ISTANBUL UNIVERSITY MEDICAL FACULTY
CARDIOLOGY INSTITUTE

Subject Initials: ---

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

[Back to Form](#)

Item	Date	User	Comment
Form	Dec-30-2020 19:44:23 (UTC+03:00) Istanbul	(b) (4), (b) (6)	Not Applicable

090177e196ae3d5d\Final\Final On: 01-Apr-2021 04:32 (GMT)

Header Text: C4591001

Visit: Disposition

Form Version: 22-Apr-2020 21:03

Site No: 1214

Subject No: 12141018

Generated By: (b) (4)

Form: WITHDRAWAL OF CONSENT - Comments

Form Status: Data Complete, Verified

Site Name: (1214) ISTANBUL UNIVERSITY MEDICAL FACULTY
CARDIOLOGY INSTITUTE

Subject Initials: ---

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

[Back to Form](#)

Item	Date	User	Comment
1	Dec-30-2020 19:44:23 (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: 1214

Subject No: 12141018

Generated By: (b) (4)

Form: DEATH DETAILS CODED - Comments

Form Status: Data Complete, Verified

Site Name: (1214) ISTANBUL UNIVERSITY MEDICAL FACULTY
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Subject Initials: ---

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

[Back to Form](#)

Item	Date	User	Comment
Form	Jan-04-2021 11:03:11 (UTC+03:00) Istanbul	(b) (4), (b) (6)	Not Applicable
Form	Dec-31-2020 17:45:20 (UTC+03:00) Istanbul	(b) (4), (b) (6)	
Form	Dec-30-2020 19:44:38 (UTC+03:00) Istanbul	(b) (4), (b) (6)	Not Applicable

090177e196ae3d5d\Final\Final On: 01-Apr-2021 04:32 (GMT)

Header Text: C4591001

Visit: Disposition

Form Version: 22-Apr-2020 21:03

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Generated By: (b) (4)

Form: DEATH DETAILS CODED - Comments

Form Status: Data Complete, Verified

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Subject Initials: ---

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

[Back to Form](#)

Item	Date	User	Comment
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1	Dec-30-2020 19:44:38 (UTC+03:00) Istanbul	(b) (4), (b) (6)	Not Applicable

Header Text: C4591001

Visit: Investigator Signature - Unscheduled

Form: CASEBOOK SIGNATURE FORM - Signature History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Signed, Verified

Site No: 1214

Site Name: (1214) ISTANBUL UNIVERSITY MEDICAL FACULTY
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Subject No: 12141018

Subject Initials: ---

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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

Name	Signature Meaning	Date	Type	Action
Serap Yavuz	Approved	Feb-02-2021 17:00:13 (UTC+03:00) Istanbul	BOOK	Signed

Affidavit:

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

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

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

(b) (6)	N/A	Feb-01-2021 18:51:31 (UTC+03:00) Istanbul		Edit - All signatures invalidated
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Affidavit:

N/A

Serap Yavuz	Approved	Jan-28-2021 23:31:07 (UTC+03:00) Istanbul	BOOK	Signed
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Affidavit:

By my dated signature below, I, SerapYavuz, 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-28-2021 16:39:02 (UTC+03:00) Istanbul		Edit - All signatures invalidated
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Affidavit:

N/A

Serap Yavuz	Approved	Jan-12-2021 22:14:11 (UTC+03:00) Istanbul	BOOK	Signed
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090177e196ae3d5d\Final\Final On: 01-Apr-2021 04:32 (GMT)

Header Text: C4591001**Visit:** Investigator Signature - Unscheduled**Form Version:** 22-Apr-2020 21:04**Site No:** 1214**Subject No:** 12141018**Generated By:** (b) (4)**Form:** CASEBOOK SIGNATURE FORM - Signature History**Form Status:** Data Complete, Signed, Verified**Site Name:** (1214) ISTANBUL UNIVERSITY MEDICAL FACULTY
CARDIOLOGY INSTITUTE**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 13:11**Affidavit:**

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

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

(b) (6)	N/A	Jan-12-2021 17:10:27 (UTC+03:00) Istanbul		Edit - All signatures invalidated
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Affidavit:

N/A

Serap Yavuz	Approved	Jan-11-2021 17:30:42 (UTC+03:00) Istanbul	BOOK	Signed
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Affidavit:

By my dated signature below, I, SerapYavuz, 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-08-2021 12:20:11 (UTC+03:00) Istanbul		Edit - All signatures invalidated
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Affidavit:

N/A

Serap Yavuz	Approved	Jan-08-2021 12:17:26 (UTC+03:00) Istanbul	BOOK	Signed
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Affidavit:

By my dated signature below, I, SerapYavuz, 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.

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Visit: Investigator Signature - Unscheduled

Form: CASEBOOK SIGNATURE FORM - Signature History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Signed, Verified

Site No: 1214

Site Name: (1214) ISTANBUL UNIVERSITY MEDICAL FACULTY
CARDIOLOGY INSTITUTE

Subject No: 12141018

Subject Initials: ---

Generated By: (b) (4)

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

(b) (6)	N/A	Jan-08-2021 12:10:47 (UTC+03:00) Istanbul		Edit - All signatures invalidated
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Affidavit:

N/A

Serap Yavuz	Approved	Jan-07-2021 11:19:57 (UTC+03:00) Istanbul	BOOK	Signed
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Affidavit:

By my dated signature below, I, Serap Yavuz, 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-04-2021 11:03:11 (UTC+03:00) Istanbul		Edit - All signatures invalidated
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Affidavit:

N/A

Serap Yavuz	Approved	Dec-31-2020 18:52:24 (UTC+03:00) Istanbul	BOOK	Signed
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Affidavit:

By my dated signature below, I, Serap Yavuz, 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-30-2020 14:20:00 (UTC+03:00) Istanbul		Edit - All signatures invalidated
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Affidavit:

N/A

Serap Yavuz	Approved	Dec-23-2020 10:51:41 (UTC+03:00) Istanbul	BOOK	Signed
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090177e196ae3d5d\Final\Final On: 01-Apr-2021 04:32 (GMT)

Header Text: C4591001**Visit:** Investigator Signature - Unscheduled**Form Version:** 22-Apr-2020 21:04**Site No:** 1214**Subject No:** 12141018**Generated By:** (b) (4)**Form:** CASEBOOK SIGNATURE FORM - Signature History**Form Status:** Data Complete, Signed, Verified**Site Name:** (1214) ISTANBUL UNIVERSITY MEDICAL FACULTY
CARDIOLOGY INSTITUTE**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 13:11**Affidavit:**

By my dated signature below, I, SerapYavuz, 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-22-2020 12:12:42 (UTC+03:00) Istanbul		Edit - All signatures invalidated
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Affidavit:

N/A

Serap Yavuz	Approved	Dec-22-2020 10:50:50 (UTC+03:00) Istanbul	BOOK	Signed
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Affidavit:

By my dated signature below, I, SerapYavuz, 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-21-2020 11:15:33 (UTC+03:00) Istanbul		Edit - All signatures invalidated
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Affidavit:

N/A

Serap Yavuz	Approved	Dec-02-2020 11:03:55 (UTC+03:00) Istanbul	BOOK	Signed
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Affidavit:

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

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

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

Header Text: C4591001

Visit: Investigator Signature - Unscheduled

Form: CASEBOOK SIGNATURE FORM - Signature History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Signed, Verified

Site No: 1214

Site Name: (1214) ISTANBUL UNIVERSITY MEDICAL FACULTY
CARDIOLOGY INSTITUTE

Subject No: 12141018

Subject Initials: ---

Generated By: (b) (4)

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

(b) (6)	N/A	Nov-23-2020 11:22:32 (UTC+03:00) Istanbul		Edit - All signatures invalidated
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Affidavit:

N/A

Serap Yavuz	Approved	Nov-20-2020 15:50:18 (UTC+03:00) Istanbul	BOOK	Signed
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Affidavit:

By my dated signature below, I, Serap Yavuz, 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.

090177e196ae3d5d\Final\Final On: 01-Apr-2021 04:32 (GMT)

Header Text: C4591001

Visit: COHORT_SELECTION

Form Version: 10-Oct-2020 16:01

Site No: 1214

Subject No: 12141018

Generated By: (b) (4)

Form: COHORT_SELECTION - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1214) ISTANBUL UNIVERSITY MEDICAL FACULTY
CARDIOLOGY INSTITUTE

Subject Initials: ---

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

[Back to Form](#)

1. Select appropriate response - Protocol version

Date	Location	User	Value	Reason
Nov-02-2020 19:56:55 (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
Nov-02-2020 19:56:55 (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: 1214

Subject No: 12141018

Generated By: (b) (4)

Form: MAIN INFORMED CONSENT - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1214) ISTANBUL UNIVERSITY MEDICAL FACULTY
CARDIOLOGY INSTITUTE

Subject Initials: ---

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

[Back to Form](#)

1. Consent Was:

Date	Location	User	Value	Reason
Nov-02-2020 19:57:19 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: OBTAINED Date Written Consent Obtained Nov/2/2020	Initial Entry

090177e196ae3d5d\Final\Final On: 01-Apr-2021 04:32 (GMT)

Header Text: C4591001

Visit: COHORT_SELECTION

Form Version: 15-Sep-2020 21:54

Site No: 1214

Subject No: 12141018

Generated By: (b) (4)

Form: DEMOGRAPHY - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1214) ISTANBUL UNIVERSITY MEDICAL FACULTY
CARDIOLOGY INSTITUTE

Subject Initials: ---

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

[Back to Form](#)

1. Subject ID

Date	Location	User	Value	Reason
Nov-02-2020 19:56:43 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 12141018	Item copied from previous form

2. Birth Date:

Date	Location	User	Value	Reason
Nov-02-2020 19:56:37 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: (b) (6)/1990	Enrollment Entry

3. Sex:

Date	Location	User	Value	Reason
Nov-02-2020 19:57:34 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: MALE	Initial Entry

4. Ethnicity:

Date	Location	User	Value	Reason
Nov-02-2020 19:57:34 (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
Nov-02-2020 19:57:34 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: WHITE	Initial Entry

090177e196ae3d5d\Final\Final On: 01-Apr-2021 04:32 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:02

Site No: 1214

Subject No: 12141018

Generated By: (b) (4)

Form: DATE OF VISIT - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1214) ISTANBUL UNIVERSITY MEDICAL FACULTY
CARDIOLOGY INSTITUTE

Subject Initials: ---

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

[Back to Form](#)

I. Date of Visit

Date	Location	User	Value	Reason
Nov-02-2020 19:58:07 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Nov/2/2020	Initial Entry

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 15-Sep-2020 21:52

Site No: 1214

Subject No: 12141018

Generated By: (b) (4)

Form: DISPOSITION - SCREENING - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1214) ISTANBUL UNIVERSITY MEDICAL FACULTY
CARDIOLOGY INSTITUTE

Subject Initials: ---

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

[Back to Form](#)

1. Date of Completion/Discontinuation/Death

Date	Location	User	Value	Reason
Nov-02-2020 19:59:09 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Nov/2/2020	Initial Entry

2. Phase of Disposition:

Date	Location	User	Value	Reason
Nov-02-2020 19:59:09 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SCREENING	Initial Entry

3. Status:

Date	Location	User	Value	Reason
Nov-02-2020 19:59:09 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: COMPLETED	Initial Entry

090177e196ae3d5d\Final\Final On: 01-Apr-2021 04:32 (GMT)

Header Text: C4591001**Visit:** V1_DAY1_VAX1_L**Form Version:** 22-Apr-2020 21:03**Site No:** 1214**Subject No:** 12141018**Generated By:** (b) (4)**Form:** GENERAL MEDICAL HISTORY - eCRF Audit Trail History**Form Status:** Data Complete, Frozen, Verified**Site Name:** (1214) ISTANBUL UNIVERSITY MEDICAL FACULTY
CARDIOLOGY INSTITUTE**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 13:11[Back to Form](#)**1.a**

Date	Location	User	Value	Reason
Nov-23-2020 11:55:18 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Nu 1 mber: Medical Hist vertebral disk herni ory Term: ation surgery Start Date: UNK/UNK/2010 Ongoing: NO End Date: UNK/UNK/201 0	Initial Entry

1.a Line/MH Number:

Date	Location	User	Value	Reason
Nov-23-2020 11:55:18 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 1	Initial Entry

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

Date	Location	User	Value	Reason
Nov-23-2020 11:55:18 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: vertebral disk herniation surgery	Initial Entry

1.a Start Date:

Date	Location	User	Value	Reason
Nov-23-2020 11:55:18 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: UNK/UNK/2010	Initial Entry

1.a Ongoing:

Date	Location	User	Value	Reason
Nov-23-2020 11:55:18	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Initial Entry

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1214

Subject No: 12141018

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1214) ISTANBUL UNIVERSITY MEDICAL FACULTY
CARDIOLOGY INSTITUTE

Subject Initials: ---

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

(UTC+03:00) Istanbul	(b) (4), (b) (6)	NO End Date: UNK/UNK/2010
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Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 15-Sep-2020 21:57

Site No: 1214

Subject No: 12141018

Generated By: (b) (4)

Form: HIV STATUS - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1214) ISTANBUL UNIVERSITY MEDICAL FACULTY
CARDIOLOGY INSTITUTE

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
Nov-02-2020 20:00:58 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: The subject is NOT known to be H IV POSITIVE	Initial Entry

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 10-Oct-2020 16:04

Site No: 1214

Subject No: 12141018

Generated By: (b) (4)

Form: VITAL SIGNS - BASELINE - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1214) ISTANBUL UNIVERSITY MEDICAL FACULTY
CARDIOLOGY INSTITUTE

Subject Initials: ---

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

[Back to Form](#)

1. Date:

Date	Location	User	Value	Reason
Nov-02-2020 20:02:14 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Nov/2/2020	Initial Entry

2. Weight:

Date	Location	User	Value	Reason
Nov-02-2020 20:02:14 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> 88.2	Initial Entry

3. Unit:

Date	Location	User	Value	Reason
Nov-02-2020 20:02:14 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> kg	Initial Entry

4. Height:

Date	Location	User	Value	Reason
Nov-02-2020 20:02:14 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> 186.0	Initial Entry

5. Unit:

Date	Location	User	Value	Reason
Nov-02-2020 20:02:14 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> cm	Initial Entry

6. Body Mass Index:

Date	Location	User	Value	Reason
Nov-02-2020 20:02:14 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> 25.5	Initial Entry

7.a

Date	Location	User	Value	Reason
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090177e196ae3d5d\Final\Final On: 01-Apr-2021 04:32 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 10-Oct-2020 16:04

Site No: 1214

Subject No: 12141018

Generated By: (b) (4)

Form: VITAL SIGNS - BASELINE - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1214) ISTANBUL UNIVERSITY MEDICAL FACULTY
CARDIOLOGY INSTITUTE

Subject Initials: ---

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

Nov-02-2020 20:02:14 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Record Identifier:: 1 Temperature: 37.0 Temperature Unit: C Temperature Location: FOREHEAD	Initial Entry
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7.a Record Identifier:

Date	Location	User	Value	Reason
Nov-02-2020 20:02:14 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 1	Initial Entry

7.a Temperature:

Date	Location	User	Value	Reason
Nov-02-2020 20:02:14 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 37.0	Initial Entry

7.a Unit:

Date	Location	User	Value	Reason
Nov-02-2020 20:02:14 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: C	Initial Entry

7.a Temperature Location:

Date	Location	User	Value	Reason
Nov-02-2020 20:02:14 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: FOREHEAD	Initial Entry

090177e196ae3d5d\Final\Final On: 01-Apr-2021 04:32 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1214

Subject No: 12141018

Generated By: (b) (4)

Form: RANDOMIZATION - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1214) ISTANBUL UNIVERSITY MEDICAL FACULTY
CARDIOLOGY INSTITUTE

Subject Initials: ---

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

[Back to Form](#)

1. Randomization Date :

Date	Location	User	Value	Reason
Nov-02-2020 20:02:47 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Nov/2/2020	Initial Entry

2. Randomization Number:

Date	Location	User	Value	Reason
Nov-02-2020 20:02:47 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 115208	Initial Entry

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1214

Site Name: (1214) ISTANBUL UNIVERSITY MEDICAL FACULTY CARDIOLOGY INSTITUTE

Subject No: 12141018

Subject Initials: ---

Generated By: (b) (4)

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

[Back to Form](#)

1. Data Origin

Date	Location	User	Value	Reason
Nov-02-2020 20:03:05 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Nov-02-2020 20:03:05 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SERUM	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Nov-02-2020 20:48:42 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Nov-02-2020 20:03:05 (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-02-2020 20:03:05 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Date of Collection: Nov/2/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Nov-02-2020 20:48:42 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BPZD2S	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
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090177e196ae3d5d\Final\Final On: 01-Apr-2021 04:32 (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, Frozen, Verified

Site No: 1214

Site Name: (1214) ISTANBUL UNIVERSITY MEDICAL FACULTY CARDIOLOGY INSTITUTE

Subject No: 12141018

Subject Initials: ---

Generated By: (b) (4)

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

Nov-02-2020 20:48:42 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BPZD2S	Initial Entry
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5.b

Date	Location	User	Value	Reason
Nov-02-2020 20:48:54 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BPZD2T	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Nov-02-2020 20:48:54 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BPZD2T	Initial Entry

5.c

Date	Location	User	Value	Reason
Nov-02-2020 20:49:03 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BSHCW8	Initial Entry

5.c Sample ID

Date	Location	User	Value	Reason
Nov-02-2020 20:49:03 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BSHCW8	Initial Entry

5.d

Date	Location	User	Value	Reason
Nov-02-2020 20:49:17 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BSHCW9	Initial Entry

5.d Sample ID

Date	Location	User	Value	Reason
Nov-02-2020 20:49:17 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BSHCW9	Initial Entry

090177e196ae3d5d\Final\Final On: 01-Apr-2021 04:32 (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, Frozen, Verified

Site No: 1214

Site Name: (1214) ISTANBUL UNIVERSITY MEDICAL FACULTY
CARDIOLOGY INSTITUTE

Subject No: 12141018

Subject Initials: ---

Generated By: (b) (4)

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

[Back to Form](#)

1. Data Origin

Date	Location	User	Value	Reason
Nov-02-2020 20:03:25 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Nov-02-2020 20:03:25 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: NASAL_SWAB	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Nov-02-2020 20:48:30 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Nov-02-2020 20:03:25 (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-02-2020 20:03:25 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Date of Collection: Nov/2/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Nov-02-2020 20:48:30 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BPZD2J	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
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090177e196ae3d5d\Final\Final On: 01-Apr-2021 04:32 (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, Frozen, Verified

Site No: 1214

Site Name: (1214) ISTANBUL UNIVERSITY MEDICAL FACULTY
CARDIOLOGY INSTITUTE

Subject No: 12141018

Subject Initials: ---

Generated By: (b) (4)

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

Nov-02-2020 20:48:30 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BPZD2J	Initial Entry
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Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:04

Site No: 1214

Subject No: 12141018

Generated By: (b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1214) ISTANBUL UNIVERSITY MEDICAL FACULTY
CARDIOLOGY INSTITUTE

Subject Initials: ---

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

[Back to Form](#)

1. Was there a temporary delay of vaccination?

Date	Location	User	Value	Reason
Nov-02-2020 20:04:16 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2. Treatment Name

Date	Location	User	Value	Reason
Nov-02-2020 20:04:16 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: BLINDED THERAPY	Initial Entry

3. Formulation:

Date	Location	User	Value	Reason
Nov-02-2020 20:04:16 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: INJECTION	Initial Entry

4. Dose Date Time:

Date	Location	User	Value	Reason
Nov-02-2020 20:04:16 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Nov/2/2020 12:36	Initial Entry

5. Anatomical Location:

Date	Location	User	Value	Reason
Nov-02-2020 20:04:16 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: DELTOID MUSCLE	Initial Entry

6. Body Side:

Date	Location	User	Value	Reason
Nov-02-2020 20:04:16 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: LEFT	Initial Entry

7. Route:

Date	Location	User	Value	Reason
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090177e196ae3d5d\Final\Final On: 01-Apr-2021 04:32 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:04

Site No: 1214

Subject No: 12141018

Generated By: (b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1214) ISTANBUL UNIVERSITY MEDICAL FACULTY
CARDIOLOGY INSTITUTE

Subject Initials: ---

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

Nov-02-2020 20:04:16 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: INTRAMUSCULAR	Initial Entry
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10. Timeframe Subject Was Observed

Date	Location	User	Value	Reason
Nov-02-2020 20:04:16 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: THE PROTOCOL SPECIFIED OB SERVATION PERIOD	Initial Entry

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

Date	Location	User	Value	Reason
Nov-02-2020 20:04:16 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

090177e196ae3d5d\Final\Final On: 01-Apr-2021 04:32 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 06-Jul-2020 21:53

Site No: 1214

Subject No: 12141018

Generated By: (b) (4)

Form: REACTOGENICITY DIARY - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1214) ISTANBUL UNIVERSITY MEDICAL FACULTY
CARDIOLOGY INSTITUTE

Subject Initials: ---

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

[Back to Form](#)

1. Select appropriate response - Reactogenicity diary collection

Date	Location	User	Value	Reason
Nov-02-2020 20:04:26 (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: 1214

Subject No: 12141018

Generated By: (b) (4)

Form: DATE OF VISIT - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1214) ISTANBUL UNIVERSITY MEDICAL FACULTY
CARDIOLOGY INSTITUTE

Subject Initials: ---

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

[Back to Form](#)

I. Date of Visit

Date	Location	User	Value	Reason
Nov-23-2020 11:24:43 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Nov/23/2020	Initial Entry

Header Text: C4591001

Visit: V2_VAX2_L

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

Form Version: 10-Oct-2020 16:03

Form Status: Data Complete, Frozen, Verified

Site No: 1214

Site Name: (1214) ISTANBUL UNIVERSITY MEDICAL FACULTY CARDIOLOGY INSTITUTE

Subject No: 12141018

Subject Initials: ---

Generated By: (b) (4)

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

[Back to Form](#)

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

Date	Location	User	Value	Reason
Nov-23-2020 11:25:11 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2.a

Date	Location	User	Value	Reason
Nov-23-2020 11:25:11 (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?: NO	Initial Entry

2.a Symptom:

Date	Location	User	Value	Reason
Nov-23-2020 11:25:11 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: FEVER	Initial Entry

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

Date	Location	User	Value	Reason
Nov-23-2020 11:25:11 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2.b

Date	Location	User	Value	Reason
Nov-23-2020 11:25:11 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom:: FAT	Initial Entry

090177e196ae3d5d\Final\Final On: 01-Apr-2021 04:32 (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: 1214

Site Name: (1214) ISTANBUL UNIVERSITY MEDICAL FACULTY CARDIOLOGY INSTITUTE

Subject No: 12141018

Subject Initials: ---

Generated By: (b) (4)

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

			IG UE Were fever or systemic symptoms present on the last day the Subject Diary was completed?: NO
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2.b Symptom:

Date	Location	User	Value	Reason
Nov-23-2020 11:25:11 (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
Nov-23-2020 11:25:11 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2.c

Date	Location	User	Value	Reason
Nov-23-2020 11:25:11 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom: HEA DA CHE Were fever or systemic symptoms present on the last day the Subject Diary was completed?: NO	Initial Entry

090177e196ae3d5d\Final\Final On: 01-Apr-2021 04:32 (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: 1214

Site Name: (1214) ISTANBUL UNIVERSITY MEDICAL FACULTY
CARDIOLOGY INSTITUTE

Subject No: 12141018

Subject Initials: ---

Generated By: (b) (4)

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

2.c Symptom:

Date	Location	User	Value	Reason
Nov-23-2020 11:25:11 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: HEADACHE	Initial Entry

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

Date	Location	User	Value	Reason
Nov-23-2020 11:25:11 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2.d

Date	Location	User	Value	Reason
Nov-23-2020 11:25:11 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom:: CH IL LS Were fever or systemic symp NO toms present on the last day the Subject Diary was compl eted?:	Initial Entry

2.d Symptom:

Date	Location	User	Value	Reason
Nov-23-2020 11:25:11 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: CHILLS	Initial Entry

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

Date	Location	User	Value	Reason
Nov-23-2020 11:25:11 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2.e

090177e196ae3d5d\Final\Final On: 01-Apr-2021 04:32 (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: 1214

Site Name: (1214) ISTANBUL UNIVERSITY MEDICAL FACULTY CARDIOLOGY INSTITUTE

Subject No: 12141018

Subject Initials: ---

Generated By: (b) (4)

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

Date	Location	User	Value	Reason
Nov-23-2020 11:25:11 (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
Nov-23-2020 11:25:11 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: VOMITING	Initial Entry

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

Date	Location	User	Value	Reason
Nov-23-2020 11:25:11 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2.f

Date	Location	User	Value	Reason
Nov-23-2020 11:25:11 (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

090177e196ae3d5d\Final\Final On: 01-Apr-2021 04:32 (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: 1214

Site Name: (1214) ISTANBUL UNIVERSITY MEDICAL FACULTY CARDIOLOGY INSTITUTE

Subject No: 12141018

Subject Initials: ---

Generated By: (b) (4)

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

2.f Symptom:

Date	Location	User	Value	Reason
Nov-23-2020 11:25:11 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: DIARRHEA	Initial Entry

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

Date	Location	User	Value	Reason
Nov-23-2020 11:25:11 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2.g

Date	Location	User	Value	Reason
Nov-23-2020 11:25:11 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom:: NEW OR WORSE ED MUS CLE PAIN Were fever or systemi c symptoms present o n the last day the Sub ject Diary was comple ted?: NO	Initial Entry

2.g Symptom:

Date	Location	User	Value	Reason
Nov-23-2020 11:25:11 (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
Nov-23-2020 11:25:11 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

090177e196ae3d5d\Final\Final On: 01-Apr-2021 04:32 (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: 1214

Site Name: (1214) ISTANBUL UNIVERSITY MEDICAL FACULTY
CARDIOLOGY INSTITUTE

Subject No: 12141018

Subject Initials: ---

Generated By: (b) (4)

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

2.h

Date	Location	User	Value	Reason
Nov-23-2020 11:25:11 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom:: NEW OR WORSE NED JOINT PAIN Were fever or systemic symptoms present on the last day the Subject Diary was completed?: NO	Initial Entry

2.h Symptom:

Date	Location	User	Value	Reason
Nov-23-2020 11:25:11 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NEW OR WORSE NED JOINT PAIN	Initial Entry

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

Date	Location	User	Value	Reason
Nov-23-2020 11:25:11 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

3. Injection Site Location:

Date	Location	User	Value	Reason
Nov-23-2020 11:25:11 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: DELTOID MUSCLE	Initial Entry

4. Injection Site Body Side:

Date	Location	User	Value	Reason
Nov-23-2020 11:25:11 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: LEFT	Initial Entry

090177e196ae3d5d\Final\Final On: 01-Apr-2021 04:32 (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: 1214

Site Name: (1214) ISTANBUL UNIVERSITY MEDICAL FACULTY CARDIOLOGY INSTITUTE

Subject No: 12141018

Subject Initials: ---

Generated By: (b) (4)

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

5.a

Date	Location	User	Value	Reason
Nov-23-2020 11:25:11 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Injection Site Reaction:: RE DN ESS Were injection site reactions present on the last day the Subject Diary was completed?: NO	Initial Entry

5.a Injection Site Reaction:

Date	Location	User	Value	Reason
Nov-23-2020 11:25:11 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: REDNESS	Initial Entry

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

Date	Location	User	Value	Reason
Nov-23-2020 11:25:11 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

5.b

Date	Location	User	Value	Reason
Nov-23-2020 11:25:11 (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

090177e196ae3d5d\Final\Final On: 01-Apr-2021 04:32 (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: 1214

Site Name: (1214) ISTANBUL UNIVERSITY MEDICAL FACULTY
CARDIOLOGY INSTITUTE

Subject No: 12141018

Subject Initials: ---

Generated By: (b) (4)

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

5.b Injection Site Reaction:

Date	Location	User	Value	Reason
Nov-23-2020 11:25:11 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: SWELLING	Initial Entry

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

Date	Location	User	Value	Reason
Nov-23-2020 11:25:11 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

5.c

Date	Location	User	Value	Reason
Nov-23-2020 11:25:11 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Injection Site Reaction: PAIN AT INJECTION SITE Were injection site reactions present on the last day the Subject Diary was completed?: NO	Initial Entry

5.c Injection Site Reaction:

Date	Location	User	Value	Reason
Nov-23-2020 11:25:11 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: PAIN AT INJECTION SITE	Initial Entry

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

Date	Location	User	Value	Reason
Nov-23-2020 11:25:11 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

090177e196ae3d5d\Final\Final On: 01-Apr-2021 04:32 (GMT)

Header Text: C4591001

Visit: V2_VAX2_L

Form Version: 10-Oct-2020 16:01

Site No: 1214

Subject No: 12141018

Generated By: (b) (4)

Form: VITAL SIGNS - TEMP - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1214) ISTANBUL UNIVERSITY MEDICAL FACULTY
CARDIOLOGY INSTITUTE

Subject Initials: ---

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

[Back to Form](#)

1. Date:

Date	Location	User	Value	Reason
Nov-23-2020 11:25:41 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Nov/23/2020	Initial Entry

2.a

Date	Location	User	Value	Reason
Nov-23-2020 11:25:41 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Record Identifier:: 1 Temperature: 36.5 Temperature Unit: C Temperature Location:: FOREHEAD	Initial Entry

2.a Record Identifier:

Date	Location	User	Value	Reason
Nov-23-2020 11:25:41 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 1	Initial Entry

2.a Temperature:

Date	Location	User	Value	Reason
Nov-23-2020 11:25:41 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 36.5	Initial Entry

2.a Unit:

Date	Location	User	Value	Reason
Nov-23-2020 11:25:41 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: C	Initial Entry

2.a Temperature Location:

090177e196ae3d5d\Final\Final On: 01-Apr-2021 04:32 (GMT)

Header Text: C4591001

Visit: V2_VAX2_L

Form Version: 10-Oct-2020 16:01

Site No: 1214

Subject No: 12141018

Generated By: (b) (4)

Form: VITAL SIGNS - TEMP - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1214) ISTANBUL UNIVERSITY MEDICAL FACULTY
CARDIOLOGY INSTITUTE

Subject Initials: ---

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

Date	Location	User	Value	Reason
Nov-23-2020 11:25:41 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: FOREHEAD	Initial Entry

Header Text: C4591001

Visit: V2_VAX2_L

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1214

Site Name: (1214) ISTANBUL UNIVERSITY MEDICAL FACULTY
CARDIOLOGY INSTITUTE

Subject No: 12141018

Subject Initials: ---

Generated By: (b) (4)

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

[Back to Form](#)

1. Data Origin

Date	Location	User	Value	Reason
Nov-23-2020 11:25:58 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Nov-23-2020 11:25:58 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: NASAL_SWAB	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Nov-23-2020 11:51:47 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Nov-23-2020 11:25:58 (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-23-2020 11:25:58 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Date of Collection: Nov/23/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Nov-23-2020 11:51:47 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BPZD72	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
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090177e196ae3d5d\Final\Final On: 01-Apr-2021 04:32 (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: 1214

Site Name: (1214) ISTANBUL UNIVERSITY MEDICAL FACULTY
CARDIOLOGY INSTITUTE

Subject No: 12141018

Subject Initials: ---

Generated By: (b) (4)

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

Nov-23-2020 11:51:47 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BPZD72	Initial Entry
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Header Text: C4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:04

Site No: 1214

Subject No: 12141018

Generated By: (b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1214) ISTANBUL UNIVERSITY MEDICAL FACULTY
CARDIOLOGY INSTITUTE

Subject Initials: ---

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

[Back to Form](#)

1. Was there a temporary delay of vaccination?

Date	Location	User	Value	Reason
Nov-23-2020 11:26:55 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2. Treatment Name

Date	Location	User	Value	Reason
Nov-23-2020 11:26:55 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: BLINDED THERAPY	Initial Entry

3. Formulation:

Date	Location	User	Value	Reason
Nov-23-2020 11:26:55 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: INJECTION	Initial Entry

4. Dose Date Time:

Date	Location	User	Value	Reason
Nov-23-2020 11:26:55 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Nov/23/2020 09:43	Initial Entry

5. Anatomical Location:

Date	Location	User	Value	Reason
Nov-23-2020 11:26:55 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: DELTOID MUSCLE	Initial Entry

6. Body Side:

Date	Location	User	Value	Reason
Nov-23-2020 11:26:55 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: LEFT	Initial Entry

090177e196ae3d5d\Final\Final On: 01-Apr-2021 04:32 (GMT)

Header Text: C4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:04

Site No: 1214

Subject No: 12141018

Generated By: (b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1214) ISTANBUL UNIVERSITY MEDICAL FACULTY
CARDIOLOGY INSTITUTE

Subject Initials: ---

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

7. Route:

Date	Location	User	Value	Reason
Nov-23-2020 11:26:55 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: INTRAMUSCULAR	Initial Entry

10. Timeframe Subject Was Observed

Date	Location	User	Value	Reason
Nov-23-2020 11:26:55 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: THE PROTOCOL SPECIFIED OB SERVATION PERIOD	Initial Entry

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

Date	Location	User	Value	Reason
Nov-23-2020 11:26:55 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

090177e196ae3d5d\Final\Final On: 01-Apr-2021 04:32 (GMT)

Header Text: C4591001

Visit: V3_MONTH1_POSTVAX2_L

Form Version: 22-Apr-2020 21:02

Site No: 1214

Subject No: 12141018

Generated By: (b) (4)

Form: DATE OF VISIT - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1214) ISTANBUL UNIVERSITY MEDICAL FACULTY
CARDIOLOGY INSTITUTE

Subject Initials: ---

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

[Back to Form](#)

I. Date of Visit

Date	Location	User	Value	Reason
Dec-21-2020 11:15:33 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Dec/21/2020	Initial Entry

Header Text: C4591001

Visit: V3_MONTH1_POSTVAX2_L

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

Form Version: 10-Oct-2020 16:03

Form Status: Data Complete, Frozen, Verified

Site No: 1214

Site Name: (1214) ISTANBUL UNIVERSITY MEDICAL FACULTY CARDIOLOGY INSTITUTE

Subject No: 12141018

Subject Initials: ---

Generated By: (b) (4)

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

[Back to Form](#)

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

Date	Location	User	Value	Reason
Dec-21-2020 11:16:14 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2.a

Date	Location	User	Value	Reason
Dec-21-2020 11:16:14 (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?: NO	Initial Entry

2.a Symptom:

Date	Location	User	Value	Reason
Dec-21-2020 11:16:14 (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-21-2020 11:16:14 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2.b

Date	Location	User	Value	Reason
Dec-21-2020 11:16:14 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom:: FAT	Initial Entry

090177e196ae3d5d\Final\Final On: 01-Apr-2021 04:32 (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: 1214
Site Name: (1214) ISTANBUL UNIVERSITY MEDICAL FACULTY CARDIOLOGY INSTITUTE
Subject No: 12141018
Subject Initials: ---
Generated By: (b) (4)
Generated Time (GMT): 29-Mar-2021 13:11

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

2.b Symptom:

Date	Location	User	Value	Reason
Dec-21-2020 11:16:14 (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
Dec-21-2020 11:16:14 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2.c

Date	Location	User	Value	Reason
Dec-21-2020 11:16:14 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom:: HEA DA CHE Were fever or systemic symptoms present on the last day the Subject Diary was completed?: NO	Initial Entry

090177e196ae3d5d\Final\Final On: 01-Apr-2021 04:32 (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: 1214

Site Name: (1214) ISTANBUL UNIVERSITY MEDICAL FACULTY CARDIOLOGY INSTITUTE

Subject No: 12141018

Subject Initials: ---

Generated By: (b) (4)

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

2.c Symptom:

Date	Location	User	Value	Reason
Dec-21-2020 11:16:14 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: HEADACHE	Initial Entry

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

Date	Location	User	Value	Reason
Dec-21-2020 11:16:14 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2.d

Date	Location	User	Value	Reason
Dec-21-2020 11:16:14 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom:: CH IL LS Were fever or systemic symptoms present on the last day the Subject Diary was completed?: NO	Initial Entry

2.d Symptom:

Date	Location	User	Value	Reason
Dec-21-2020 11:16:14 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: CHILLS	Initial Entry

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

Date	Location	User	Value	Reason
Dec-21-2020 11:16:14 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2.e

090177e196ae3d5d\Final\Final On: 01-Apr-2021 04:32 (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: 1214

Site Name: (1214) ISTANBUL UNIVERSITY MEDICAL FACULTY CARDIOLOGY INSTITUTE

Subject No: 12141018

Subject Initials: ---

Generated By: (b) (4)

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

Date	Location	User	Value	Reason
Dec-21-2020 11:16:14 (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-21-2020 11:16:14 (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-21-2020 11:16:14 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2.f

Date	Location	User	Value	Reason
Dec-21-2020 11:16:14 (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

090177e196ae3d5d\Final\Final On: 01-Apr-2021 04:32 (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: 1214

Site Name: (1214) ISTANBUL UNIVERSITY MEDICAL FACULTY CARDIOLOGY INSTITUTE

Subject No: 12141018

Subject Initials: ---

Generated By: (b) (4)

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

2.f Symptom:

Date	Location	User	Value	Reason
Dec-21-2020 11:16:14 (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-21-2020 11:16:14 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2.g

Date	Location	User	Value	Reason
Dec-21-2020 11:16:14 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom:: NEW OR WORSE ED MUS CLE PAIN Were fever or systemi c symptoms present o n the last day the Sub ject Diary was comple ted?: NO	Initial Entry

2.g Symptom:

Date	Location	User	Value	Reason
Dec-21-2020 11:16:14 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NEW OR WORSE NED MUS CLE 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-21-2020 11:16:14 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

090177e196ae3d5d\Final\Final On: 01-Apr-2021 04:32 (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: 1214

Site Name: (1214) ISTANBUL UNIVERSITY MEDICAL FACULTY CARDIOLOGY INSTITUTE

Subject No: 12141018

Subject Initials: ---

Generated By: (b) (4)

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

2.h

Date	Location	User	Value	Reason
Dec-21-2020 11:16:14 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom:: NEW OR WORSE NED JOINT PAIN Were fever or systemic symptoms present on the last day the Subject Diary was completed?: NO	Initial Entry

2.h Symptom:

Date	Location	User	Value	Reason
Dec-21-2020 11:16:14 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NEW OR WORSE NED JOINT PAIN	Initial Entry

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

Date	Location	User	Value	Reason
Dec-21-2020 11:16:14 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

3. Injection Site Location:

Date	Location	User	Value	Reason
Dec-21-2020 11:16:14 (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-21-2020 11:16:14 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: LEFT	Initial Entry

090177e196ae3d5d\Final\Final On: 01-Apr-2021 04:32 (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: 1214

Site Name: (1214) ISTANBUL UNIVERSITY MEDICAL FACULTY CARDIOLOGY INSTITUTE

Subject No: 12141018

Subject Initials: ---

Generated By: (b) (4)

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

5.a

Date	Location	User	Value	Reason
Dec-21-2020 11:16:14 (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-21-2020 11:16:14 (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-21-2020 11:16:14 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

5.b

Date	Location	User	Value	Reason
Dec-21-2020 11:16:14 (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

090177e196ae3d5d\Final\Final On: 01-Apr-2021 04:32 (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: 1214

Site Name: (1214) ISTANBUL UNIVERSITY MEDICAL FACULTY CARDIOLOGY INSTITUTE

Subject No: 12141018

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-21-2020 11:16:14 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: SWELLING	Initial Entry

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

Date	Location	User	Value	Reason
Dec-21-2020 11:16:14 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

5.c

Date	Location	User	Value	Reason
Dec-21-2020 11:16:14 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Injection Site Reaction: PAIN AT INJECTION SITE Were injection site reactions present on the last day the Subject Diary was completed?: NO	Initial Entry

5.c Injection Site Reaction:

Date	Location	User	Value	Reason
Dec-21-2020 11:16:14 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: PAIN AT INJECTION SITE	Initial Entry

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

Date	Location	User	Value	Reason
Dec-21-2020 11:16:14 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

090177e196ae3d5d\Final\Final On: 01-Apr-2021 04:32 (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:** 1214**Site Name:** (1214) ISTANBUL UNIVERSITY MEDICAL FACULTY CARDIOLOGY INSTITUTE**Subject No:** 12141018**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
Dec-21-2020 11:16:51 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Dec-21-2020 11:16:51 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SERUM	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Dec-21-2020 14:05:24 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Dec-21-2020 11:16:51 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Dec-21-2020 11:16:51 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Date of Collection: Dec/21/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Dec-21-2020 14:05:24 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BPZD9H	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
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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: 1214

Site Name: (1214) ISTANBUL UNIVERSITY MEDICAL FACULTY CARDIOLOGY INSTITUTE

Subject No: 12141018

Subject Initials: ---

Generated By: (b) (4)

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

Dec-21-2020 14:05:24 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BPZD9H	Initial Entry
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5.b

Date	Location	User	Value	Reason
Dec-21-2020 14:05:36 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BPZD9J	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Dec-21-2020 14:05:36 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BPZD9J	Initial Entry

5.c

Date	Location	User	Value	Reason
Dec-21-2020 14:05:47 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BSHD4S	Initial Entry

5.c Sample ID

Date	Location	User	Value	Reason
Dec-21-2020 14:05:47 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BSHD4S	Initial Entry

5.d

Date	Location	User	Value	Reason
Dec-21-2020 14:05:57 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BSHD4T	Initial Entry

5.d Sample ID

Date	Location	User	Value	Reason
Dec-21-2020 14:05:57 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BSHD4T	Initial Entry

090177e196ae3d5d\Final\Final On: 01-Apr-2021 04:32 (GMT)

Header Text: C4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1214

Subject No: 12141018

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - Audit Trail

Form Status:

Site Name: (1214) ISTANBUL UNIVERSITY MEDICAL FACULTY
CARDIOLOGY INSTITUTE

Subject Initials: ---

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

[Back to Form](#)

Date	Location	User	Value	Reason
Nov-23-2020 11:22:32 (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: 1214

Subject No: 12141018

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - Audit Trail

Form Status:

Site Name: (1214) ISTANBUL UNIVERSITY MEDICAL FACULTY
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Subject Initials: ---

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

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

[Back to Form](#)

Date	Location	User	Value	Reason
Jan-08-2021 12:25:16 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Deleted	Transcription Error
Dec-21-2020 14:22:31 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Created	

090177e196ae3d5d\Final\Final On: 01-Apr-2021 04:32 (GMT)

Header Text: C4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1214

Subject No: 12141018

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - Audit Trail

Form Status:

Site Name: (1214) ISTANBUL UNIVERSITY MEDICAL FACULTY
CARDIOLOGY INSTITUTE

Subject Initials: ---

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

[Back to Form](#)

Date	Location	User	Value	Reason
Dec-21-2020 14:28:43 (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: 1214

Subject No: 12141018

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - Audit Trail

Form Status:

Site Name: (1214) ISTANBUL UNIVERSITY MEDICAL FACULTY
CARDIOLOGY INSTITUTE

Subject Initials: ---

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

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

[Back to Form](#)

Date	Location	User	Value	Reason
Jan-28-2021 16:39:02 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Deleted	Changed Information
Jan-08-2021 12:20:11 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Created	

090177e196ae3d5d\Final\Final On: 01-Apr-2021 04:32 (GMT)

Header Text: C4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1214

Subject No: 12141018

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Not Complete

Site Name: (1214) ISTANBUL UNIVERSITY MEDICAL FACULTY
CARDIOLOGY INSTITUTE

Subject Initials: ---

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

[Back to Form](#)

1. Category:

Date	Location	User	Value	Reason
Nov-23-2020 11:22:32 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: ADVERSE EVENT	Initial Entry

2. AE ID:

Date	Location	User	Value	Reason
Nov-23-2020 11:22:32 (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
Jan-28-2021 16:40:55 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: recurrence vertebral disc herniation	Transcription Error
Jan-08-2021 19:38:22 (UTC+03:00) Istanbul	ACV0PFEINFP6000	Quan Jason Gong (b) (4)	Query 1: Closed	Response satisfies query
Jan-08-2021 12:10:47 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: recurrent vertebral disk herniation	Transcription Error
Jan-06-2021 09:44:56 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	recurrent vertebral disc herniation
Jan-05-2021 21:16:53 (UTC+03:00) Istanbul	ACV0PFEINFP6000	Quan Jason Gong (b) (4)	Query 1: Opened	GPDClin: Please clarify if the term should be "Worsening of vertebral disc herniation" or "Recurrent vertebral disc herniation" or and make the change as appropriate.
Nov-23-2020 11:22:32 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: vertebral disk herniation	Initial Entry

090177e196ae3d5d\Final\Final On: 01-Apr-2021 04:32 (GMT)

Header Text: C4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1214

Subject No: 12141018

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Not Complete

Site Name: (1214) ISTANBUL UNIVERSITY MEDICAL FACULTY
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Subject Initials: ---

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

4. Start Date Time:

Date	Location	User	Value	Reason
Nov-23-2020 11:22:32 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Nov/18/2020 UNK:UNK	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Dec-22-2020 12:12:42 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO End Date Time: Dec/2/2020 UNK:UNK	New Information
Nov-23-2020 11:22:32 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

6. Toxicity Grade:

Date	Location	User	Value	Reason
Feb-03-2021 00:09:08 (UTC+03:00) Istanbul	ACV0PFEINFP6000	Quan Jason Gong (b) (4)	Query 2: Closed	Response satisfies query
Feb-02-2021 11:34:12 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Answered	Transcription Error
Feb-02-2021 11:34:12 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 2	Transcription Error
Feb-01-2021 18:37:35 (UTC+03:00) Istanbul	ACV0PFEINFP6000	Quan Jason Gong (b) (4)	Query 2: Opened	GPDClin: As this AE required bed rest and analgesic, then ultimately required surgery and hospitalization, a higher grade/severity may be more appropriate.
Jan-08-2021 19:38:37 (UTC+03:00) Istanbul	ACV0PFEINFP6000	Quan Jason Gong (b) (4)	Query 1: Closed	Response satisfies query

090177e196ae3d5d\Final\Final On: 01-Apr-2021 04:32 (GMT)

Header Text: C4591001**Visit:** Logs - Unscheduled**Form Version:** 22-Apr-2020 21:02**Site No:** 1214**Subject No:** 12141018**Generated By:** (b) (4)**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History**Form Status:** Data Complete, Frozen, Not Complete**Site Name:** (1214) ISTANBUL UNIVERSITY MEDICAL FACULTY
CARDIOLOGY INSTITUTE**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 13:11

Jan-06-2021 10:01:34 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	When AE was reported, surgery was not required so grade was determined as G1. Grade of surgery was already determined as G2.
Jan-05-2021 21:19:15 (UTC+03:00) Istanbul	ACV0PFEINFP6000	Quan Jason Gong (b) (4)	Query 1: Reissued:Opened	GPDClin: As this AE ultimately required surgery and hospitalization, a higher grade/severity may be more appropriate. If agree, please make appropriate change.
Dec-22-2020 13:54:33 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	When AE was reported, surgery was not required so grade was determined as G1
Dec-22-2020 10:27:44 (UTC+03:00) Istanbul	ACV0PFEINFP6000	Quan Jason Gong (b) (4)	Query 1: Opened	GPDClin: For a AE requiring surgery intervention, its grade can not be mild (G1), please report the AE grade appropriately.
Nov-23-2020 11:22:32 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 1	Initial Entry

7. Is the adverse event serious?**If Yes, NOTIFY PFIZER IMMEDIATELY.****Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).**

Date	Location	User	Value	Reason
Feb-01-2021 18:51:31 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Deleted	Close Auto Query

Header Text: C4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1214

Subject No: 12141018

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Not Complete

Site Name: (1214) ISTANBUL UNIVERSITY MEDICAL FACULTY
CARDIOLOGY INSTITUTE

Subject Initials: ---

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

Jan-28-2021 16:43:52 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Candidate	For AE recurrence vertebral disc herniation: Response to "Is the adverse event serious?" is 'Yes' but "Serious Adverse Event Number" is blank.
Jan-28-2021 16:43:52 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Is this serious event associated with congenital anomaly or birt h defect? NO Did this serious event result in d eath? NO Did this serious event require or prolong hospitalization? YES Did this serious event result in p ersistent or significant disability /incapacity? NO Is this serious event life threaten ing? NO Other medically important serio us event NO	Changed Information
Jan-08-2021 19:38:50 (UTC+03:00) Istanbul	ACV0PFEINFP6000	Quan Jason Gong (b) (4)	Query 1: Closed	Response satisfies query

090177e196ae3d5d\Final\Final On: 01-Apr-2021 04:32 (GMT)

Header Text: C4591001**Visit:** Logs - Unscheduled**Form Version:** 22-Apr-2020 21:02**Site No:** 1214**Subject No:** 12141018**Generated By:** (b) (4)**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History**Form Status:** Data Complete, Frozen, Not Complete**Site Name:** (1214) ISTANBUL UNIVERSITY MEDICAL FACULTY
CARDIOLOGY INSTITUTE**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 13:11

Jan-06-2021 09:59:14 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	When AE was reported, hospitalization was not needed and it was reported as AE. For the rest, surgery and hospitalization was reported as SAE when they were needed.
Jan-05-2021 21:22:45 (UTC+03:00) Istanbul	ACV0PFEINFP6000	Quan Jason Gong (b) (4)	Query 1: Reissued:Opened	GPDClin: Per SAE report, this AE ultimately resulted in surgery and hospitalization. Therefore, it should be a SAE (per hospitalization criterion). The fusion surgery was not an AE/SAE, but was the non-drug treatment of this SAE.
Dec-22-2020 13:51:48 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	When AE was reported, surgery was not required.
Dec-22-2020 10:29:19 (UTC+03:00) Istanbul	ACV0PFEINFP6000	Quan Jason Gong (b) (4)	Query 1: Opened	GPDClin: As this AE resulted in hospitalization for surgery, it should be reported as a SAE due to hospitalization.
Nov-23-2020 11:22:32 (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
Nov-23-2020 11:22:32 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

Header Text: C4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1214

Subject No: 12141018

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Not Complete

Site Name: (1214) ISTANBUL UNIVERSITY MEDICAL FACULTY
CARDIOLOGY INSTITUTE

Subject Initials: ---

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

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

9. Is this event related to study treatment:

Date	Location	User	Value	Reason
Nov-23-2020 11:22:32 (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: disk herniation	Initial Entry

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Nov-23-2020 11:22:32 (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-23-2020 11:22:32 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Dec-23-2020 19:12:13 (UTC+03:00) Istanbul	ACV0PFEINFP6000	Quan Jason Gong (b) (4)	Query 1: Closed	Response satisfies query
Dec-22-2020 13:54:58 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Changed Information
Dec-22-2020 13:54:58 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Changed Information

090177e196ae3d5d\Final\Final On: 01-Apr-2021 04:32 (GMT)

Header Text: C4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1214

Subject No: 12141018

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Not Complete

Site Name: (1214) ISTANBUL UNIVERSITY MEDICAL FACULTY
CARDIOLOGY INSTITUTE

Subject Initials: ---

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

Dec-22-2020 10:30:53 (UTC+03:00) Istanbul	ACV0PFEINFP6000	Quan Jason Gong (b) (4)	Query 1: Opened	GPDClin: As surgery (which is a non-drug treatment) was performed for this condition, please update this to "Yes".
Nov-23-2020 11:22:32 (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-22-2020 13:52:25 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Dec-22-2020 13:52:25 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: RECOVERED/RESOLVED	New Information
Dec-22-2020 12:12:42 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	For AE vertebral disk herniation: Response to "What was the outcome of this adverse event?" is 'Not Recovered/Not Resolved' but AE End Date/Time is present.
Nov-23-2020 11:22:32 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NOT RECOVERED/NOT RESOLVED	Initial Entry

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

Date	Location	User	Value	Reason
Nov-23-2020 11:22:32 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

15. Serious Adverse Event Number: For Pfizer Use Only

090177e196ae3d5d\Final\Final On: 01-Apr-2021 04:32 (GMT)

Header Text: C4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1214

Subject No: 12141018

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Not Complete

Site Name: (1214) ISTANBUL UNIVERSITY MEDICAL FACULTY
CARDIOLOGY INSTITUTE

Subject Initials: ---

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

Date	Location	User	Value	Reason
Feb-01-2021 18:51:31 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 2020505098	Initial Entry

090177e196ae3d5d\Final\Final On: 01-Apr-2021 04:32 (GMT)

Header Text: C4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1214

Subject No: 12141018

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Deleted

Site Name: (1214) ISTANBUL UNIVERSITY MEDICAL FACULTY
CARDIOLOGY INSTITUTE

Subject Initials: ---

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

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

[Back to Form](#)

1. Category:

Date	Location	User	Value	Reason
Dec-21-2020 14:22:31 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: ADVERSE EVENT	Initial Entry

2. AE ID:

Date	Location	User	Value	Reason
Dec-21-2020 14:22:31 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 2	Initial Entry

3. Adverse Event:

(If possible specify diagnosis, not individual symptoms)

Date	Location	User	Value	Reason
Jan-08-2021 19:42:11 (UTC+03:00) Istanbul	ACV0PFEINFP6000	Quan Jason Gong (b) (4)	Query 1: Closed	Response satisfies query
Jan-06-2021 09:44:27 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	spinal fusion surgery caused the hospitalization so it was commented as SAE
Jan-05-2021 21:26:31 (UTC+03:00) Istanbul	ACV0PFEINFP6000	Quan Jason Gong (b) (4)	Query 1: Reissued:Opened	GPDClin: Per protocol 10.3.1, the spinal fusion surgery should not be an AE/SAE, but the non-drug treatment for the SAE of vertebral disc herniation (please see query for the AE). Please remove this from the AE log.
Dec-22-2020 13:53:31 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	When AE (vertebral disk herniation) was

090177e196ae3d5d\Final\Final On: 01-Apr-2021 04:32 (GMT)

Header Text: C4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1214

Subject No: 12141018

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Deleted

Site Name: (1214) ISTANBUL UNIVERSITY MEDICAL FACULTY
CARDIOLOGY INSTITUTE

Subject Initials: ---

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

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		(b) (4), (b) (6)		reported, surgery was not required.
Dec-22-2020 10:24:44 (UTC+03:00) Istanbul	ACV0PFEINFP6000	Quan Jason Gong (b) (4)	Query 1: Opened	GPDClin: Per Protocol 10.3.1, Medical or surgical procedure is not an AE, but the condition that leads to the procedure is the AE. Therefore, please remove it from AE log and report the other AE, "vertebral disk herniation" as a SAE.
Dec-21-2020 14:22:31 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: spinal fusion surgery	Initial Entry

4. Start Date Time:

Date	Location	User	Value	Reason
Dec-21-2020 14:29:19 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Dec/2/2020 UNK:UNK	Transcription Error
Dec-21-2020 14:22:31 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Dec/5/2020 UNK:UNK	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Dec-21-2020 14:29:34 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO End Date Time: Dec/2/2020 UNK:UNK	Transcription Error
Dec-21-2020 14:22:31 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO End Date Time:	Initial Entry

090177e196ae3d5d\Final\Final On: 01-Apr-2021 04:32 (GMT)

Header Text: C4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1214

Subject No: 12141018

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Deleted

Site Name: (1214) ISTANBUL UNIVERSITY MEDICAL FACULTY
CARDIOLOGY INSTITUTE

Subject Initials: ---

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

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

Dec/5/2020 UNK:UNK

6. Toxicity Grade:

Date	Location	User	Value	Reason
Dec-21-2020 14:26:13 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (4), (b) (6)	<u>Data Entry:</u> 2	Initial Entry

7. Is the adverse event serious?

If Yes, NOTIFY PFIZER IMMEDIATELY.

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

Date	Location	User	Value	Reason
Dec-31-2020 11:51:19 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Closed	Response satisfies query
Dec-23-2020 11:10:50 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (4), (b) (6)	Query 2: Answered	Subject reported SAE to study site on 21Dec2020. SAE was reported to Pfizer on 21Dec2020
Dec-22-2020 17:39:27 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Opened	SAE RECON:spinal fusion surgery(Onset date:02Dec2020) 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
Dec-22-2020 16:50:46 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Deleted	Query can be addressed internally

090177e196ae3d5d\Final\Final On: 01-Apr-2021 04:32 (GMT)

Header Text: C4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1214

Subject No: 12141018

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Deleted

Site Name: (1214) ISTANBUL UNIVERSITY MEDICAL FACULTY
CARDIOLOGY INSTITUTE

Subject Initials: ---

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

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

		(b) (4), (b) (6)		
Dec-21-2020 14:22:31 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	For AE spinal fusion surgery: Response to "Is the adverse event serious?" is 'Yes' but "Serious Adverse Event Number" is blank.
Dec-21-2020 14:22:31 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<p>Data Entry: YES</p> <p>Is this serious event associated with congenital anomaly or birth defect?</p> <p>NO</p> <p>Did this serious event result in death?</p> <p>NO</p> <p>Did this serious event require or prolong hospitalization?</p> <p>YES</p> <p>Did this serious event result in persistent or significant disability/incapacity?</p> <p>NO</p> <p>Is this serious event life threatening?</p> <p>NO</p> <p>Other medically important serious event</p> <p>NO</p>	Initial Entry

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

090177e196ae3d5d\Final\Final On: 01-Apr-2021 04:32 (GMT)

Header Text: C4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1214

Subject No: 12141018

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Deleted

Site Name: (1214) ISTANBUL UNIVERSITY MEDICAL FACULTY
CARDIOLOGY INSTITUTE

Subject Initials: ---

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

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

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

Date	Location	User	Value	Reason
Dec-21-2020 14:22:31 (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-21-2020 14:22:31 (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: vertebral disc herniation	Initial Entry

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Dec-21-2020 14:22:31 (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
Dec-21-2020 14:22:31 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Dec-21-2020 14:22:31 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

090177e196ae3d5d\Final\Final On: 01-Apr-2021 04:32 (GMT)

Header Text: C4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1214

Subject No: 12141018

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Deleted

Site Name: (1214) ISTANBUL UNIVERSITY MEDICAL FACULTY
CARDIOLOGY INSTITUTE

Subject Initials: ---

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

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

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

Date	Location	User	Value	Reason
Dec-21-2020 14:22:31 (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-21-2020 14:22:31 (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-31-2020 11:50:28 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 2020505098	Initial Entry

090177e196ae3d5d\Final\Final On: 01-Apr-2021 04:32 (GMT)

Header Text: C4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen

Site No: 1214

Site Name: (1214) ISTANBUL UNIVERSITY MEDICAL FACULTY
CARDIOLOGY INSTITUTE

Subject No: 12141018

Subject Initials: ---

Generated By: (b) (4)

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

[Back to Form](#)

1. Category:

Date	Location	User	Value	Reason
Dec-21-2020 14:28:43 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: ADVERSE EVENT	Initial Entry

2. AE ID:

Date	Location	User	Value	Reason
Dec-21-2020 14:28:43 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 3	Initial Entry

3. Adverse Event:

(If possible specify diagnosis, not individual symptoms)

Date	Location	User	Value	Reason
Jan-08-2021 17:17:16 (UTC+03:00) Istanbul	ACV0PFEINFP6000	Giselle Castillo (b) (4)	Query 1: Closed	Response satisfies query
Jan-05-2021 11:11:15 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	All lab results were reported in SAE form and source document for SAE
Jan-04-2021 17:19:50 (UTC+03:00) Istanbul	ACV0PFEINFP6000	Giselle Castillo (b) (4)	Query 1: Reissued:Opened	Thank you for your response. Kindly provide work-up/imaging and other lab tests performed during hospital stay in a FU form. Thanks!
Dec-24-2020 11:59:06 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Subject said that COVID-19 test worked up in hospital and result was negative.
Dec-23-2020 23:17:29 (UTC+03:00) Istanbul	ACV0PFEINFP6000	Giselle Castillo (b) (4)	Query 1: Opened	Clinical_ AER#2020505098. Per SAE form

090177e196ae3d5d\Final\Final On: 01-Apr-2021 04:32 (GMT)

Header Text: C4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1214

Subject No: 12141018

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Frozen

Site Name: (1214) ISTANBUL UNIVERSITY MEDICAL FACULTY
CARDIOLOGY INSTITUTE

Subject Initials: ---

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

				submitted to safety, subject was hospitalized during 10 days, however work-up/imaging and lab tests (including covid test) are not reported. Kindly provide missing information in a FU report. Thank you.
Dec-21-2020 14:28:43 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: pulmonary embolism	Initial Entry

4. Start Date Time:

Date	Location	User	Value	Reason
Dec-21-2020 14:28:43 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Dec/5/2020 UNK:UNK	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Dec-21-2020 14:28:43 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO End Date Time: Dec/5/2020 UNK:UNK	Initial Entry

6. Toxicity Grade:

Date	Location	User	Value	Reason
Dec-21-2020 14:28:43 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 2	Initial Entry

7. Is the adverse event serious?

If Yes, NOTIFY PFIZER IMMEDIATELY.

Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may

090177e196ae3d5d\Final\Final On: 01-Apr-2021 04:32 (GMT)

Header Text: C4591001

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Form Version: 22-Apr-2020 21:02

Site No: 1214

Subject No: 12141018

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Frozen

Site Name: (1214) ISTANBUL UNIVERSITY MEDICAL FACULTY
CARDIOLOGY INSTITUTE

Subject Initials: ---

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

require medical/surgical intervention to prevent above outcomes).

Date	Location	User	Value	Reason
Dec-22-2020 15:01:19 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Dec-21-2020 14:28:43 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	For AE pulmonary embolism: Response to "Is the adverse event serious?" is 'Yes' but "Serious Adverse Event Number" is blank.
Dec-21-2020 14:28:43 (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/in capacity?</p> <p>NO</p> <p>Is this serious event life threatening?</p> <p>NO</p> <p>Other medically important serious event</p>	Initial Entry

090177e196ae3d5d\Final\Final On: 01-Apr-2021 04:32 (GMT)

Header Text: C4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1214

Subject No: 12141018

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Frozen

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Subject Initials: ---

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

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.

Date	Location	User	Value	Reason
Dec-21-2020 14:28:43 (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-21-2020 14:28:43 (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: immobility and surgery	Initial Entry

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Dec-21-2020 14:28:43 (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
Dec-21-2020 14:28:43 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Dec-21-2020 14:28:43 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

090177e196ae3d5d\Final\Final On: 01-Apr-2021 04:32 (GMT)

Header Text: C4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1214

Subject No: 12141018

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Frozen

Site Name: (1214) ISTANBUL UNIVERSITY MEDICAL FACULTY
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Subject Initials: ---

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

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

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

Date	Location	User	Value	Reason
Dec-21-2020 14:28:43 (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-21-2020 14:28:43 (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-22-2020 15:01:19 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 2020505098	Initial Entry

090177e196ae3d5d\Final\Final On: 01-Apr-2021 04:32 (GMT)

Header Text: C4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1214

Subject No: 12141018

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Deleted

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Subject Initials: ---

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

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[Back to Form](#)

1. Category:

Date	Location	User	Value	Reason
Jan-08-2021 12:20:11 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: ADVERSE EVENT	Initial Entry

2. AE ID:

Date	Location	User	Value	Reason
Jan-08-2021 12:20:11 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 4	Initial Entry

3. Adverse Event:

(If possible specify diagnosis, not individual symptoms)

Date	Location	User	Value	Reason
Jan-08-2021 12:20:11 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Worsening of vertebral disc herniation	Initial Entry

4. Start Date Time:

Date	Location	User	Value	Reason
Jan-08-2021 12:20:32 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Jan-08-2021 12:20:32 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Dec/2/2020 UNK:UNK	Transcription Error
Jan-08-2021 12:20:11 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	For AE Worsening of vertebral disc herniation: Start Date is the same as a Vaccination Date, but time is not provided. Please review and update as appropriate.

090177e196ae3d5d\Final\Final On: 01-Apr-2021 04:32 (GMT)

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Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1214

Subject No: 12141018

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Deleted

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Subject Initials: ---

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

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Jan-08-2021 12:20:11 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Nov/2/2020 UNK:UNK	Initial Entry
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5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Jan-08-2021 12:20:11 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NO End Date Time: Dec/2/2020 UNK:UNK	Initial Entry

6. Toxicity Grade:

Date	Location	User	Value	Reason
Jan-08-2021 12:22:02 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> 2	Initial Entry

7. Is the adverse event serious?

If Yes, NOTIFY PFIZER IMMEDIATELY.

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

Date	Location	User	Value	Reason
Jan-11-2021 10:21:46 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Jan-08-2021 12:21:43 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Closed	Close Auto Query
Jan-08-2021 12:21:43 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> YES Is this serious event associated with congenital anomaly or birth defect? NO	Transcription Error

090177e196ae3d5d\Final\Final On: 01-Apr-2021 04:32 (GMT)

Header Text: C4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1214

Subject No: 12141018

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

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Site Name: (1214) ISTANBUL UNIVERSITY MEDICAL FACULTY
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Subject Initials: ---

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

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			<p>Did this serious event result in death?</p> <p>NO</p> <p>Did this serious event require or prolong hospitalization?</p> <p>YES</p> <p>Did this serious event result in persistent or significant disability/incapacity?</p> <p>NO</p> <p>Is this serious event life threatening?</p> <p>NO</p> <p>Other medically important serious event</p> <p>NO</p>	
Jan-08-2021 12:21:16 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<p>Data Entry:</p> <p>YES</p> <p>Did this serious event require or prolong hospitalization?</p> <p>YES</p> <p>Other medically important serious event</p>	Transcription Error
Jan-08-2021 12:20:11 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Opened	Is this adverse event serious?' is reported 'Yes', but at least one seriousness criteria is missing. Please review and update as appropriate.
Jan-08-2021 12:20:11	ACV0PFEINFP6000	auto query	Query 1: Candidate	For AE Worsening

090177e196ae3d5d\Final\Final On: 01-Apr-2021 04:32 (GMT)

Header Text: C4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1214

Subject No: 12141018

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Deleted

Site Name: (1214) ISTANBUL UNIVERSITY MEDICAL FACULTY
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Subject Initials: ---

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

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(UTC+03:00) Istanbul		(autoquery)		of vertebral disc herniation: Response to "Is the adverse event serious?" is 'Yes' but "Serious Adverse Event Number" is blank.
Jan-08-2021 12:20:11 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Other medically important serious event YES	Initial Entry

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

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

Date	Location	User	Value	Reason
Jan-08-2021 12:20:11 (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
Jan-08-2021 12:22:45 (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: vertebral disc herniation	Transcription Error
Jan-08-2021 12:20:11 (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	Initial Entry

090177e196ae3d5d\Final\Final On: 01-Apr-2021 04:32 (GMT)

Header Text: C4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1214

Subject No: 12141018

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Deleted

Site Name: (1214) ISTANBUL UNIVERSITY MEDICAL FACULTY
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Subject Initials: ---

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

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

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Jan-08-2021 12:20:11 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NOT APPLICABLE	Initial Entry

11. Was a Concomitant Medication given?

Date	Location	User	Value	Reason
Jan-08-2021 12:20:11 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> YES	Initial Entry

12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Jan-08-2021 12:20:11 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> YES	Initial Entry

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

Date	Location	User	Value	Reason
Jan-08-2021 12:20:11 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> RECOVERED/RESOLVED	Initial Entry

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

Date	Location	User	Value	Reason
Jan-08-2021 12:20:11 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NO	Initial Entry

15. Serious Adverse Event Number: For Pfizer Use Only

Date	Location	User	Value	Reason
Jan-11-2021 10:21:46 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> 2020505098	Initial Entry

090177e196ae3d5d\Final\Final On: 01-Apr-2021 04:32 (GMT)

Header Text: C4591001

Visit: Logs - Unscheduled

Form Version: 17-Jul-2020 21:54

Site No: 1214

Subject No: 12141018

Generated By: (b) (4)

Form: MEDICATION ERROR - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1214) ISTANBUL UNIVERSITY MEDICAL FACULTY
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Subject Initials: ---

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

[Back to Form](#)

1. Category:

Date	Location	User	Value	Reason
Nov-23-2020 11:22:48 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

2. Medication Error (Type of Medication Error):

Date	Location	User	Value	Reason
Nov-23-2020 11:22:48 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

3. Start Date:

Date	Location	User	Value	Reason
Nov-23-2020 11:22:48 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

4. Is the medication error still ongoing?

Date	Location	User	Value	Reason
Nov-23-2020 11:22:48 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Nov-23-2020 11:22:48 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

6. Was a Concomitant Medication given?

Date	Location	User	Value	Reason
Nov-23-2020 11:22:48 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

090177e196ae3d5d\Final\Final On: 01-Apr-2021 04:32 (GMT)

Header Text: C4591001

Visit: Logs - Unscheduled

Form Version: 17-Jul-2020 21:54

Site No: 1214

Subject No: 12141018

Generated By: (b) (4)

Form: MEDICATION ERROR - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1214) ISTANBUL UNIVERSITY MEDICAL FACULTY
CARDIOLOGY INSTITUTE

Subject Initials: ---

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

		(b) (4), (b) (6)		
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7. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Nov-23-2020 11:22:48 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

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

Date	Location	User	Value	Reason
Nov-23-2020 11:22:48 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

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

Date	Location	User	Value	Reason
Nov-23-2020 11:22:48 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

10. Serious Adverse Event Number: For Pfizer Use Only

Date	Location	User	Value	Reason
Nov-23-2020 11:22:48 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

090177e196ae3d5d\Final\Final On: 01-Apr-2021 04:32 (GMT)

Header Text: C4591001

Visit: Logs - Unscheduled

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1214

Site Name: (1214) ISTANBUL UNIVERSITY MEDICAL FACULTY
CARDIOLOGY INSTITUTE

Subject No: 12141018

Subject Initials: ---

Generated By: (b) (4)

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

[Back to Form](#)

1. What is the medication identifier?

Date	Location	User	Value	Reason
Nov-23-2020 11:23:11 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

2. Category:

Date	Location	User	Value	Reason
Nov-23-2020 11:23:11 (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-23-2020 11:23:11 (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-23-2020 11:23:11 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5. Date:

Date	Location	User	Value	Reason
Nov-23-2020 11:23:11 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

090177e196ae3d5d\Final\Final On: 01-Apr-2021 04:32 (GMT)

Header Text: C4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1214

Subject No: 12141018

Generated By: (b) (4)

Form: CONCOMITANT MEDICATIONS - PROHIBITED - Audit Trail

Form Status:

Site Name: (1214) ISTANBUL UNIVERSITY MEDICAL FACULTY
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Subject Initials: ---

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

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

[Back to Form](#)

Date	Location	User	Value	Reason
Jan-12-2021 17:14:01 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Deleted	Transcription Error
Jan-12-2021 17:13:00 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Undeleted	Transcription Error
Jan-12-2021 17:10:27 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Deleted	Transcription Error

Header Text: C4591001

Visit: Logs - Unscheduled

Form: CONCOMITANT MEDICATIONS - PROHIBITED - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Incomplete, Data Complete, Deleted, Verified

Site No: 1214

Site Name: (1214) ISTANBUL UNIVERSITY MEDICAL FACULTY CARDIOLOGY INSTITUTE

Subject No: 12141018

Subject Initials: ---

Generated By: (b) (4)

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

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

[Back to Form](#)

1. What is the medication identifier?

Date	Location	User	Value	Reason
Jan-11-2021 10:54:48 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Initial Entry
Nov-23-2020 11:23:30 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

2. Category:

Date	Location	User	Value	Reason
Jan-11-2021 10:54:48 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Initial Entry
Nov-23-2020 11:23:30 (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
Jan-11-2021 10:54:48 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Initial Entry
Nov-23-2020 11:23:30 (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
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090177e196ae3d5d\Final\Final On: 01-Apr-2021 04:32 (GMT)

Jan-15-2021 17:14:59 (UTC+03:00) Istanbul	ACV0PFEINFP6000	Giselle Castillo (b) (4)	Query 1: Closed	Ok, thank you.
Jan-13-2021 15:05:01 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Closed	log line is deleted.
Jan-12-2021 17:13:42 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Answered	This log line was deleted.
Jan-12-2021 10:02:18 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Opened	DM: If there is no data expected to be enter on this form then kindly consider deleting this log line or else update details. Thank you.
Jan-12-2021 10:01:53 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Closed	New issued
Jan-12-2021 09:58:12 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Opened	DM: If there is no data expected to be enter on this form then kindly consider marking this form as Not Applicable by selecting form level comment or else update details. Thank you.
Jan-11-2021 10:55:27 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Original value is correct
Jan-11-2021 10:54:48 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Initial Entry
Jan-08-2021 23:06:02 (UTC+03:00) Istanbul	ACV0PFEINFP6000	Giselle Castillo (b) (4)	Query 1: Reissued:Opened	If this is a mistake, kindly submit a FU form for correction of the information provided. Thanks
Jan-07-2021 15:59:14 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	The subject did not use Dexamethasone.
Jan-06-2021 23:01:50 (UTC+03:00) Istanbul	ACV0PFEINFP6000	Giselle Castillo (b) (4)	Query 1: Reissued:Opened	Please revisit report submitted to safety where records the subject "was treated with DEXAMETHASONE" after spinal fusion surgery. If this is a mistake, kindly submit a FU form for correction of the information provided. Thanks

Jan-05-2021 08:37:07 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	The subject used clexane (2*0,4 ml) at between 06.12.2020-08.12.2020, clexane (2*0,6 ml) at between 08.12.2020-15.12.2020 and clexane (2*0,8 ml) at between 15.12.2020-22.12.2020
Jan-04-2021 17:17:41 (UTC+03:00) Istanbul	ACV0PFEINFP6000	Giselle Castillo (b) (4)	Query 1: Reissued:Opened	Thank you for your response. Per report, The subject "was treated with dexamethasone (DEXONE) 2x 0.8 ml between 02Dec2020 to 16Dec2020." Kindly clarify.
Dec-24-2020 11:51:57 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Subject used clexane for 14 days and subject continues to use xarelto since 16Dec2020. These medicines are not steroid / prohibited medication. These medicines were used for blood thinner.
Dec-24-2020 00:45:05 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	Subject received dexamethasone while in the emergency room, per protocol if the steroids >20mg was given for more than 14 days – that needs to be added to the con med CRF. Please revise accordingly. Thank you.
Dec-23-2020 23:26:58 (UTC+03:00) Istanbul	ACV0PFEINFP6000	Giselle Castillo (b) (4)	Query 1: Candidate	Subject received dexamethasone while in the emergency room, per protocol if the steroids >20mg was given for more than 14 days – that needs to be added to the con med CRF. Please revise accordingly. Thank you.
Nov-23-2020 11:23:30	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Initial Entry

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

Date	Location	User	Value	Reason
Jan-11-2021 10:54:48 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u>	Initial Entry
Nov-23-2020 11:23:30 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Applicable	Initial Entry

6. Dose Unit:

Date	Location	User	Value	Reason
Jan-11-2021 10:54:48 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u>	Initial Entry
Nov-23-2020 11:23:30 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Applicable	Initial Entry

7. Dose Frequency:

Date	Location	User	Value	Reason
Jan-11-2021 10:54:48 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u>	Initial Entry
Nov-23-2020 11:23:30 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Applicable	Initial Entry

8. Route:

Date	Location	User	Value	Reason
Jan-11-2021 10:54:48 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u>	Initial Entry
Nov-23-2020 11:23:30 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Applicable	Initial Entry

9. Start Date:

Date	Location	User	Value	Reason
Jan-11-2021 10:54:48 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u>	Initial Entry

090177e196ae3d5d\Final\Final On: 01-Apr-2021 04:32 (GMT)

Nov-23-2020 11:23:30 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) [redacted] (4), (b) (6)	Data Entry: Not Applicable	Initial Entry
10. Ongoing?				
Date	Location	User	Value	Reason
Jan-11-2021 10:54:48 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) [redacted] (4), (b) (6)	Data Entry:	Initial Entry
Nov-23-2020 11:23:30 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) [redacted] (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

Header Text: C4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1214

Subject No: 12141018

Generated By: (b) (4)

Form: RADIATION TREATMENT - eCRF Audit Trail History

Form Status: Data Complete, Verified

Site Name: (1214) ISTANBUL UNIVERSITY MEDICAL FACULTY
CARDIOLOGY INSTITUTE

Subject Initials: ---

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

[Back to Form](#)

1. Category:

Date	Location	User	Value	Reason
Nov-23-2020 11:23:50 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

2. What is the treatment Identifier?

Date	Location	User	Value	Reason
Nov-23-2020 11:23:50 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

3. Concomitant Non-drug Treatment Pre-specified:

Date	Location	User	Value	Reason
Nov-23-2020 11:23:50 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

4. Treatment:

Date	Location	User	Value	Reason
Nov-23-2020 11:23:50 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5. Start Date:

Date	Location	User	Value	Reason
Nov-23-2020 11:23:50 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

6. Ongoing?

Date	Location	User	Value	Reason
Nov-23-2020 11:23:50 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

090177e196ae3d5d\Final\Final On: 01-Apr-2021 04:32 (GMT)

Header Text: C4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1214

Subject No: 12141018

Generated By: (b) (4)

Form: RADIATION TREATMENT - eCRF Audit Trail History

Form Status: Data Complete, Verified

Site Name: (1214) ISTANBUL UNIVERSITY MEDICAL FACULTY
CARDIOLOGY INSTITUTE

Subject Initials: ---

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

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

090177e196ae3d5d\Final\Final On: 01-Apr-2021 04:32 (GMT)

Header Text: C4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1214

Subject No: 12141018

Generated By: (b) (4)

Form: TRANSFUSIONS - eCRF Audit Trail History

Form Status: Data Complete, Verified

Site Name: (1214) ISTANBUL UNIVERSITY MEDICAL FACULTY
CARDIOLOGY INSTITUTE

Subject Initials: ---

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

[Back to Form](#)

1. Transfusion Type:

Date	Location	User	Value	Reason
Nov-23-2020 11:24:10 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

2. Date of Transfusion:

Date	Location	User	Value	Reason
Nov-23-2020 11:24:10 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

090177e196ae3d5d\Final\Final On: 01-Apr-2021 04:32 (GMT)

Header Text: C4591001

Visit: End of Treatment - Unscheduled

Form Version: 10-Dec-2020 02:29

Site No: 1214

Subject No: 12141018

Generated By: (b) (4)

Form: DISPOSITION - TREATMENT - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1214) ISTANBUL UNIVERSITY MEDICAL FACULTY
CARDIOLOGY INSTITUTE

Subject Initials: ---

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

[Back to Form](#)

1. Date of Completion/Discontinuation/Death :

Date	Location	User	Value	Reason
Dec-21-2020 11:17:18 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Dec/21/2020	Initial Entry

2. Phase of Disposition:

Date	Location	User	Value	Reason
Dec-21-2020 11:17:18 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: VACCINATION	Initial Entry

3. Status:

Date	Location	User	Value	Reason
Dec-21-2020 11:17:18 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: COMPLETED	Initial Entry

090177e196ae3d5d\Final\Final On: 01-Apr-2021 04:32 (GMT)

Header Text: C4591001

Visit: Potential ReVax Initial Contact -
Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1214

Subject No: 12141018

Generated By: (b) (4)

Form: DATE OF VISIT - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1214) ISTANBUL UNIVERSITY MEDICAL FACULTY
CARDIOLOGY INSTITUTE

Subject Initials: ---

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

[Back to Form](#)

1. Date of Visit

Date	Location	User	Value	Reason
Dec-30-2020 14:20:00 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Dec/30/2020	Initial Entry

Header Text: C4591001

Visit: Potential ReVax Initial Contact -
Unscheduled

Form Version: 10-Dec-2020 02:25

Site No: 1214

Subject No: 12141018

Generated By: (b) (4)

Form: FURTHER VACCINATION CONFIRMATION - eCRF Audit
Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1214) ISTANBUL UNIVERSITY MEDICAL FACULTY
CARDIOLOGY INSTITUTE

Subject Initials: ---

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

[Back to Form](#)

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

Date	Location	User	Value	Reason
Dec-30-2020 19:44:12 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Dec-30-2020 14:20:12 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	The response indicates participant was unblinded, however the TREATMENT UNBLINDED date is missing in the DISP visit. Please complete this date.
Dec-30-2020 14:20:12 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Participant is willing to return for Vaccination 3 Participant is: eligible and NOT confirmed to have received only placebo at Vaccination 1/2	Initial Entry

090177e196ae3d5d\Final\Final On: 01-Apr-2021 04:32 (GMT)

Header Text: C4591001

Visit: Disposition - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1214

Subject No: 12141018

Generated By: (b) (4)

Form: TREATMENT UNBLINDED - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1214) ISTANBUL UNIVERSITY MEDICAL FACULTY
CARDIOLOGY INSTITUTE

Subject Initials: ---

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

[Back to Form](#)

1. Date Treatment Unblinded :

Date	Location	User	Value	Reason
Dec-30-2020 19:44:12 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Dec/30/2020	Initial Entry

2. Primary Reason for Unblinding:

Date	Location	User	Value	Reason
Dec-30-2020 19:44:12 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: ASSESS ELIGIBILITY FOR ADD ITIONAL VACCINATION	Initial Entry

090177e196ae3d5d\Final\Final On: 01-Apr-2021 04:32 (GMT)

Header Text: C4591001

Visit: Disposition - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1214

Subject No: 12141018

Generated By: (b) (4)

Form: WITHDRAWAL OF CONSENT - eCRF Audit Trail History

Form Status: Data Complete, Verified

Site Name: (1214) ISTANBUL UNIVERSITY MEDICAL FACULTY
CARDIOLOGY INSTITUTE

Subject Initials: ---

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

[Back to Form](#)

1. Withdrawal of Consent Date :

Date	Location	User	Value	Reason
Dec-30-2020 19:44:23 (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: 1214

Subject No: 12141018

Generated By: (b) (4)

Form: DEATH DETAILS CODED - eCRF Audit Trail History

Form Status: Data Complete, Verified

Site Name: (1214) ISTANBUL UNIVERSITY MEDICAL FACULTY
CARDIOLOGY INSTITUTE

Subject Initials: ---

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

[Back to Form](#)

1. Date of Collection / Notification of Death:

Date	Location	User	Value	Reason
Jan-05-2021 12:12:52 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Closed	Response satisfies query
Jan-04-2021 11:03:22 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Answered	Changed data per query
Jan-04-2021 11:03:11 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry : Not Applicable	Initial Entry
Jan-04-2021 08:22:00 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Opened	DM: If there is no data needs to be reported on this page, kindly consider marking form as Not Applicable by selecting form level comment or else update the details. Thank you.
Dec-31-2020 23:53:07 (UTC+03:00) Istanbul	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (b) (4)	Query 1: Closed	Auto closed by Validation Check: VC_DD002_01
Dec-31-2020 17:54:14 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry :	Transcription Error
Dec-31-2020 17:54:00 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Initial Entry

090177e196ae3d5d\Final\Final On: 01-Apr-2021 04:32 (GMT)

Header Text: C4591001

Visit: Disposition - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1214

Subject No: 12141018

Generated By: (b) (4)

Form: DEATH DETAILS CODED - eCRF Audit Trail History

Form Status: Data Complete, Verified

Site Name: (1214) ISTANBUL UNIVERSITY MEDICAL FACULTY
CARDIOLOGY INSTITUTE

Subject Initials: ---

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

Dec-31-2020 17:54:00 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry : Dec/3 0/202 0	Initial Entry
Dec-31-2020 17:45:20 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry :	Initial Entry
Dec-31-2020 13:54:18 (UTC+03:00) Istanbul	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (b) (4)	Query 1: Op ened	DMW6671032;Date of Collection/Notification of Death is not expected to be Unknown or Not Applicable. Please review and update appropriately or clarify
Dec-30-2020 19:44:38 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry : Not A pplica ble	Initial Entry

090177e196ae3d5d\Final\Final On: 01-Apr-2021 04:32 (GMT)

Header Text: C4591001

Visit: Subject Status - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1214

Subject No: 12141018

Generated By: (b) (4)

Form: SUBJECT STATUS - eCRF Audit Trail History

Form Status: Data Complete, Verified

Site Name: (1214) ISTANBUL UNIVERSITY MEDICAL FACULTY
CARDIOLOGY INSTITUTE

Subject Initials: ---

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

[Back to Form](#)

1. Subject Status

Date	Location	User	Value	Reason
Dec-21-2020 11:17:18 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: FOLLOW-UP	Initial Entry
Nov-02-2020 20:02:47 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: ENROLLED/RANDOMIZED	Initial Entry
Nov-02-2020 19:59:09 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SCREENED	Initial Entry

2. Subject Status Date

Date	Location	User	Value	Reason
Dec-21-2020 11:17:18 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Dec/21/2020	Initial Entry
Nov-02-2020 20:02:47 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Nov/2/2020	Initial Entry
Nov-02-2020 19:59:09 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Nov/2/2020	Initial Entry

090177e196ae3d5d\Final\Final On: 01-Apr-2021 04:32 (GMT)

Header Text: C4591001

Visit: Investigator Signature - Unscheduled

Form Version: 22-Apr-2020 21:04

Site No: 1214

Subject No: 12141018

Generated By: (b) (4)

Form: CASEBOOK SIGNATURE FORM - eCRF Audit Trail History

Form Status: Data Complete, Signed, Verified

Site Name: (1214) ISTANBUL UNIVERSITY MEDICAL FACULTY
CARDIOLOGY INSTITUTE

Subject Initials: ---

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

[Back to Form](#)

I. Casebook Signature

Date	Location	User	Value	Reason
Nov-20-2020 15:25:05 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Click Here to Enable	Initial Entry