

Header Text: C4591001

Visit: COHORT_SELECTION

Form Version: 10-Oct-2020 16:01

Site No: 1214

Subject No: 12141039

Generated By: (b) (4)

Form: COHORT_SELECTION

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](#)

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: 12141039

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/6/2020
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Header Text: C4591001

Visit: COHORT_SELECTION

Form Version: 15-Sep-2020 21:54

Site No: 1214

Subject No: 12141039

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	[12141039]
2.	Birth Date:	(b) (6)/1982
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:	

090177e196ae3d63\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: 12141039

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/6/2020
2.	Erroneous Visit	

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 10-Oct-2020 16:00

Site No: 1214

Subject No: 12141039

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 _____
----	---	-------------------------

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: 12141039

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/6/2020
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: 12141039

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

Medical History Details

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

090177e196ae3d63\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: 12141039

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
----	---	---

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 10-Oct-2020 16:04

Site No: 1214

Subject No: 12141039

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/6/2020
2.	Weight:	[84.0]
3.	Unit:	kg
4.	Height:	[172.0]
5.	Unit:	cm
6.	Body Mass Index:	[28.4]

Vital Signs Details

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

090177e196ae3d63\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: 12141039

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/6/2020
2.	Randomization Number:	[115789]
3.	Randomization Group:	[]

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1214

Subject No: 12141039

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/6/2020
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	[BPZD5B]
5.b	Sample ID	[BPZD5C]
5.c	Sample ID	[BSHCXN]
5.d	Sample ID	[BSHCXP]

090177e196ae3d63\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: 12141039

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/6/2020
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	[BPZD4P]
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Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:04

Site No: 1214

Subject No: 12141039

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/6/2020 11:30
5.	Anatomical Location:	DELTOID MUSCLE
6.	Body Side:	RIGHT
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

090177e196ae3d63\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: 12141039

Generated By: (b) (4)

Form: REACTOGENICITY DIARY

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](#)

Reactogenicity Diary

1.	Select appropriate response - Reactogenicity diary collection	YES - REACTOGENICITY E-DIARY COLLECTED FOR THIS SUBJECT
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Header Text: C4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:02

Site No: 1214

Subject No: 12141039

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/27/2020
2.	Erroneous Visit	

Header Text: C4591001

Visit: V2_VAX2_L

Form Version: 10-Oct-2020 16:03

Site No: 1214

Subject No: 12141039

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

090177e196ae3d63\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: 12141039

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?	YES Ongoing? NO Stop Date: Nov/12/2020
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:	RIGHT
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

090177e196ae3d63\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: 12141039

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/27/2020
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Vital Signs Details

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

Header Text: C4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:03

Site No: 1214

Subject No: 12141039

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/27/2020
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[]

Aliquot

Please enter barcode for each aliquot.

5.a	Sample ID	[BPZD7S]
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090177e196ae3d63\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: 12141039

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/27/2020 12:20
5.	Anatomical Location:	DELTOID MUSCLE
6.	Body Side:	RIGHT
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

090177e196ae3d63\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: 12141039

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/28/2020
2.	Erroneous Visit	

Header Text: C4591001

Visit: V3_MONTH1_POSTVAX2_L

Form Version: 10-Oct-2020 16:03

Site No: 1214

Subject No: 12141039

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

090177e196ae3d63\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: 12141039

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:	RIGHT
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

090177e196ae3d63\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: 12141039

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/28/2020
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[]

Aliquot

Please enter barcode for each aliquot.

5.a	Sample ID	[BSHD1J]
5.b	Sample ID	[BSHD1K]
5.c	Sample ID	[BPZDC2]
5.d	Sample ID	[BPZDC3]

090177e196ae3d63\Final\Final On: 01-Apr-2021 04:32 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** DATE OF VISIT - ILLNESS ONSET
on Jan/08/2021

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: 12141039

Subject Initials: ---

Generated By: (b) (4)

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

[eCRF Audit Trail History](#)

Date of Visit

1.	Date of Visit	Jan/8/2021
2.	Erroneous Visit	

COVID-19 Illness Visit

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

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** SIGNS AND SYMPTOMS OF POTENTIAL COVID-19
on Jan/08/2021

Form Version: 10-Dec-2020 02:29

Form Status: Data Complete

Site No: 1214

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

Subject No: 12141039

Subject Initials: ---

Generated By: (b) (4)

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

[eCRF Audit Trail History](#)

Signs and Symptoms

1.	Date of Assessment:	Jan/8/2021
2.	Date of First Symptom Started:	Jan/5/2021
3.	Symptoms Ongoing?	NO Date of Last Symptom Resolved: Jan/9/2021

Symptoms

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

090177e196ae3d63\Final\Final On: 01-Apr-2021 04:32 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** SIGNS AND SYMPTOMS OF POTENTIAL COVID-19
on Jan/08/2021

Form Version: 10-Dec-2020 02:29

Form Status: Data Complete

Site No: 1214

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

Subject No: 12141039

Subject Initials: ---

Generated By: (b) (4)

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

4.i	Symptoms:	VOMITING
	Was symptom present?	NO

Symptoms - Other

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

Visit: POT_COVID_ILL 1

Form: MICROBIOLOGY SPECIMEN

Form Version: 06-Jul-2020 21:54

Site No: 1214

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

Subject No: 12141039

Subject Initials: ---

Generated By: (b) (4)

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

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

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** MICROBIOLOGY SPECIMEN
on Jan/08/2021

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete

Site No: 1214

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

Subject No: 12141039

Subject Initials: ---

Generated By: (b) (4)

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

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

Microbiology Specimen

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

090177e196ae3d63\Final\Final On: 01-Apr-2021 04:32 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit
on Jan/08/2021

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB SELF

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: 12141039

Subject Initials: ---

Generated By: (b) (4)

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

[Form Comments](#)

[eCRF Audit Trail History](#)

Electronic Sample Tracking

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

Aliquot

Please enter barcode for each aliquot.

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

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB
on Jan/08/2021

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: 12141039

Subject Initials: ---

Generated By: (b) (4)

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

[eCRF Audit Trail History](#)

Electronic Sample Tracking

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB
3.	Sample Collected?	YES Date of Collection: Jan/8/2021
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[]

Aliquot

Please enter barcode for each aliquot.

5.a	Sample ID	[BR5CW1]
-----	-----------	----------

090177e196ae3d63\Final\Final On: 01-Apr-2021 04:32 (GMT)

Header Text: C4591001**Visit:** POT_COVID_ILL 1 - Unscheduled Visit **Form:** HEALTH CARE UTILIZATION
on Jan/08/2021**Form Version:** 10-Dec-2020 02:26**Form Status:** Data Complete**Site No:** 1214**Site Name:** (1214) ISTANBUL UNIVERSITY MEDICAL FACULTY
CARDIOLOGY INSTITUTE**Subject No:** 12141039**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 13:11[eCRF Audit Trail History](#)**Health Care Utilization**

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

Health Care Utilization Other

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

Health Care Utilization

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

Header Text: C4591001

Visit: POT_COVID_ILL 1

Form: RESPIRATORY TREATMENT

Form Version: 06-Jul-2020 21:53

Site No: 1214

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

Subject No: 12141039

Subject Initials: ---

Generated By: (b) (4)

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

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

090177e196ae3d63\Final\Final On: 01-Apr-2021 04:32 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** RESPIRATORY TREATMENT
on Jan/08/2021

Form Version: 06-Jul-2020 21:53

Form Status: Data Complete

Site No: 1214

Site Name: (1214) ISTANBUL UNIVERSITY MEDICAL FACULTY
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Subject No: 12141039

Subject Initials: ---

Generated By: (b) (4)

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

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Respiratory Treatment

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

090177e196ae3d63\Final\Final On: 01-Apr-2021 04:32 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** ILLNESS DETAILS
on Jan/08/2021

Form Version: 06-Jul-2020 21:52

Form Status: Data Complete

Site No: 1214

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

Subject No: 12141039

Subject Initials: ---

Generated By: (b) (4)

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

[eCRF Audit Trail History](#)

Illness Details

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

Header Text: C4591001

Visit: POT_COVID_ILL 1

Form: ILLNESS DETAILS - SEVERE

Form Version: 17-Jul-2020 21:55

Site No: 1214

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

Subject No: 12141039

Subject Initials: ---

Generated By: (b) (4)

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

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

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** ILLNESS DETAILS - SEVERE
on Jan/08/2021

Form Version: 17-Jul-2020 21:55

Form Status: Data Complete

Site No: 1214

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

Subject No: 12141039

Subject Initials: ---

Generated By: (b) (4)

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

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Illness Details

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

Header Text: C4591001

Visit: POT_COVID_ILL 1

Form Version: 10-Oct-2020 15:58

Site No: 1214

Subject No: 12141039

Generated By: (b) (4)

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY

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

Subject Initials: ---

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

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

090177e196ae3d63\Final\Final On: 01-Apr-2021 04:32 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Jan/08/2021

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY

Form Version: 10-Oct-2020 15:58

Form Status: Data Complete

Site No: 1214

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

Subject No: 12141039

Subject Initials: ---

Generated By: (b) (4)

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

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Lab Chemistry Details

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

Lab Result

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

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Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY
on Jan/08/2021

Form Version: 10-Oct-2020 15:58

Form Status: Data Complete

Site No: 1214

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

Subject No: 12141039

Subject Initials: ---

Generated By: (b) (4)

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

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

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

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Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY
on Jan/08/2021

Form Version: 10-Oct-2020 15:58

Form Status: Data Complete

Site No: 1214

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

Subject No: 12141039

Subject Initials: ---

Generated By: (b) (4)

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

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

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

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Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY
on Jan/08/2021

Form Version: 10-Oct-2020 15:58

Form Status: Data Complete

Site No: 1214

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

Subject No: 12141039

Subject Initials: ---

Generated By: (b) (4)

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

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

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

090177e196ae3d63\Final\Final On: 01-Apr-2021 04:32 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1

Form Version: 10-Oct-2020 16:02

Site No: 1214

Subject No: 12141039

Generated By: (b) (4)

Form: LOCAL LABORATORY DATA - REPEATING Hematology

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

Subject Initials: ---

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

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

090177e196ae3d63\Final\Final On: 01-Apr-2021 04:32 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit Form: LOCAL LABORATORY DATA - REPEATING Hematology on Jan/08/2021

Form Version: 10-Oct-2020 16:02

Form Status: Data Complete

Site No: 1214

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

Subject No: 12141039

Subject Initials: ---

Generated By: (b) (4)

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

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Laboratory Data Hematology

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

Lab Result

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

090177e196ae3d63\Final\Final On: 01-Apr-2021 04:32 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** LOCAL LABORATORY DATA - REPEATING Hematology on Jan/08/2021

Form Version: 10-Oct-2020 16:02

Form Status: Data Complete

Site No: 1214

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

Subject No: 12141039

Subject Initials: ---

Generated By: (b) (4)

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

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

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

090177e196ae3d63\Final\Final On: 01-Apr-2021 04:32 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** LOCAL LABORATORY DATA - REPEATING Hematology
on Jan/08/2021

Form Version: 10-Oct-2020 16:02

Form Status: Data Complete

Site No: 1214

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

Subject No: 12141039

Subject Initials: ---

Generated By: (b) (4)

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

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

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

090177e196ae3d63\Final\Final On: 01-Apr-2021 04:32 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** LOCAL LABORATORY DATA - REPEATING Hematology on Jan/08/2021

Form Version: 10-Oct-2020 16:02

Form Status: Data Complete

Site No: 1214

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

Subject No: 12141039

Subject Initials: ---

Generated By: (b) (4)

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

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

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

090177e196ae3d63\Final\Final On: 01-Apr-2021 04:32 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** LOCAL LABORATORY DATA - REPEATING Hematology on Jan/08/2021

Form Version: 10-Oct-2020 16:02

Form Status: Data Complete

Site No: 1214

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

Subject No: 12141039

Subject Initials: ---

Generated By: (b) (4)

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

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

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

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Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** LOCAL LABORATORY DATA - REPEATING Hematology
on Jan/08/2021

Form Version: 10-Oct-2020 16:02

Form Status: Data Complete

Site No: 1214

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

Subject No: 12141039

Subject Initials: ---

Generated By: (b) (4)

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

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

090177e196ae3d63\Final\Final On: 01-Apr-2021 04:32 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1

Form: VITAL SIGNS - COVID

Form Version: 10-Oct-2020 15:59

Site No: 1214

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

Subject No: 12141039

Subject Initials: ---

Generated By: (b) (4)

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

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

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** VITAL SIGNS - COVID
on Jan/08/2021

Form Version: 10-Oct-2020 15:59

Form Status: Data Complete

Site No: 1214

Site Name: (1214) ISTANBUL UNIVERSITY MEDICAL FACULTY
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Subject No: 12141039

Subject Initials: ---

Generated By: (b) (4)

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

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Vital Signs

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

Vital Signs Details

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

090177e196ae3d63\Final\Final On: 01-Apr-2021 04:32 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1

Form: VITAL SIGNS - PULSE OX ROOM AIR

Form Version: 10-Oct-2020 16:04

Site No: 1214

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

Subject No: 12141039

Subject Initials: ---

Generated By: (b) (4)

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

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

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** VITAL SIGNS - PULSE OX ROOM AIR
on Jan/08/2021

Form Version: 10-Oct-2020 16:04

Form Status: Data Complete

Site No: 1214

Site Name: (1214) ISTANBUL UNIVERSITY MEDICAL FACULTY
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Subject No: 12141039

Subject Initials: ---

Generated By: (b) (4)

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

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[Form Comments](#)

[eCRF Audit Trail History](#)

Vital Signs

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

Vital Signs Details

2.a	Record Identifier:	Not Applicable _____ 1	
	SPO2 Pulse Oximetry %	Not Applicable _____ []	Comments

090177e196ae3d63\Final\Final On: 01-Apr-2021 04:32 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1

Form: OXYGENATION PARAMETERS

Form Version: 06-Jul-2020 21:52

Site No: 1214

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

Subject No: 12141039

Subject Initials: ---

Generated By: (b) (4)

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

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

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** OXYGENATION PARAMETERS
on Jan/08/2021

Form Version: 06-Jul-2020 21:52

Form Status: Data Complete

Site No: 1214

Site Name: (1214) ISTANBUL UNIVERSITY MEDICAL FACULTY
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Subject No: 12141039

Subject Initials: ---

Generated By: (b) (4)

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

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[eCRF Audit Trail History](#)

Oxygenation Parameters

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

090177e196ae3d63\Final\Final On: 01-Apr-2021 04:32 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1

Form Version: 06-Jul-2020 21:55

Site No: 1214

Subject No: 12141039

Generated By: (b) (4)

Form: CONCOMITANT MEDICATIONS - VASOPRESSORS

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

Subject Initials: ---

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: POT_COVID_ILL 1 - Unscheduled Visit **Form:** CONCOMITANT MEDICATIONS - VASOPRESSORS
on Jan/08/2021

Form Version: 06-Jul-2020 21:55

Form Status: Data Complete

Site No: 1214

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

Subject No: 12141039

Subject Initials: ---

Generated By: (b) (4)

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

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Concomitant Medications

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

090177e196ae3d63\Final\Final On: 01-Apr-2021 04:32 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1

Form: IMAGING

Form Version: 06-Jul-2020 21:53

Site No: 1214

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

Subject No: 12141039

Subject Initials: ---

Generated By: (b) (4)

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

#	Date of Assessment	Location of Assessment	Imaging Method	Overall Assessment	Form Instance
1.	Not Applicable	Not Applicable	Not Applicable	Not Applicable	Repeating Pages

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** IMAGING
on Jan/08/2021

Form Version: 06-Jul-2020 21:53

Form Status: Data Complete

Site No: 1214

Site Name: (1214) ISTANBUL UNIVERSITY MEDICAL FACULTY
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Subject No: 12141039

Subject Initials: ---

Generated By: (b) (4)

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

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Imaging

1.	Date of Assessment:	Not Applicable _____ //	Comments
2.	Location of Assessment:	Not Applicable _____	Comments
3.	Type of Imaging Exam:	Not Applicable _____	Comments
4.	Assessment:	Not Applicable _____	Comments

090177e196ae3d63\Final\Final On: 01-Apr-2021 04:32 (GMT)

Header Text: C4591001

Visit: POT_COVID_CONVA 1 - Unscheduled
Visit on Feb/08/2021

Form: DATE OF VISIT - ILLNESS CONVALESCENT

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Frozen, Verified

Site No: 1214

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

Subject No: 12141039

Subject Initials: ---

Generated By: (b) (4)

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

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Date of Visit

1.	Date of Visit	Feb/8/2021
2.	Erroneous Visit	

COVID-19 Illness Visit

3.	COVID-19 Illness Visit:	COVID_A1
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Header Text: C4591001

Visit: POT_COVID_CONVA 1 - Unscheduled
Visit on Feb/08/2021

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1214

Site Name: (1214) ISTANBUL UNIVERSITY MEDICAL FACULTY
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Subject No: 12141039

Subject Initials: ---

Generated By: (b) (4)

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

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[eCRF Audit Trail History](#)

Electronic Sample Tracking

1.	Data Origin	SITE
2.	Sample Type	SERUM
3.	Sample Collected?	YES Date of Collection: Feb/8/2021
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[]

Aliquot

Please enter barcode for each aliquot.

5.a	Sample ID	[BR5CXW]
5.b	Sample ID	[BR5CXX]
5.c	Sample ID	[BSHD05]
5.d	Sample ID	[BSHD06]

090177e196ae3d63\Final\Final On: 01-Apr-2021 04:32 (GMT)

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
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Subject No: 12141039

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: 12141039

Subject Initials: ---

Generated By: (b) (4)

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

Electronic Sample Tracking

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

Aliquot

Please enter barcode for each aliquot.

5.	Sample ID	[]
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Header Text: C4591001

Visit: 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: 12141039

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	diarrhea	Nov/26/2020 17:00	NO End Date Time: Nov/27/2020 11:00	Repeating Pages
2.	ADVERSE EVENT	2	lymphadenomegaly in the right submandibular	Jan/6/2021 UNK:UNK	NO End Date Time: Jan/15/2021 UNK:UNK	Repeating Pages
3.	ADVERSE EVENT	3	pain at the injection site	Feb/8/2021 18:00	NO End Date Time: Feb/10/2021 10:00	Repeating Pages
4.	ADVERSE EVENT	4	pain at the injection site	Mar/3/2021 17:00	NO End Date Time: Mar/5/2021 12:00	Repeating Pages

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Header Text: C4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1214

Subject No: 12141039

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Frozen

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

Subject Initials: ---

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Adverse Event Report

1.	Category:	ADVERSE EVENT
2.	AE ID:	[1]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[diarrhea]
4.	Start Date Time:	Nov/26/2020 17:00
5.	Is the adverse event still ongoing?	NO End Date Time: Nov/27/2020 11:00
6.	Toxicity Grade:	1
7.	Is the adverse event serious? If Yes, NOTIFY PFIZER IMMEDIATELY. Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).	NO
8.	Is this adverse event the result of a study Medication Error? If Yes, record the type of medication error on the Medication Error Log.	NO
9.	Is this event related to study treatment:	NOT RELATED If Not Related to study treatment(s), this event is due to: OTHER If Other, specify: [prepared foods]

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Header Text: C4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1214

Subject No: 12141039

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

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

Header Text: C4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1214

Subject No: 12141039

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Frozen

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

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Adverse Event Report

1.	Category:	ADVERSE EVENT
2.	AE ID:	[2]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[lymphadenomegaly in the right submandibular]
4.	Start Date Time:	Jan/6/2021 UNK:UNK
5.	Is the adverse event still ongoing?	NO End Date Time: Jan/15/2021 UNK:UNK
6.	Toxicity Grade:	1
7.	Is the adverse event serious? If Yes, NOTIFY PFIZER IMMEDIATELY. Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).	NO
8.	Is this adverse event the result of a study Medication Error? If Yes, record the type of medication error on the Medication Error Log.	NO
9.	Is this event related to study treatment:	NOT RELATED If Not Related to study treatment(s), this event is due to: OTHER If Other, specify: [Bacteria]
10.	Latest Action Taken with Study Treatment:	NOT APPLICABLE

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Header Text: C4591001

Visit: Logs - Unscheduled

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Site No: 1214

Subject No: 12141039

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Frozen

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

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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	[]

Header Text: C4591001

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Site No: 1214

Subject No: 12141039

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Frozen

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

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Adverse Event Report

1.	Category:	ADVERSE EVENT
2.	AE ID:	[3]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[pain at the injection site]
4.	Start Date Time:	Feb/8/2021 18:00
5.	Is the adverse event still ongoing?	NO End Date Time: Feb/10/2021 10:00
6.	Toxicity Grade:	2
7.	Is the adverse event serious? If Yes, NOTIFY PFIZER IMMEDIATELY. Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).	NO
8.	Is this adverse event the result of a study Medication Error? If Yes, record the type of medication error on the Medication Error Log.	NO
9.	Is this event related to study treatment:	RELATED
10.	Latest Action Taken with Study Treatment:	NOT APPLICABLE
11.	Was a Concomitant Medication given?	YES

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Header Text: C4591001

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Site No: 1214

Subject No: 12141039

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Frozen

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

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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	[]

Header Text: C4591001

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Site No: 1214

Subject No: 12141039

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete

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

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Adverse Event Report

1.	Category:	ADVERSE EVENT
2.	AE ID:	[4]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[pain at the injection site]
4.	Start Date Time:	Mar/3/2021 17:00
5.	Is the adverse event still ongoing?	NO End Date Time: Mar/5/2021 12:00
6.	Toxicity Grade:	2
7.	Is the adverse event serious? If Yes, NOTIFY PFIZER IMMEDIATELY. Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).	NO
8.	Is this adverse event the result of a study Medication Error? If Yes, record the type of medication error on the Medication Error Log.	NO
9.	Is this event related to study treatment:	RELATED
10.	Latest Action Taken with Study Treatment:	NOT APPLICABLE
11.	Was a Concomitant Medication given?	NO

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Header Text: C4591001

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Form Version: 22-Apr-2020 21:02

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Subject No: 12141039

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete

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

Subject Initials: ---

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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	[]

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: 12141039

Subject Initials: ---

Generated By: (b) (4)

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

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

090177e196ae3d63\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: 12141039

Generated By: (b) (4)

Form: MEDICATION ERROR

Form Status: Data Complete, Frozen, 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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Medication Error

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

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Header Text: C4591001

Visit: Logs

Form: CONCOMITANT MEDICATIONS - NON STUDY
VACCINATIONS

Form Version: 22-Apr-2020 21:03

Site No: 1214

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

Subject No: 12141039

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: CONCOMITANT MEDICATIONS - NON STUDY VACCINATIONS

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: 12141039

Subject Initials: ---

Generated By: (b) (4)

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

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Concomitant Medications

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

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Header Text: C4591001

Visit: Logs

Form: CONCOMITANT MEDICATIONS - PROHIBITED

Form Version: 22-Apr-2020 21:03

Site No: 1214

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

Subject No: 12141039

Subject Initials: ---

Generated By: (b) (4)

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

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

090177e196ae3d63\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: 12141039

Generated By: (b) (4)

Form: CONCOMITANT MEDICATIONS - PROHIBITED

Form Status: Data Complete, Frozen, 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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Concomitant Medications

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

090177e196ae3d63\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: 12141039

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

090177e196ae3d63\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: 12141039

Generated By: (b) (4)

Form: RADIATION 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

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Radiation Treatment

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

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Header Text: C4591001

Visit: Logs

Form: TRANSFUSIONS

Form Version: 22-Apr-2020 21:03

Site No: 1214

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

Subject No: 12141039

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: 12141039

Generated By: (b) (4)

Form: TRANSFUSIONS

Form Status: Data Complete, Frozen, 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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1.	Transfusion Type:	Not Applicable _____	Comments
2.	Date of Transfusion:	Not Applicable _____ //	Comments

Header Text: C4591001

Visit: Unplanned 1 - Unscheduled Visit on
Jan/06/2021

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
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Subject No: 12141039

Subject Initials: ---

Generated By: (b) (4)

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

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Date of Visit

1.	Date of Visit	Jan/6/2021
2.	Erroneous Visit	

Header Text: C4591001

Visit: Unplanned 1 - Unscheduled Visit on
Jan/06/2021

Form: UNPLANNED VISIT

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Frozen, Verified

Site No: 1214

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

Subject No: 12141039

Subject Initials: ---

Generated By: (b) (4)

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

[eCRF Audit Trail History](#)

Unplanned Assessments

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

090177e196ae3d63\Final\Final On: 01-Apr-2021 04:32 (GMT)

Header Text: C4591001

Visit: Unplanned 1 - Unscheduled Visit on
Jan/06/2021

Form: CONTACT OUTCOME - UNPLANNED

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Frozen, Verified

Site No: 1214

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

Subject No: 12141039

Subject Initials: ---

Generated By: (b) (4)

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

[eCRF Audit Trail History](#)

Contact Outcome

1.	Contact Type:	TELEPHONE VISIT
2.	Was contact made?	YES Date of Contact: Jan/6/2021 Contact Outcome: VISIT ARRANGED
3.	Comments:	[PI contacted with subject]

090177e196ae3d63\Final\Final On: 01-Apr-2021 04:32 (GMT)

Header Text: C4591001

Visit: Unplanned 1 - Unscheduled Visit on
Jan/06/2021

Form: VITAL SIGNS - TEMP

Form Version: 10-Dec-2020 02:27

Form Status: Data Complete, Frozen, Verified

Site No: 1214

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

Subject No: 12141039

Subject Initials: ---

Generated By: (b) (4)

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

[eCRF Audit Trail History](#)

Vital Signs

1.	Date:	Jan/8/2021
----	-------	------------

Vital Signs Details

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

Header Text: C4591001**Visit:** Unplanned 1 - Unscheduled Visit on
Jan/06/2021**Form Version:** 10-Dec-2020 02:22**Site No:** 1214**Subject No:** 12141039**Generated By:** (b) (4)**Form:** UNPLANNED ASSESSMENT OF LOCAL REACTION -
SYSTEMIC EVENT**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](#)**Unplanned Assessment Of Local Reaction**

1.	Date of Assessment:	Not Applicable _____ //	Comments
2.	Injection Site Location	Not Applicable _____	Comments
3.	Injection Site Body Side:	Not Applicable _____	Comments

Reaction

4.a	Reaction:	REDNESS	
	Reaction Present:	Not Applicable _____	Comments
4.b	Reaction:	SWELLING	
	Reaction Present:	Not Applicable _____	Comments

Symptom

5.a	Symptom:	PAIN AT INJECTION SITE	
	Symptom Present:	Not Applicable _____	Comments
5.b	Symptom:	FATIGUE/TIREDNESS	
	Symptom Present:	Not Applicable _____	Comments
5.c	Symptom:	HEADACHE	
	Symptom Present:	Not Applicable _____	Comments
5.d	Symptom:	VOMITING	
	Symptom Present:	Not Applicable _____	Comments

Header Text: C4591001

Visit: Unplanned 1 - Unscheduled Visit on
Jan/06/2021

Form Version: 10-Dec-2020 02:22

Site No: 1214

Subject No: 12141039

Generated By: (b) (4)

Form: UNPLANNED ASSESSMENT OF LOCAL REACTION -
SYSTEMIC EVENT

Form Status: Data Complete, Verified

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

Subject Initials: ---

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

5.e	Symptom:	DIARRHEA	
	Symptom Present:	Not Applicable _____	Comments
5.f	Symptom:	NEW OR WORSENERED MUSCLE PAIN	
	Symptom Present:	Not Applicable _____	Comments
5.g	Symptom:	NEW OR WORSENERED JOINT PAIN	
	Symptom Present:	Not Applicable _____	Comments
5.h	Symptom:	CHILLS	
	Symptom Present:	Not Applicable _____	Comments

090177e196ae3d63\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: 12141039

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: 12141039

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: 12141039

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?	

090177e196ae3d63\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: 12141039

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: 12141039

Subject Initials: ---

Generated By: (b) (4)

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

Contact Outcome

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

Header Text: C4591001

Visit: End of Treatment - Unscheduled

Form Version: 10-Dec-2020 02:29

Site No: 1214

Subject No: 12141039

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/28/2020
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: 12141039

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/31/2020
2.	Erroneous Visit	

090177e196ae3d63\Final\Final On: 01-Apr-2021 04:32 (GMT)

Header Text: C4591001

Visit: Potential ReVax Initial Contact -
Unscheduled

Form Version: 10-Dec-2020 02:25

Site No: 1214

Subject No: 12141039

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 per local/national recommendations and confirmed to have received only placebo at Vaccination 1/2
----	---	---

Header Text: C4591001

Visit: Follow-Up - Unscheduled

Form Version: 15-Sep-2020 21:53

Site No: 1214

Subject No: 12141039

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: V101_VAX3

Form Version: 22-Apr-2020 21:02

Site No: 1214

Subject No: 12141039

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	Feb/8/2021
2.	Erroneous Visit	

Header Text: C4591001

Visit: V101_VAX3

Form Version: 10-Dec-2020 02:31

Site No: 1214

Subject No: 12141039

Generated By: (b) (4)

Form: INFORMED CONSENT - FURTHER 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](#)

Informed Consent - Further Vaccination

1.	Consent Was:	OBTAINED Date Written Consent Obtained Feb/8/2021
----	--------------	---

Header Text: C4591001

Visit: V101_VAX3

Form: INCLUSION/EXCLUSION CRITERIA - FURTHER VACCINATION

Form Version: 10-Dec-2020 02:30

Form Status: Data Complete, Frozen, Verified

Site No: 1214

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

Subject No: 12141039

Subject Initials: ---

Generated By: (b) (4)

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

Form Comments

Inclusion Criteria Not Met

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

Exclusion Criteria Met

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

Header Text: C4591001

Visit: V101_VAX3

Form Version: 10-Dec-2020 02:31

Site No: 1214

Subject No: 12141039

Generated By: (b) (4)

Form: DISPOSITION - SCREENING FOR FURTHER 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](#)

Disposition - Screening for Further Vaccination

1.	Date of Completion/Discontinuation /Death :	Feb/8/2021
2.	Phase of Disposition:	REPEAT SCREENING 1
3.	Status:	COMPLETED
4.	Specify Status:	[]

Header Text: C4591001

Visit: V101_VAX3

Form Version: 22-Apr-2020 21:03

Site No: 1214

Subject No: 12141039

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?	NO
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[Since the V101_VAX3 visit occurs at the same time as the Potential COVID-19 Convalescent visit, the sample collection date and barcodes were recorded at the original visit(Covid-19 Convalescent visit)]

Aliquot

Please enter barcode for each aliquot.

S.a	Sample ID	[]
S.b	Sample ID	[]
S.c	Sample ID	[]
S.d	Sample ID	[]

090177e196ae3d63\Final\Final On: 01-Apr-2021 04:32 (GMT)

Header Text: C4591001

Visit: V101_VAX3

Form Version: 22-Apr-2020 21:03

Site No: 1214

Subject No: 12141039

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: Feb/8/2021
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[]

Aliquot

Please enter barcode for each aliquot.

5.a	Sample ID	[BR5CXV]
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090177e196ae3d63\Final\Final On: 01-Apr-2021 04:32 (GMT)

Header Text: C4591001

Visit: V101_VAX3

Form Version: 10-Dec-2020 02:26

Site No: 1214

Subject No: 12141039

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	[BNT162b2]
3.	Formulation:	INJECTION
4.	Dose Date Time:	Feb/8/2021 10:40
5.	Anatomical Location:	DELTOID MUSCLE
6.	Body Side:	RIGHT
7.	Route:	INTRAMUSCULAR
8.	Actual Dose:	[30.0]
9.	Unit:	ug
10.	Timeframe Subject Was Observed	30 MINUTES
11.	Was the subject observed for at least the protocol specified observation period after investigational product administration?	YES

090177e196ae3d63\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: 12141039

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/31/2020
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: 12141039

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

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

Header Text: C4591001

Visit: Disposition - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1214

Subject No: 12141039

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 _____ []

090177e196ae3d63\Final\Final On: 01-Apr-2021 04:32 (GMT)

Header Text: C4591001

Visit: V102_VAX4

Form Version: 22-Apr-2020 21:02

Site No: 1214

Subject No: 12141039

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	Mar/3/2021
2.	Erroneous Visit	

Header Text: C4591001

Visit: V102_VAX4

Form Version: 22-Apr-2020 21:03

Site No: 1214

Subject No: 12141039

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

Aliquot

Please enter barcode for each aliquot.

5.a	Sample ID	[BR5CYZ]
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090177e196ae3d63\Final\Final On: 01-Apr-2021 04:32 (GMT)

Header Text: C4591001

Visit: V102_VAX4

Form Version: 10-Dec-2020 02:26

Site No: 1214

Subject No: 12141039

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	[BNT162b2]
3.	Formulation:	INJECTION
4.	Dose Date Time:	Mar/3/2021 10:45
5.	Anatomical Location:	DELTOID MUSCLE
6.	Body Side:	RIGHT
7.	Route:	INTRAMUSCULAR
8.	Actual Dose:	[30.0]
9.	Unit:	ug
10.	Timeframe Subject Was Observed	30 MINUTES
11.	Was the subject observed for at least the protocol specified observation period after investigational product administration?	YES

090177e196ae3d63\Final\Final On: 01-Apr-2021 04:32 (GMT)

Header Text: C4591001

Visit: V103_MONTH1

Form Version: 22-Apr-2020 21:02

Site No: 1214

Subject No: 12141039

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: V103_MONTH1

Form Version: 22-Apr-2020 21:04

Site No: 1214

Subject No: 12141039

Generated By: (b) (4)

Form: CONTACT OUTCOME

Form Status: Not Started

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

Subject Initials: ---

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

Contact Outcome

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

Header Text: C4591001

Visit: V104_MONTH6

Form Version: 22-Apr-2020 21:02

Site No: 1214

Subject No: 12141039

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: V104_MONTH6

Form Version: 22-Apr-2020 21:04

Site No: 1214

Subject No: 12141039

Generated By: (b) (4)

Form: CONTACT OUTCOME

Form Status: Not Started

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

Subject Initials: ---

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

Contact Outcome

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

Header Text: C4591001

Visit: V105_MONTH18

Form Version: 22-Apr-2020 21:02

Site No: 1214

Subject No: 12141039

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: V105_MONTH18

Form Version: 22-Apr-2020 21:04

Site No: 1214

Subject No: 12141039

Generated By: (b) (4)

Form: CONTACT OUTCOME

Form Status: Not Started

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

Subject Initials: ---

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

Contact Outcome

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

Header Text: C4591001

Visit: FURTHER_VACCINATION_EOT -
Unscheduled

Form: DISPOSITION - TREATMENT

Form Version: 20-Feb-2021 02:26

Form Status: Not Started

Site No: 1214

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

Subject No: 12141039

Subject Initials: ---

Generated By: (b) (4)

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

Disposition - Treatment

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

Header Text: C4591001

Visit: Subject Status - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1214

Subject No: 12141039

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/28/2020

Header Text: C4591001

Visit: Investigator Signature - Unscheduled

Form Version: 22-Apr-2020 21:04

Site No: 1214

Subject No: 12141039

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
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Subject No: 12141039

Subject Initials: ---

Generated By: (b) (4)

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

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

- CRF_Sign

Name	Signature Meaning	Date	Type	Action
Serap Yavuz	Approved	Mar-12-2021 17:02:02 (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.

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Visit: V1_DAY1_VAX1_L

Form Version: 10-Oct-2020 16:00

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Form: INCLUSION/EXCLUSION CRITERIA - Comments

Form Status: Data Complete, Frozen, Verified

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Header Text: C4591001

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Form Version: 22-Apr-2020 21:03

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Form: GENERAL MEDICAL HISTORY - Comments

Form Status: Data Complete, Frozen, Verified

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Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** MICROBIOLOGY SPECIMEN - Comments
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Form Version: 06-Jul-2020 21:54

Form Status: Data Complete

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Header Text: C4591001

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Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB SELF - Comments

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

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Form	Jan-08-2021 18:29:28 (UTC+03:00) Istanbul	(b) (4), (b) (6)	Not Done

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Header Text: C4591001

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Form Status: Data Complete

Site No: 1214

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

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Item	Date	User	Comment
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Form Status: Data Complete

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2.a	Jan-08-2021 18:32:15 (UTC+03:00) Istanbul	(b) (4), (b) (6)	Not Applicable

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** VITAL SIGNS - PULSE OX ROOM AIR - Comments
on Jan/08/2021

Form Version: 10-Oct-2020 16:04

Form Status: Data Complete

Site No: 1214

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

Subject No: 12141039

Subject Initials: ---

Generated By: (b) (4)

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

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Item	Date	User	Comment
Form	Jan-08-2021 18:32:31 (UTC+03:00) Istanbul	(b) (4), (b) (6)	Not Applicable

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** VITAL SIGNS - PULSE OX ROOM AIR - Comments
on Jan/08/2021

Form Version: 10-Oct-2020 16:04

Form Status: Data Complete

Site No: 1214

Site Name: (1214) ISTANBUL UNIVERSITY MEDICAL FACULTY
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Subject No: 12141039

Subject Initials: ---

Generated By: (b) (4)

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

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Item	Date	User	Comment
1	Jan-08-2021 18:32:31 (UTC+03:00) Istanbul	(b) (4), (b) (6)	Not Applicable

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** VITAL SIGNS - PULSE OX ROOM AIR - Comments
on Jan/08/2021

Form Version: 10-Oct-2020 16:04

Form Status: Data Complete

Site No: 1214

Site Name: (1214) ISTANBUL UNIVERSITY MEDICAL FACULTY
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Subject No: 12141039

Subject Initials: ---

Generated By: (b) (4)

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

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Item	Date	User	Comment
2.a	Jan-08-2021 18:32:31 (UTC+03:00) Istanbul	(b) (4), (b) (6)	Not Applicable

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** OXYGENATION PARAMETERS - Comments
on Jan/08/2021

Form Version: 06-Jul-2020 21:52

Form Status: Data Complete

Site No: 1214

Site Name: (1214) ISTANBUL UNIVERSITY MEDICAL FACULTY
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Subject No: 12141039

Subject Initials: ---

Generated By: (b) (4)

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

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Item	Date	User	Comment
Form	Jan-08-2021 18:32:47 (UTC+03:00) Istanbul	(b) (4), (b) (6)	Not Applicable

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** OXYGENATION PARAMETERS - Comments
on Jan/08/2021

Form Version: 06-Jul-2020 21:52

Form Status: Data Complete

Site No: 1214

Site Name: (1214) ISTANBUL UNIVERSITY MEDICAL FACULTY
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Subject No: 12141039

Subject Initials: ---

Generated By: (b) (4)

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

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Item	Date	User	Comment
1	Jan-08-2021 18:32:47 (UTC+03:00) Istanbul	(b) (4), (b) (6)	Not Applicable

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** OXYGENATION PARAMETERS - Comments
on Jan/08/2021

Form Version: 06-Jul-2020 21:52

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3	Jan-08-2021 18:32:47 (UTC+03:00) Istanbul	(b) (4), (b) (6)	Not Applicable

Header Text: C4591001

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Form: CONCOMITANT MEDICATIONS - VASOPRESSORS - Comments

Form Version: 06-Jul-2020 21:55

Form Status: Data Complete

Site No: 1214

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

Subject No: 12141039

Subject Initials: ---

Generated By: (b) (4)

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

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Item	Date	User	Comment
Form	Jan-08-2021 18:33:02 (UTC+03:00) Istanbul	(b) (4), (b) (6)	Not Applicable

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Jan/08/2021

Form: CONCOMITANT MEDICATIONS - VASOPRESSORS - Comments

Form Version: 06-Jul-2020 21:55

Form Status: Data Complete

Site No: 1214

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Item	Date	User	Comment
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Header Text: C4591001

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Item	Date	User	Comment
5	Jan-08-2021 18:33:02 (UTC+03:00) Istanbul	(b) (4), (b) (6)	Not Applicable

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Jan/08/2021

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Item	Date	User	Comment
6	Jan-08-2021 18:33:02 (UTC+03:00) Istanbul	(b) (4), (b) (6)	Not Applicable

Header Text: C4591001

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Form Status: Data Complete

Site No: 1214

Site Name: (1214) ISTANBUL UNIVERSITY MEDICAL FACULTY
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Subject No: 12141039

Subject Initials: ---

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Item	Date	User	Comment
Form	Jan-08-2021 18:33:17 (UTC+03:00) Istanbul	(b) (4), (b) (6)	Not Applicable

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** IMAGING - Comments
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Item	Date	User	Comment
2	Jan-08-2021 18:33:17 (UTC+03:00) Istanbul	(b) (4), (b) (6)	Not Applicable

Header Text: C4591001

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

Form Status: Data Complete

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Item	Date	User	Comment
3	Jan-08-2021 18:33:17 (UTC+03:00) Istanbul	(b) (4), (b) (6)	Not Applicable

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** IMAGING - Comments
on Jan/08/2021

Form Version: 06-Jul-2020 21:53

Form Status: Data Complete

Site No: 1214

Site Name: (1214) ISTANBUL UNIVERSITY MEDICAL FACULTY
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Subject No: 12141039

Subject Initials: ---

Generated By: (b) (4)

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Item	Date	User	Comment
4	Jan-08-2021 18:33:17 (UTC+03:00) Istanbul	(b) (4), (b) (6)	Not Applicable

Header Text: C4591001

Visit: POT_COVID_CONVA 1 - Unscheduled Visit on Feb/08/2021

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - Comments

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: 12141039

Subject Initials: ---

Generated By: (b) (4)

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

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Item	Date	User	Comment
Form	Feb-09-2021 14:20:48 (UTC+03:00) Istanbul	(b) (4), (b) (6)	Since the V101_VAX3 visit occurs at the same time as the Potential COVID-19 Convalescent visit, the sample collection date and barcodes were recorded at the original visit (Potential Covid-19 Convalescent visit).

Header Text: C4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1214

Subject No: 12141039

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - Comments

Form Status: Data Complete, Frozen

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

Subject Initials: ---

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

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Item	Date	User	Comment
Form	Dec-19-2020 22:00:08 (UTC+03:00) Istanbul	(b) (4), (b) (6)	PI confirmed that this subject had only diarrhea due to eating foods that upset the digestive system and evaluated diarrhea as not COVID symptoms.

Header Text: C4591001

Visit: Logs - Unscheduled

Form Version: 17-Jul-2020 21:54

Site No: 1214

Subject No: 12141039

Generated By: (b) (4)

Form: MEDICATION ERROR - 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

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Item	Date	User	Comment
Form	Dec-08-2020 14:18:48 (UTC+03:00) Istanbul	(b) (4), (b) (6)	Not Applicable

090177e196ae3d63\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: 12141039

Generated By: (b) (4)

Form: MEDICATION ERROR - Comments

Form Status: Data Complete, Frozen, 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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Item	Date	User	Comment
1	Dec-08-2020 14:18:48 (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: 12141039

Generated By: (b) (4)

Form: MEDICATION ERROR - Comments

Form Status: Data Complete, Frozen, Verified

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Subject Initials: ---

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Item	Date	User	Comment
2	Dec-08-2020 14:18:48 (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: 12141039

Generated By: (b) (4)

Form: MEDICATION ERROR - Comments

Form Status: Data Complete, Frozen, Verified

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Subject Initials: ---

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

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Item	Date	User	Comment
3	Dec-08-2020 14:18:48 (UTC+03:00) Istanbul	(b) (4), (b) (6)	Not Applicable

Header Text: C4591001

Visit: Logs - Unscheduled

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Item	Date	User	Comment
4	Dec-08-2020 14:18:48 (UTC+03:00) Istanbul	(b) (4), (b) (6)	Not Applicable

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Subject Initials: ---

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Item	Date	User	Comment
5	Dec-08-2020 14:18:48 (UTC+03:00) Istanbul	(b) (4), (b) (6)	Not Applicable

Header Text: C4591001

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Form: MEDICATION ERROR - Comments

Form Status: Data Complete, Frozen, Verified

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Subject Initials: ---

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

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Item	Date	User	Comment
6	Dec-08-2020 14:18:48 (UTC+03:00) Istanbul	(b) (4), (b) (6)	Not Applicable

090177e196ae3d63\Final\Final On: 01-Apr-2021 04:32 (GMT)

Header Text: C4591001

Visit: Logs - Unscheduled

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Site No: 1214

Subject No: 12141039

Generated By: (b) (4)

Form: MEDICATION ERROR - Comments

Form Status: Data Complete, Frozen, Verified

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

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Item	Date	User	Comment
7	Dec-08-2020 14:18:48 (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: 12141039

Generated By: (b) (4)

Form: MEDICATION ERROR - Comments

Form Status: Data Complete, Frozen, Verified

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

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Item	Date	User	Comment
8	Dec-08-2020 14:18:48 (UTC+03:00) Istanbul	(b) (4), (b) (6)	Not Applicable

090177e196ae3d63\Final\Final On: 01-Apr-2021 04:32 (GMT)

Header Text: C4591001

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9	Dec-08-2020 14:18:48 (UTC+03:00) Istanbul	(b) (4), (b) (6)	Not Applicable

Header Text: C4591001

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Site No: 1214

Subject No: 12141039

Generated By: (b) (4)

Form: MEDICATION ERROR - Comments

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Item	Date	User	Comment
10	Dec-08-2020 14:18:48 (UTC+03:00) Istanbul	(b) (4), (b) (6)	Not Applicable

090177e196ae3d63\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: 12141039

Generated By: (b) (4)

Form: CONCOMITANT MEDICATIONS - NON STUDY
VACCINATIONS - Comments

Form Status: Data Complete, Frozen, 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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Item	Date	User	Comment
Form	Dec-08-2020 14:19:04 (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: 12141039

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Form: CONCOMITANT MEDICATIONS - NON STUDY
VACCINATIONS - Comments

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Subject Initials: ---

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Header Text: C4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1214

Subject No: 12141039

Generated By: (b) (4)

Form: CONCOMITANT MEDICATIONS - PROHIBITED - Comments

Form Status: Data Complete, Frozen, Verified

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

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Header Text: C4591001

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Subject No: 12141039

Generated By: (b) (4)

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9	Dec-08-2020 14:19:19 (UTC+03:00) Istanbul	(b) (4), (b) (6)	Not Applicable

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Subject No: 12141039

Generated By: (b) (4)

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Generated By: (b) (4)

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Generated By: (b) (4) [REDACTED]

Form: INCLUSION/EXCLUSION CRITERIA - FURTHER
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Form Status: Data Complete, Frozen, Verified

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Visit: Disposition - Unscheduled

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Generated By: (b) (4)

Form: WITHDRAWAL OF CONSENT - Comments

Form Status: Data Complete, Verified

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Generated By: (b) (4)

Form: DEATH DETAILS CODED - Comments

Form Status: Data Complete, Verified

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Form	Dec-31-2020 18:03:58 (UTC+03:00) Istanbul	(b) (4), (b) (6)	
Form	Dec-31-2020 11:23:37 (UTC+03:00) Istanbul	(b) (4), (b) (6)	Not Applicable

Header Text: C4591001

Visit: Disposition

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Form: DEATH DETAILS CODED - Comments

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

Subject Initials: ---

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

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Item	Date	User	Comment
1	Jan-04-2021 11:18:57 (UTC+03:00) Istanbul	(b) (4), (b) (6)	Not Applicable
1	Dec-31-2020 18:03:58 (UTC+03:00) Istanbul	(b) (4), (b) (6)	
1	Dec-31-2020 11:23:37 (UTC+03:00) Istanbul	(b) (4), (b) (6)	Not Applicable

090177e196ae3d63\Final\Final On: 01-Apr-2021 04:32 (GMT)

Header Text: C4591001

Visit: Investigator Signature - Unscheduled

Form: CASEBOOK SIGNATURE FORM - Signature History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Signed, Verified

Site No: 1214

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

Subject No: 12141039

Subject Initials: ---

Generated By: (b) (4)

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

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

- CRF_Sign

Name	Signature Meaning	Date	Type	Action
Serap Yavuz	Approved	Mar-12-2021 17:02:02 (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	Mar-12-2021 14:57:41 (UTC+03:00) Istanbul		Edit - All signatures invalidated
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Affidavit:

N/A

Serap Yavuz	Approved	Mar-03-2021 15:51:43 (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	Mar-03-2021 12:30:18 (UTC+03:00) Istanbul		Edit - All signatures invalidated
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Affidavit:

N/A

Serap Yavuz	Approved	Feb-09-2021 21:17:38 (UTC+03:00) Istanbul	BOOK	Signed
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090177e196ae3d63\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:** 12141039**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	Feb-08-2021 15:39:02 (UTC+03:00) Istanbul		Edit - All signatures invalidated
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Affidavit:

N/A

Serap Yavuz	Approved	Feb-08-2021 13:10:10 (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	Feb-08-2021 12:17:30 (UTC+03:00) Istanbul		Edit - All signatures invalidated
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Affidavit:

N/A

Serap Yavuz	Approved	Jan-25-2021 16:26:11 (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: 12141039

Subject Initials: ---

Generated By: (b) (4)

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

(b) (6)	N/A	Jan-25-2021 16:08:28 (UTC+03:00) Istanbul		Edit - All signatures invalidated
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Affidavit:

N/A

Serap Yavuz	Approved	Jan-21-2021 17:16:54 (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-18-2021 13:04:43 (UTC+03:00) Istanbul		Edit - All signatures invalidated
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Affidavit:

N/A

Serap Yavuz	Approved	Jan-12-2021 22:14:33 (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.

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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 17:07:32 (UTC+03:00) Istanbul		Edit - All signatures invalidated
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Affidavit:

N/A

Serap Yavuz	Approved	Jan-11-2021 17:32:14 (UTC+03:00) Istanbul	BOOK	Signed
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090177e196ae3d63\Final\Final On: 01-Apr-2021 04:32 (GMT)

Header Text: C4591001

Visit: Investigator Signature - Unscheduled

Form: CASEBOOK SIGNATURE FORM - Signature History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Signed, Verified

Site No: 1214

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

Subject No: 12141039

Subject Initials: ---

Generated By: (b) (4)

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

Affidavit:

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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-08-2021 17:15:02 (UTC+03:00) Istanbul		Edit - All signatures invalidated
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Affidavit:

N/A

Serap Yavuz	Approved	Jan-07-2021 11:34:27 (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-04-2021 11:18:57 (UTC+03:00) Istanbul		Edit - All signatures invalidated
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Affidavit:

N/A

Serap Yavuz	Approved	Dec-31-2020 18:56:26 (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.

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

090177e196ae3d63\Final\Final On: 01-Apr-2021 04:32 (GMT)

Header Text: C4591001

Visit: Investigator Signature - Unscheduled

Form: CASEBOOK SIGNATURE FORM - Signature History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Signed, Verified

Site No: 1214

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

Subject No: 12141039

Subject Initials: ---

Generated By: (b) (4)

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

(b) (6)	N/A	Dec-31-2020 11:22:31 (UTC+03:00) Istanbul		Edit - All signatures invalidated
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Affidavit:

N/A

Serap Yavuz	Approved	Dec-28-2020 19:03:08 (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-28-2020 13:26:28 (UTC+03:00) Istanbul		Edit - All signatures invalidated
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Affidavit:

N/A

Serap Yavuz	Approved	Dec-21-2020 09:18:45 (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-19-2020 22:00:08 (UTC+03:00) Istanbul		Edit - All signatures invalidated
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Affidavit:

N/A

Serap Yavuz	Approved	Dec-08-2020 18:16:15 (UTC+03:00) Istanbul	BOOK	Signed
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090177e196ae3d63\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:** 12141039**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-08-2020 14:18:33 (UTC+03:00) Istanbul		Edit - All signatures invalidated
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Affidavit:

N/A

Serap Yavuz	Approved	Dec-02-2020 11:14:42 (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	Nov-27-2020 15:28:32 (UTC+03:00) Istanbul		Edit - All signatures invalidated
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Affidavit:

N/A

Serap Yavuz	Approved	Nov-20-2020 16:10:46 (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: COHORT_SELECTION

Form Version: 10-Oct-2020 16:01

Site No: 1214

Subject No: 12141039

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

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1. Select appropriate response - Protocol version

Date	Location	User	Value	Reason
Nov-06-2020 15:12:02 (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-06-2020 15:12:02 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: STAGE 3 COHORTS	Initial Entry

090177e196ae3d63\Final\Final On: 01-Apr-2021 04:32 (GMT)

Header Text: C4591001

Visit: COHORT_SELECTION

Form Version: 22-Apr-2020 21:02

Site No: 1214

Subject No: 12141039

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

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I. Consent Was:

Date	Location	User	Value	Reason
Nov-06-2020 15:12:30 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: OBTAINED Date Written Consent Obtained Nov/6/2020	Initial Entry

Header Text: C4591001

Visit: COHORT_SELECTION

Form Version: 15-Sep-2020 21:54

Site No: 1214

Subject No: 12141039

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

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1. Subject ID

Date	Location	User	Value	Reason
Nov-06-2020 15:11:44 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 12141039	Item copied from previous form

2. Birth Date:

Date	Location	User	Value	Reason
Nov-06-2020 15:11:40 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: (b) (6)/1982	Enrollment Entry

3. Sex:

Date	Location	User	Value	Reason
Nov-06-2020 15:12:52 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: MALE	Initial Entry

4. Ethnicity:

Date	Location	User	Value	Reason
Nov-06-2020 15:12:52 (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-06-2020 15:12:52 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: WHITE	Initial Entry

090177e196ae3d63\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: 12141039

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

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1. Date of Visit

Date	Location	User	Value	Reason
Nov-06-2020 15:13:12 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Nov/6/2020	Initial Entry

090177e196ae3d63\Final\Final On: 01-Apr-2021 04:32 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 15-Sep-2020 21:52

Site No: 1214

Subject No: 12141039

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

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1. Date of Completion/Discontinuation/Death

Date	Location	User	Value	Reason
Nov-06-2020 15:15:36 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Nov/6/2020	Initial Entry

2. Phase of Disposition:

Date	Location	User	Value	Reason
Nov-06-2020 15:15:36 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SCREENING	Initial Entry

3. Status:

Date	Location	User	Value	Reason
Nov-06-2020 15:15:36 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: COMPLETED	Initial Entry

090177e196ae3d63\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: 12141039

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

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

Date	Location	User	Value	Reason
Nov-06-2020 15:16:22 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: The subject is NOT known to be HI V POSITIVE	Initial Entry

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 10-Oct-2020 16:04

Site No: 1214

Subject No: 12141039

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

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1. Date:

Date	Location	User	Value	Reason
Nov-06-2020 15:17:06 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Nov/6/2020	Initial Entry

2. Weight:

Date	Location	User	Value	Reason
Nov-06-2020 15:17:06 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 84.0	Initial Entry

3. Unit:

Date	Location	User	Value	Reason
Nov-06-2020 15:17:06 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: kg	Initial Entry

4. Height:

Date	Location	User	Value	Reason
Nov-06-2020 15:17:06 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 172.0	Initial Entry

5. Unit:

Date	Location	User	Value	Reason
Nov-06-2020 15:17:06 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: cm	Initial Entry

6. Body Mass Index:

Date	Location	User	Value	Reason
Nov-06-2020 15:17:06 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 28.4	Initial Entry

090177e196ae3d63\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: 12141039

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

7.a

Date	Location	User	Value	Reason
Nov-06-2020 15:17:06 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Record Identifier:: 1 Temperature: 36.4 Temperature Unit: C Temperature Location:: FOREHEAD	Initial Entry

7.a Record Identifier:

Date	Location	User	Value	Reason
Nov-06-2020 15:17:06 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 1	Initial Entry

7.a Temperature:

Date	Location	User	Value	Reason
Nov-06-2020 15:17:06 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 36.4	Initial Entry

7.a Unit:

Date	Location	User	Value	Reason
Nov-06-2020 15:17:06 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: C	Initial Entry

7.a Temperature Location:

Date	Location	User	Value	Reason
Nov-06-2020 15:17:06 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: FOREHEAD	Initial Entry

090177e196ae3d63\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: 12141039

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

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1. Randomization Date :

Date	Location	User	Value	Reason
Nov-06-2020 15:17:32 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Nov/6/2020	Initial Entry

2. Randomization Number:

Date	Location	User	Value	Reason
Nov-06-2020 15:17:32 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 115789	Initial Entry

Header Text: C4591001**Visit:** V1_DAY1_VAX1_L**Form Version:** 22-Apr-2020 21:03**Site No:** 1214**Subject No:** 12141039**Generated By:** (b) (4)**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - 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. Data Origin**

Date	Location	User	Value	Reason
Nov-06-2020 15:18:47 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Nov-06-2020 15:18:47 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SERUM	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Nov-06-2020 16:42:17 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Nov-06-2020 15:18:47 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Nov-06-2020 15:18:47 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Date of Collection: Nov/6/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Nov-06-2020 16:42:17 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BPZD5B	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
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Header Text: C4591001

Visit: V1_DAY1_VAX1_L

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1214

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

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Subject Initials: ---

Generated By: (b) (4)

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Nov-06-2020 16:42:17 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BPZD5B	Initial Entry
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5.b

Date	Location	User	Value	Reason
Nov-06-2020 16:42:29 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BPZD5C	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Nov-06-2020 16:42:29 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BPZD5C	Initial Entry

5.c

Date	Location	User	Value	Reason
Nov-06-2020 16:42:43 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BSHCXN	Initial Entry

5.c Sample ID

Date	Location	User	Value	Reason
Nov-06-2020 16:42:43 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BSHCXN	Initial Entry

5.d

Date	Location	User	Value	Reason
Nov-06-2020 16:42:54 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BSHCXP	Initial Entry

5.d Sample ID

Date	Location	User	Value	Reason
Nov-06-2020 16:42:54 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BSHCXP	Initial Entry

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Header Text: C4591001**Visit:** V1_DAY1_VAX1_L**Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB - eCRF
Audit Trail History**Form Version:** 22-Apr-2020 21:03**Form Status:** Data Complete, Frozen, Verified**Site No:** 1214**Site Name:** (1214) ISTANBUL UNIVERSITY MEDICAL FACULTY
CARDIOLOGY INSTITUTE**Subject No:** 12141039**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-06-2020 15:19:03 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Nov-06-2020 15:19:03 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: NASAL_SWAB	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Nov-06-2020 16:41:52 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Nov-06-2020 15:19:03 (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-06-2020 15:19:03 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Date of Collection: Nov/6/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Nov-06-2020 16:41:52 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BPZD4P	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
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Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB - eCRF
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Site No: 1214

Site Name: (1214) ISTANBUL UNIVERSITY MEDICAL FACULTY
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Generated By: (b) (4)

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Nov-06-2020 16:41:52 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BPZD4P	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: 12141039

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

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1. Was there a temporary delay of vaccination?

Date	Location	User	Value	Reason
Nov-06-2020 15:19:45 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2. Treatment Name

Date	Location	User	Value	Reason
Nov-06-2020 15:19:45 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: BLINDED THERAPY	Initial Entry

3. Formulation:

Date	Location	User	Value	Reason
Nov-06-2020 15:19:45 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: INJECTION	Initial Entry

4. Dose Date Time:

Date	Location	User	Value	Reason
Nov-06-2020 15:19:45 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Nov/6/2020 11:30	Initial Entry

5. Anatomical Location:

Date	Location	User	Value	Reason
Nov-06-2020 15:19:45 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: DELTOID MUSCLE	Initial Entry

6. Body Side:

Date	Location	User	Value	Reason
Nov-06-2020 15:19:45 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: RIGHT	Initial Entry

7. Route:

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Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:04

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Subject No: 12141039

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

Date	Location	User	Value	Reason
Nov-06-2020 15:19:45 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: INTRAMUSCULAR	Initial Entry

10. Timeframe Subject Was Observed

Date	Location	User	Value	Reason
Nov-06-2020 15:19:45 (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-06-2020 15:19:45 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

090177e196ae3d63\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: 12141039

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

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1. Select appropriate response - Reactogenicity diary collection

Date	Location	User	Value	Reason
Nov-06-2020 15:19:59 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES - REACTOGENICITY E-DIARY COLLECTED FOR THIS SUBJECT	Initial Entry

Header Text: C4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:02

Site No: 1214

Subject No: 12141039

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: ---

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1. Date of Visit

Date	Location	User	Value	Reason
Nov-27-2020 15:28:32 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Nov/27/2020	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: 12141039

Subject Initials: ---

Generated By: (b) (4)

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

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

Date	Location	User	Value	Reason
Nov-27-2020 15:30:30 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2.a

Date	Location	User	Value	Reason
Nov-27-2020 15:30:30 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom:: FEVER Were fever or systemic symptoms present on the last day the Subject Diary was completed?: NO	Initial Entry

2.a Symptom:

Date	Location	User	Value	Reason
Nov-27-2020 15:30:30 (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-27-2020 15:30:30 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2.b

Date	Location	User	Value	Reason
Nov-27-2020 15:30:30 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom:: FATIGUE	Initial Entry

090177e196ae3d63\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

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Form Status: Data Complete, Frozen, Verified

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

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Subject Initials: ---

Generated By: (b) (4)

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

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

Date	Location	User	Value	Reason
Nov-27-2020 15:30:30 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> FATIGUE	Initial Entry

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

Date	Location	User	Value	Reason
Nov-27-2020 15:30:30 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NO	Initial Entry

2.c

Date	Location	User	Value	Reason
Nov-27-2020 15:30:30 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> <u>Symptom::</u> HEA DA CHE Were fever or systemic symptoms present on the last day the Subject Diary was completed?: NO	Initial Entry

090177e196ae3d63\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
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Subject No: 12141039

Subject Initials: ---

Generated By: (b) (4)

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

2.c Symptom:

Date	Location	User	Value	Reason
Nov-27-2020 15:30:30 (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-27-2020 15:30:30 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2.d

Date	Location	User	Value	Reason
Nov-27-2020 15:30:30 (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
Nov-27-2020 15:30:30 (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-27-2020 15:30:30 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2.e

090177e196ae3d63\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

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Subject No: 12141039

Subject Initials: ---

Generated By: (b) (4)

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Date	Location	User	Value	Reason
Nov-27-2020 15:30:30 (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-27-2020 15:30:30 (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-27-2020 15:30:30 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2.f

Date	Location	User	Value	Reason
Nov-27-2020 15:30:30 (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

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Header Text: C4591001

Visit: V2_VAX2_L

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2.f Symptom:

Date	Location	User	Value	Reason
Nov-27-2020 15:30:30 (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-27-2020 15:30:30 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2.g

Date	Location	User	Value	Reason
Nov-27-2020 15:30:30 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom:: NEW OR WORSENE ORSENE MUSCLE PAIN Were fever or systemic symptoms present on the last day the Subject Diary was completed?: YES Ongoing? NO Stop Date: Nov/12/2020	Initial Entry

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Visit: V2_VAX2_L

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Subject Initials: ---

Generated By: (b) (4)

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2.g Symptom:

Date	Location	User	Value	Reason
Nov-27-2020 15:30:30 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NEW OR WORSENERED 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-27-2020 15:30:30 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Ongoing? NO Stop Date: Nov/12/2020	Initial Entry

2.h

Date	Location	User	Value	Reason
Nov-27-2020 15:30:30 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom:: NEW OR WORSENERED JOINT PAIN Were fever or systemic symptoms present on the last day the Subject Diary was completed? :	Initial Entry

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Header Text: C4591001

Visit: V2_VAX2_L

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2.h Symptom:

Date	Location	User	Value	Reason
Nov-27-2020 15:30:30 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NEW OR WORSENERD JOINT PAI N	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-27-2020 15:30:30 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

3. Injection Site Location:

Date	Location	User	Value	Reason
Nov-27-2020 15:30:30 (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-27-2020 15:30:30 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: RIGHT	Initial Entry

5.a

Date	Location	User	Value	Reason
Nov-27-2020 15:30:30 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Injection Site Reaction:: RE DN ESS Were injection site reactions NO present on the last day the S ubject Diary was completed ?:	Initial Entry

5.a Injection Site Reaction:

Date	Location	User	Value	Reason
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090177e196ae3d63\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

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Nov-27-2020 15:30:30 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: REDNESS	Initial Entry
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5.a Were injection site reactions present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Nov-27-2020 15:30:30 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

5.b

Date	Location	User	Value	Reason
Nov-27-2020 15:30:30 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Injection Site Reaction:: SWE LLI NG Were injection site reaction NO s present on the last day th e Subject Diary was compl eted?:	Initial Entry

5.b Injection Site Reaction:

Date	Location	User	Value	Reason
Nov-27-2020 15:30:30 (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-27-2020 15:30:30 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

5.c

Date	Location	User	Value	Reason
Nov-27-2020 15:30:30	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Initial Entry

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Header Text: C4591001

Visit: V2_VAX2_L

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

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Form Status: Data Complete, Frozen, Verified

Site No: 1214

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

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Subject Initials: ---

Generated By: (b) (4)

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

(UTC+03:00) Istanbul		(b) (4), (b) (6)	Injection Site Reaction:: PAIN AT INJECTION SITE Were injection site reactions present on the last day the Subject Diary was completed?: NO
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5.c Injection Site Reaction:

Date	Location	User	Value	Reason
Nov-27-2020 15:30:30 (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-27-2020 15:30:30 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

090177e196ae3d63\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: 12141039

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

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1. Date:

Date	Location	User	Value	Reason
Nov-27-2020 15:31:01 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Nov/27/2020	Initial Entry

2.a

Date	Location	User	Value	Reason
Nov-27-2020 15:31:01 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Record Identifier:: 1 Temperature: 36.1 Temperature Unit: C Temperature Location:: FOREHEAD	Initial Entry

2.a Record Identifier:

Date	Location	User	Value	Reason
Nov-27-2020 15:31:01 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 1	Initial Entry

2.a Temperature:

Date	Location	User	Value	Reason
Nov-27-2020 15:31:01 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 36.1	Initial Entry

2.a Unit:

Date	Location	User	Value	Reason
Nov-27-2020 15:31:01 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: C	Initial Entry

2.a Temperature Location:

090177e196ae3d63\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: 12141039

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-27-2020 15:31:01 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: FOREHEAD	Initial Entry

090177e196ae3d63\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:** 12141039**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-27-2020 15:31:15 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Nov-27-2020 15:31:15 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: NASAL_SWAB	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Nov-27-2020 16:04:33 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Nov-27-2020 15:31:15 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Nov-27-2020 15:31:15 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Date of Collection: Nov/27/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Nov-27-2020 16:04:33 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BPZD7S	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
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Header Text: C4591001

Visit: V2_VAX2_L

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1214

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

Subject No: 12141039

Subject Initials: ---

Generated By: (b) (4)

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

Nov-27-2020 16:04:33 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BPZD7S	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: 12141039

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

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1. Was there a temporary delay of vaccination?

Date	Location	User	Value	Reason
Nov-27-2020 15:31:54 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2. Treatment Name

Date	Location	User	Value	Reason
Nov-27-2020 15:31:54 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: BLINDED THERAPY	Initial Entry

3. Formulation:

Date	Location	User	Value	Reason
Nov-27-2020 15:31:54 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: INJECTION	Initial Entry

4. Dose Date Time:

Date	Location	User	Value	Reason
Nov-27-2020 15:31:54 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Nov/27/2020 12:20	Initial Entry

5. Anatomical Location:

Date	Location	User	Value	Reason
Nov-27-2020 15:31:54 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: DELTOID MUSCLE	Initial Entry

6. Body Side:

Date	Location	User	Value	Reason
Nov-27-2020 15:31:54 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: RIGHT	Initial Entry

7. Route:

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090177e196ae3d63\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: 12141039

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

Date	Location	User	Value	Reason
Nov-27-2020 15:31:54 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: INTRAMUSCULAR	Initial Entry

10. Timeframe Subject Was Observed

Date	Location	User	Value	Reason
Nov-27-2020 15:31:54 (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-27-2020 15:31:54 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

090177e196ae3d63\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: 12141039

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

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1. Date of Visit

Date	Location	User	Value	Reason
Dec-28-2020 13:26:28 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Dec/28/2020	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: 12141039

Subject Initials: ---

Generated By: (b) (4)

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

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

Date	Location	User	Value	Reason
Dec-28-2020 13:26:55 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NO	Initial Entry

2.a

Date	Location	User	Value	Reason
Dec-28-2020 13:26:55 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Symptom:: FEVER 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-28-2020 13:26:55 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> FEVER	Initial Entry

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

Date	Location	User	Value	Reason
Dec-28-2020 13:26:55 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NO	Initial Entry

2.b

Date	Location	User	Value	Reason
Dec-28-2020 13:26:55 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Symptom:: FATIGUE	Initial Entry

090177e196ae3d63\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: 12141039
Subject Initials: ---
Generated By: (b) (4)
Generated Time (GMT): 29-Mar-2021 13:11

			UE	
			Were fever or systemic symptoms present on the last day the Subject Diary was completed?:	

2.b Symptom:

Date	Location	User	Value	Reason
Dec-28-2020 13:26:55 (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-28-2020 13:26:55 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2.c

Date	Location	User	Value	Reason
Dec-28-2020 13:26:55 (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

090177e196ae3d63\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: 12141039

Subject Initials: ---

Generated By: (b) (4)

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

2.c Symptom:

Date	Location	User	Value	Reason
Dec-28-2020 13:26:55 (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-28-2020 13:26:55 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2.d

Date	Location	User	Value	Reason
Dec-28-2020 13:26:55 (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-28-2020 13:26:55 (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-28-2020 13:26:55 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2.e

090177e196ae3d63\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: 12141039

Subject Initials: ---

Generated By: (b) (4)

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

Date	Location	User	Value	Reason
Dec-28-2020 13:26:55 (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-28-2020 13:26:55 (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-28-2020 13:26:55 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2.f

Date	Location	User	Value	Reason
Dec-28-2020 13:26:55 (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

090177e196ae3d63\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: 12141039

Subject Initials: ---

Generated By: (b) (4)

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

2.f Symptom:

Date	Location	User	Value	Reason
Dec-28-2020 13:26:55 (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-28-2020 13:26:55 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2.g

Date	Location	User	Value	Reason
Dec-28-2020 13:26:55 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom:: NEW OR WORSE ED MUSC LE 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-28-2020 13:26:55 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NEW OR WORSE NED MUSCLE PAIN	Initial Entry

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

Date	Location	User	Value	Reason
Dec-28-2020 13:26:55 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

090177e196ae3d63\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: 12141039

Subject Initials: ---

Generated By: (b) (4)

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

2.h

Date	Location	User	Value	Reason
Dec-28-2020 13:26:55 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom:: NEW OR WORSE ED JOINT PAIN Were fever or systemic NO symptoms present on the last day the Subject Diary was completed? :	Initial Entry

2.h Symptom:

Date	Location	User	Value	Reason
Dec-28-2020 13:26:55 (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-28-2020 13:26:55 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

3. Injection Site Location:

Date	Location	User	Value	Reason
Dec-28-2020 13:26:55 (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-28-2020 13:26:55 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: RIGHT	Initial Entry

090177e196ae3d63\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: 12141039

Subject Initials: ---

Generated By: (b) (4)

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

5.a

Date	Location	User	Value	Reason
Dec-28-2020 13:26:55 (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-28-2020 13:26:55 (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-28-2020 13:26:55 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

5.b

Date	Location	User	Value	Reason
Dec-28-2020 13:26:55 (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

090177e196ae3d63\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: 12141039

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-28-2020 13:26:55 (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-28-2020 13:26:55 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

5.c

Date	Location	User	Value	Reason
Dec-28-2020 13:26:55 (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?:	Initial Entry

5.c Injection Site Reaction:

Date	Location	User	Value	Reason
Dec-28-2020 13:26:55 (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-28-2020 13:26:55 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

090177e196ae3d63\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:** 12141039**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-28-2020 13:27:11 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Dec-28-2020 13:27:11 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SERUM	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Dec-28-2020 14:50:32 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Dec-28-2020 13:27:11 (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-28-2020 13:27:11 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Date of Collection: Dec/28/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Dec-28-2020 14:50:32 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BSHD1J	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: 12141039

Subject Initials: ---

Generated By: (b) (4)

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

Dec-28-2020 14:50:32 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BSHD1J	Initial Entry
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5.b

Date	Location	User	Value	Reason
Dec-28-2020 14:50:42 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BSHD1K	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Dec-28-2020 14:50:42 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BSHD1K	Initial Entry

5.c

Date	Location	User	Value	Reason
Dec-28-2020 14:50:51 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BPZDC2	Initial Entry

5.c Sample ID

Date	Location	User	Value	Reason
Dec-28-2020 14:50:51 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BPZDC2	Initial Entry

5.d

Date	Location	User	Value	Reason
Dec-28-2020 14:51:00 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BPZDC3	Initial Entry

5.d Sample ID

Date	Location	User	Value	Reason
Dec-28-2020 14:51:00 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BPZDC3	Initial Entry

090177e196ae3d63\Final\Final On: 01-Apr-2021 04:32 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** DATE OF VISIT - ILLNESS ONSET - eCRF Audit Trail History on Jan/08/2021

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: 12141039

Subject Initials: ---

Generated By: (b) (4)

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

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1. Date of Visit

Date	Location	User	Value	Reason
Jan-08-2021 18:29:47 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Jan-08-2021 18:28:49 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Deleted	Close Auto Query
Jan-08-2021 18:22:09 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Candidate	Date of Visit is completed but Date of Assessment in the Signs and Symptoms form is missing. Please review and update as appropriate.
Jan-08-2021 18:22:09 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	Date of Visit is completed but Date of Collection in both Nasal Swab Self and Nasal Swab are missing. Please review and update as appropriate.
Jan-08-2021 18:22:09 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Jan/8/2021	Initial Entry

3. COVID-19 Illness Visit:

Date	Location	User	Value	Reason
Jan-08-2021 18:22:09 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: COVID_A	Initial Entry

090177e196ae3d63\Final\Final On: 01-Apr-2021 04:32 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Jan/08/2021

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

Form Version: 10-Dec-2020 02:29

Form Status: Data Complete

Site No: 1214

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

Subject No: 12141039

Subject Initials: ---

Generated By: (b) (4)

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

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1. Date of Assessment:

Date	Location	User	Value	Reason
Jan-08-2021 18:28:49 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Jan/8/2021	Initial Entry

2. Date of First Symptom Started:

Date	Location	User	Value	Reason
Jan-08-2021 18:28:49 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Jan/5/2021	Initial Entry

3. Symptoms Ongoing?

Date	Location	User	Value	Reason
Feb-10-2021 15:10:00 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Feb-09-2021 18:33:08 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Changed Information
Feb-09-2021 18:33:08 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO Date of Last Symptom Resolved : Jan/9/2021	Changed Information
Feb-09-2021 17:20:29 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	clinical query: subject has been revaccinated but symptoms are still ongoing? can you please check and update the eCRF with a stop date?
Jan-08-2021 18:28:49 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

4.a

090177e196ae3d63\Final\Final On: 01-Apr-2021 04:32 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Jan/08/2021

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

Form Version: 10-Dec-2020 02:29

Form Status: Data Complete

Site No: 1214

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

Subject No: 12141039

Subject Initials: ---

Generated By: (b) (4)

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

Date	Location	User	Value	Reason
Jan-08-2021 18:28:49 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptoms: FEVER Symptom Present: YES	Initial Entry

4.a Symptoms:

Date	Location	User	Value	Reason
Jan-08-2021 18:28:49 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: FEVER	Initial Entry

4.a Was symptom present?

Date	Location	User	Value	Reason
Jan-08-2021 18:28:49 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

4.b

Date	Location	User	Value	Reason
Jan-08-2021 18:28:49 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptoms: NEW OR INCREASED COUGH Symptom Present: NO	Initial Entry

4.b Symptoms:

Date	Location	User	Value	Reason
Jan-08-2021 18:28:49 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NEW OR INCREASED COUGH	Initial Entry

4.b Was symptom present?

Date	Location	User	Value	Reason
Jan-08-2021 18:28:49 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

4.c

090177e196ae3d63\Final\Final On: 01-Apr-2021 04:32 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Jan/08/2021

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

Form Version: 10-Dec-2020 02:29

Form Status: Data Complete

Site No: 1214

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

Subject No: 12141039

Subject Initials: ---

Generated By: (b) (4)

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

Date	Location	User	Value	Reason
Jan-08-2021 18:28:49 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom: NEW OR INCREASED SHORTNESS OF BREATH Symptom Present: NO	Initial Entry

4.c Symptoms:

Date	Location	User	Value	Reason
Jan-08-2021 18:28:49 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NEW OR INCREASED SHORTNESS OF BREATH	Initial Entry

4.c Was symptom present?

Date	Location	User	Value	Reason
Jan-08-2021 18:28:49 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

4.d

Date	Location	User	Value	Reason
Jan-08-2021 18:28:49 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptoms: CHILLS Symptom Present: NO	Initial Entry

4.d Symptoms:

Date	Location	User	Value	Reason
Jan-08-2021 18:28:49 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: CHILLS	Initial Entry

4.d Was symptom present?

Date	Location	User	Value	Reason
Jan-08-2021 18:28:49 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

090177e196ae3d63\Final\Final On: 01-Apr-2021 04:32 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Jan/08/2021

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

Form Version: 10-Dec-2020 02:29

Form Status: Data Complete

Site No: 1214

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

Subject No: 12141039

Subject Initials: ---

Generated By: (b) (4)

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

4.e

Date	Location	User	Value	Reason
Jan-08-2021 18:28:49 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom NEW OR INCREASED MUSCLE PAIN Symptom YES Present:	Initial Entry

4.e Symptoms:

Date	Location	User	Value	Reason
Jan-08-2021 18:28:49 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NEW OR INCREASED MUSCLE PAIN	Initial Entry

4.e Was symptom present?

Date	Location	User	Value	Reason
Jan-08-2021 18:28:49 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

4.f

Date	Location	User	Value	Reason
Jan-08-2021 18:28:49 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptoms NEW LOSS OF TASTE OR SMELL Symptom NO Present:	Initial Entry

090177e196ae3d63\Final\Final On: 01-Apr-2021 04:32 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Jan/08/2021

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

Form Version: 10-Dec-2020 02:29

Form Status: Data Complete

Site No: 1214

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

Subject No: 12141039

Subject Initials: ---

Generated By: (b) (4)

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

4.f Symptoms:

Date	Location	User	Value	Reason
Jan-08-2021 18:28:49 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NEW LOSS OF TASTE OR SWEET TASTE	Initial Entry

4.f Was symptom present?

Date	Location	User	Value	Reason
Jan-08-2021 18:28:49 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

4.g

Date	Location	User	Value	Reason
Jan-08-2021 18:28:49 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom NEW OR INCREASED SORE THROAT Symptom NO Present:	Initial Entry

4.g Symptoms:

Date	Location	User	Value	Reason
Jan-08-2021 18:28:49 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NEW OR INCREASED SORE THROAT	Initial Entry

4.g Was symptom present?

Date	Location	User	Value	Reason
Jan-08-2021 18:28:49 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

4.h

Date	Location	User	Value	Reason
Jan-08-2021 18:28:49 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptoms: DIARRHEA Symptom Present: NO	Initial Entry

090177e196ae3d63\Final\Final On: 01-Apr-2021 04:32 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Jan/08/2021

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

Form Version: 10-Dec-2020 02:29

Form Status: Data Complete

Site No: 1214

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

Subject No: 12141039

Subject Initials: ---

Generated By: (b) (4)

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

4.h Symptoms:

Date	Location	User	Value	Reason
Jan-08-2021 18:28:49 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: DIARRHEA	Initial Entry

4.h Was symptom present?

Date	Location	User	Value	Reason
Jan-08-2021 18:28:49 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

4.i

Date	Location	User	Value	Reason
Jan-08-2021 18:28:49 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptoms: VOMITING Symptom Present: NO	Initial Entry

4.i Symptoms:

Date	Location	User	Value	Reason
Jan-08-2021 18:28:49 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: VOMITING	Initial Entry

4.i Was symptom present?

Date	Location	User	Value	Reason
Jan-08-2021 18:28:49 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

090177e196ae3d63\Final\Final On: 01-Apr-2021 04:32 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit Form: MICROBIOLOGY SPECIMEN - eCRF Audit Trail History on Jan/08/2021

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete

Site No: 1214

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

Subject No: 12141039

Subject Initials: ---

Generated By: (b) (4)

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

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1. Actual Date of Collection:

Date	Location	User	Value	Reason
Jan-08-2021 18:29:04 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

2. Specimen Type:

Date	Location	User	Value	Reason
Jan-08-2021 18:29:04 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

3. Specimen Collection Location:

Date	Location	User	Value	Reason
Jan-08-2021 18:29:04 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

4. Assay Code and Description:

Date	Location	User	Value	Reason
Jan-08-2021 18:29:04 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

5. Device Type:

Date	Location	User	Value	Reason
Jan-08-2021 18:29:04 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

6. Trade Name:

Date	Location	User	Value	Reason
Jan-08-2021 18:29:04 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

7. Test Result:

Date	Location	User	Value	Reason
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090177e196ae3d63\Final\Final On: 01-Apr-2021 04:32 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** MICROBIOLOGY SPECIMEN - eCRF Audit Trail History
on Jan/08/2021

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete

Site No: 1214

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

Subject No: 12141039

Subject Initials: ---

Generated By: (b) (4)

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

Jan-08-2021 18:29:04 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry
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8. Comments/Findings/Details:

Date	Location	User	Value	Reason
Jan-08-2021 18:29:04 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

9. Trade Name Other, Specify:

Date	Location	User	Value	Reason
Jan-08-2021 18:29:04 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

090177e196ae3d63\Final\Final On: 01-Apr-2021 04:32 (GMT)

Header Text: C4591001**Visit:** POT_COVID_ILL 1 - Unscheduled Visit on Jan/08/2021**Form Version:** 22-Apr-2020 21:03**Site No:** 1214**Subject No:** 12141039**Generated By:** (b) (4)**Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB SELF - 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. Data Origin**

Date	Location	User	Value	Reason
Jan-12-2021 17:07:44 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry
Jan-12-2021 17:07:32 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Initial Entry
Jan-08-2021 18:29:28 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Jan-12-2021 17:07:44 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: NASAL_SWAB_SELF	Initial Entry
Jan-12-2021 17:07:32 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Initial Entry
Jan-08-2021 18:29:28 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Jan-12-2021 23:58:30 (UTC+03:00) Istanbul	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (b) (4)	Query 1: Clo sed	Auto closed by Validation Check: VC_BEETRK001_07
Jan-12-2021 17:08:31 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Clo sed	Close Auto Query
Jan-12-2021 17:07:44 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Ope ned	'Sample Collected?' is marked as No and 'If no sample was collected or sample was not collected

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Jan/08/2021

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1214

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

Subject No: 12141039

Subject Initials: ---

Generated By: (b) (4)

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

				according to protocol, please provide reason' is missing. Please review and update as appropriate.
Jan-12-2021 17:07:44 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Initial Entry
Jan-12-2021 17:07:44 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry : NO	Initial Entry
Jan-12-2021 17:07:32 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry :	Initial Entry
Jan-12-2021 11:47:20 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reissued: Opened	DM: Thank you for response , if the sample was not collected please consider updating item #3 to No and provide the reason the sample was not collected on item #4.
Jan-11-2021 10:19:30 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	sample was collected as swab pfe
Jan-11-2021 08:22:43 (UTC+03:00) Istanbul	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (b) (4)	Query 1: Opened	DMW6741626;Sample Collected is not expected to be marked Not Done. Please complete. If the sample was not obtained, Sample Collected = No. Sample Comments box should be entered with reason sample not

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Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Jan/08/2021

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1214

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

Subject No: 12141039

Subject Initials: ---

Generated By: (b) (4)

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

				collected. Please consider update.
Jan-08-2021 18:29:28 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: : Not Done	Initial Entry

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

Date	Location	User	Value	Reason
Jan-12-2021 17:08:31 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: sample was collected as swab pfe	Initial Entry
Jan-12-2021 17:07:32 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Initial Entry
Jan-08-2021 18:29:28 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

090177e196ae3d63\Final\Final On: 01-Apr-2021 04:32 (GMT)

Header Text: C4591001**Visit:** POT_COVID_ILL 1 - Unscheduled Visit
on Jan/08/2021**Form Version:** 22-Apr-2020 21:03**Site No:** 1214**Subject No:** 12141039**Generated By:** (b) (4)**Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB - 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. Data Origin**

Date	Location	User	Value	Reason
Jan-08-2021 18:29:47 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Jan-08-2021 18:29:47 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: NASAL_SWAB	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Jan-08-2021 18:30:08 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Jan-08-2021 18:29:47 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Jan-08-2021 18:29:47 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Date of Collection: Jan/8/2021	Initial Entry

5.a

Date	Location	User	Value	Reason
Jan-08-2021 18:30:08 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BR5CW1	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
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Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit
on Jan/08/2021

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: 12141039

Subject Initials: ---

Generated By: (b) (4)

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

Jan-08-2021 18:30:08 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BR5CW1	Initial Entry
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Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Jan/08/2021

Form: HEALTH CARE UTILIZATION - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:26

Form Status: Data Complete

Site No: 1214

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

Subject No: 12141039

Subject Initials: ---

Generated By: (b) (4)

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

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I.a

Date	Location	User	Value	Reason
Jan-08-2021 18:30:32 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Type of Practitioner: SPECIALIST Occurrence of Visits or Contacts: NO	Initial Entry

I.a Physician or Healthcare Professional:

Date	Location	User	Value	Reason
Jan-08-2021 18:30:32 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: SPECIALIST	Initial Entry

I.a Occurrence of Visits or Contacts:

Date	Location	User	Value	Reason
Jan-08-2021 18:30:32 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

I.b

Date	Location	User	Value	Reason
Jan-08-2021 18:30:32 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Type of Practitioner: EMERGENCY ROOM Occurrence of Visits or Contacts: NO	Initial Entry

090177e196ae3d63\Final\Final On: 01-Apr-2021 04:32 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit Form: HEALTH CARE UTILIZATION - eCRF Audit Trail History on Jan/08/2021

Form Version: 10-Dec-2020 02:26

Form Status: Data Complete

Site No: 1214

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

Subject No: 12141039

Subject Initials: ---

Generated By: (b) (4)

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

1.b Physician or Healthcare Professional:

Date	Location	User	Value	Reason
Jan-08-2021 18:30:32 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: EMERGENCY ROOM	Initial Entry

1.b Occurrence of Visits or Contacts:

Date	Location	User	Value	Reason
Jan-08-2021 18:30:32 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

1.c

Date	Location	User	Value	Reason
Jan-08-2021 18:30:32 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Type of Practitioner: PRIMARY CARE PHYSICIAN N Occurrence of Visits or Contacts NO :	Initial Entry

1.c Physician or Healthcare Professional:

Date	Location	User	Value	Reason
Jan-08-2021 18:30:32 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: PRIMARY CARE PHYSICIAN	Initial Entry

1.c Occurrence of Visits or Contacts:

Date	Location	User	Value	Reason
Jan-08-2021 18:30:32 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

1.d

Date	Location	User	Value	Reason
Jan-08-2021 18:30:32 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Type of Practitioner: URGENT CARE	Initial Entry

090177e196ae3d63\Final\Final On: 01-Apr-2021 04:32 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit Form: HEALTH CARE UTILIZATION - eCRF Audit Trail History on Jan/08/2021

Form Version: 10-Dec-2020 02:26

Form Status: Data Complete

Site No: 1214

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

Subject No: 12141039

Subject Initials: ---

Generated By: (b) (4)

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

			Occurrence of Visits NO or Contacts:	
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1.d Physician or Healthcare Professional:

Date	Location	User	Value	Reason
Jan-08-2021 18:30:32 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: URGENT CARE	Initial Entry

1.d Occurrence of Visits or Contacts:

Date	Location	User	Value	Reason
Jan-08-2021 18:30:32 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

1.e

Date	Location	User	Value	Reason
Jan-08-2021 18:30:32 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Type of Practitioner: TELEPHONE CONSULTATION Occurrence of Visits or Contacts: NO	Initial Entry

1.e Physician or Healthcare Professional:

Date	Location	User	Value	Reason
Jan-08-2021 18:30:32 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: TELEPHONE CONSULTATION	Initial Entry

1.e Occurrence of Visits or Contacts:

Date	Location	User	Value	Reason
Jan-08-2021 18:30:32 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

1.f

Date	Location	User	Value	Reason
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090177e196ae3d63\Final\Final On: 01-Apr-2021 04:32 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit Form: HEALTH CARE UTILIZATION - eCRF Audit Trail History on Jan/08/2021

Form Version: 10-Dec-2020 02:26

Form Status: Data Complete

Site No: 1214

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

Subject No: 12141039

Subject Initials: ---

Generated By: (b) (4)

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

Jan-08-2021 18:30:32 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Type of Practitioner: OTH R Occurrence of Visits or C NO ontacts:	Initial Entry
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1.f Physician or Healthcare Professional:

Date	Location	User	Value	Reason
Jan-08-2021 18:30:32 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: OTHER	Initial Entry

1.f Occurrence of Visits or Contacts:

Date	Location	User	Value	Reason
Jan-08-2021 18:30:32 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

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

Date	Location	User	Value	Reason
Jan-08-2021 18:30:32 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

090177e196ae3d63\Final\Final On: 01-Apr-2021 04:32 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit Form: RESPIRATORY TREATMENT - eCRF Audit Trail History on Jan/08/2021

Form Version: 06-Jul-2020 21:53

Form Status: Data Complete

Site No: 1214

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

Subject No: 12141039

Subject Initials: ---

Generated By: (b) (4)

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

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1. What is the treatment Identifier?

Date	Location	User	Value	Reason
Jan-08-2021 18:30:44 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

2. Concomitant Non-drug Treatment Pre-specified:

Date	Location	User	Value	Reason
Jan-08-2021 18:30:44 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

3. Treatment:

Date	Location	User	Value	Reason
Jan-08-2021 18:30:44 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

4. Treatment:

Date	Location	User	Value	Reason
Jan-08-2021 18:30:44 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5. Start Date:

Date	Location	User	Value	Reason
Jan-08-2021 18:30:44 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

6. Ongoing?

Date	Location	User	Value	Reason
Jan-08-2021 18:30:44 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

090177e196ae3d63\Final\Final On: 01-Apr-2021 04:32 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** ILLNESS DETAILS - eCRF Audit Trail History
on Jan/08/2021

Form Version: 06-Jul-2020 21:52

Form Status: Data Complete

Site No: 1214

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

Subject No: 12141039

Subject Initials: ---

Generated By: (b) (4)

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

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1. Category of Clinical Event:

Date	Location	User	Value	Reason
Jan-08-2021 18:31:11 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: POTENTIAL COVID-19 ILLNESS	Initial Entry

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

Date	Location	User	Value	Reason
Jan-08-2021 18:31:11 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

3. Toxicity Grade:

Date	Location	User	Value	Reason
Jan-08-2021 18:31:11 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 1	Initial Entry

090177e196ae3d63\Final\Final On: 01-Apr-2021 04:32 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** ILLNESS DETAILS - SEVERE - eCRF Audit Trail History on Jan/08/2021

Form Version: 17-Jul-2020 21:55

Form Status: Data Complete

Site No: 1214

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

Subject No: 12141039

Subject Initials: ---

Generated By: (b) (4)

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

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1. Category of Clinical Event:

Date	Location	User	Value	Reason
Jan-08-2021 18:31:23 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

2. Subcategory of Clinical Event:

Date	Location	User	Value	Reason
Jan-08-2021 18:31:23 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

3. Was a diagnosis obtained?

Date	Location	User	Value	Reason
Jan-08-2021 18:31:23 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

4. Toxicity Grade:

Date	Location	User	Value	Reason
Jan-08-2021 18:31:23 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

090177e196ae3d63\Final\Final On: 01-Apr-2021 04:32 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Jan/08/2021

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

Form Version: 10-Oct-2020 15:58

Form Status: Data Complete

Site No: 1214

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

Subject No: 12141039

Subject Initials: ---

Generated By: (b) (4)

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

[Back to Form](#)

1. Lab Panel:

Date	Location	User	Value	Reason
Jan-08-2021 18:31:39 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

2. Laboratory Name and Address

Date	Location	User	Value	Reason
Jan-08-2021 18:31:39 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

3. Collection Date:

Date	Location	User	Value	Reason
Jan-08-2021 18:31:39 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

4. Specimen Type:

Date	Location	User	Value	Reason
Jan-08-2021 18:31:39 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.a

Date	Location	User	Value	Reason
Jan-08-2021 18:31:39 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sponsor-Defined Identifier: Not Applicable Test:: Not Applicable Result:: Not Applicable Not Done:: Not Applicable Lab Normal Range: Not Applicable	Initial Entry

090177e196ae3d63\Final\Final On: 01-Apr-2021 04:32 (GMT)

Header Text: C4591001**Visit:** POT_COVID_ILL 1 - Unscheduled Visit on Jan/08/2021**Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History**Form Version:** 10-Oct-2020 15:58**Form Status:** Data Complete**Site No:** 1214**Site Name:** (1214) ISTANBUL UNIVERSITY MEDICAL FACULTY CARDIOLOGY INSTITUTE**Subject No:** 12141039**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 13:11**5.a Sponsor ID:**

Date	Location	User	Value	Reason
Jan-08-2021 18:31:39 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.a Test:

Date	Location	User	Value	Reason
Jan-08-2021 18:31:39 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.a Result:

Date	Location	User	Value	Reason
Jan-08-2021 18:31:39 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.a Not Done:

Date	Location	User	Value	Reason
Jan-08-2021 18:31:39 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.a LNMT

Date	Location	User	Value	Reason
Jan-08-2021 18:31:39 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.b

Date	Location	User	Value	Reason
Jan-08-2021 18:31:39 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sponsor-Defined Identifier: Not Applicable Test:: Not Applicable Result:: Not Applicable	Initial Entry

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Jan/08/2021

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

Form Version: 10-Oct-2020 15:58

Form Status: Data Complete

Site No: 1214

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

Subject No: 12141039

Subject Initials: ---

Generated By: (b) (4)

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

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

5.b Sponsor ID:

Date	Location	User	Value	Reason
Jan-08-2021 18:31:39 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.b Test:

Date	Location	User	Value	Reason
Jan-08-2021 18:31:39 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.b Result:

Date	Location	User	Value	Reason
Jan-08-2021 18:31:39 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.b Not Done:

Date	Location	User	Value	Reason
Jan-08-2021 18:31:39 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.b LNMT

Date	Location	User	Value	Reason
Jan-08-2021 18:31:39 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.c

Date	Location	User	Value	Reason
Jan-08-2021 18:31:39 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sponsor-Defined Identifier: Not Applicable	Initial Entry

090177e196ae3d63\Final\Final On: 01-Apr-2021 04:32 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Jan/08/2021

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

Form Version: 10-Oct-2020 15:58

Form Status: Data Complete

Site No: 1214

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

Subject No: 12141039

Subject Initials: ---

Generated By: (b) (4)

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

			Test:: Not Applicable Result:: Not Applicable Not Done:: Not Applicable Lab Normal Range: Not Applicable
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5.c Sponsor ID:

Date	Location	User	Value	Reason
Jan-08-2021 18:31:39 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.c Test:

Date	Location	User	Value	Reason
Jan-08-2021 18:31:39 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.c Result:

Date	Location	User	Value	Reason
Jan-08-2021 18:31:39 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.c Not Done:

Date	Location	User	Value	Reason
Jan-08-2021 18:31:39 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.c LNMT

Date	Location	User	Value	Reason
Jan-08-2021 18:31:39 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.d

090177e196ae3d63\Final\Final On: 01-Apr-2021 04:32 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Jan/08/2021

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

Form Version: 10-Oct-2020 15:58

Form Status: Data Complete

Site No: 1214

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

Subject No: 12141039

Subject Initials: ---

Generated By: (b) (4)

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

Date	Location	User	Value	Reason
Jan-08-2021 18:31:39 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sponsor-Defined Identifier: Not Applicable Test:: Not Applicable Result:: Not Applicable Not Done:: Not Applicable Lab Normal Range: Not Applicable	Initial Entry

Header Text: C4591001**Visit:** POT_COVID_ILL 1 - Unscheduled Visit on Jan/08/2021**Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History**Form Version:** 10-Oct-2020 15:58**Form Status:** Data Complete**Site No:** 1214**Site Name:** (1214) ISTANBUL UNIVERSITY MEDICAL FACULTY CARDIOLOGY INSTITUTE**Subject No:** 12141039**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 13:11**5.d Sponsor ID:**

Date	Location	User	Value	Reason
Jan-08-2021 18:31:39 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.d Test:

Date	Location	User	Value	Reason
Jan-08-2021 18:31:39 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.d Result:

Date	Location	User	Value	Reason
Jan-08-2021 18:31:39 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.d Not Done:

Date	Location	User	Value	Reason
Jan-08-2021 18:31:39 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.d LNMT

Date	Location	User	Value	Reason
Jan-08-2021 18:31:39 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.e

Date	Location	User	Value	Reason
Jan-08-2021 18:31:39 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sponsor-Defined Identifier: Not Applicable Test:: Not Applicable Result:: Not Applicable	Initial Entry

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Jan/08/2021

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

Form Version: 10-Oct-2020 15:58

Form Status: Data Complete

Site No: 1214

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

Subject No: 12141039

Subject Initials: ---

Generated By: (b) (4)

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

			Not Done:	Not Applicable
			Lab Normal Range:	Not Applicable

5.e Sponsor ID:

Date	Location	User	Value	Reason
Jan-08-2021 18:31:39 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.e Test:

Date	Location	User	Value	Reason
Jan-08-2021 18:31:39 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.e Result:

Date	Location	User	Value	Reason
Jan-08-2021 18:31:39 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.e Not Done:

Date	Location	User	Value	Reason
Jan-08-2021 18:31:39 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.e LNMT

Date	Location	User	Value	Reason
Jan-08-2021 18:31:39 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.f

Date	Location	User	Value	Reason
Jan-08-2021 18:31:39 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sponsor-Defined Identifier: Not Applicable	Initial Entry

090177e196ae3d63\Final\Final On: 01-Apr-2021 04:32 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Jan/08/2021

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

Form Version: 10-Oct-2020 15:58

Form Status: Data Complete

Site No: 1214

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

Subject No: 12141039

Subject Initials: ---

Generated By: (b) (4)

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

			Test:: Not Applicable Result:: Not Applicable Not Done:: Not Applicable Lab Normal Range: Not Applicable
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5.f Sponsor ID:

Date	Location	User	Value	Reason
Jan-08-2021 18:31:39 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.f Test:

Date	Location	User	Value	Reason
Jan-08-2021 18:31:39 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.f Result:

Date	Location	User	Value	Reason
Jan-08-2021 18:31:39 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.f Not Done:

Date	Location	User	Value	Reason
Jan-08-2021 18:31:39 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.f LNMT

Date	Location	User	Value	Reason
Jan-08-2021 18:31:39 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.g

090177e196ae3d63\Final\Final On: 01-Apr-2021 04:32 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Jan/08/2021

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

Date	Location	User	Value	Reason
Jan-08-2021 18:31:39 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sponsor-Defined Identifier: Not Applicable Test:: Not Applicable Result:: Not Applicable Not Done:: Not Applicable Lab Normal Range: Not Applicable	Initial Entry

Header Text: C4591001

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5.g Sponsor ID:

Date	Location	User	Value	Reason
Jan-08-2021 18:31:39 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.g Test:

Date	Location	User	Value	Reason
Jan-08-2021 18:31:39 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

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Jan-08-2021 18:31:39 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.g Not Done:

Date	Location	User	Value	Reason
Jan-08-2021 18:31:39 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.g LNMT

Date	Location	User	Value	Reason
Jan-08-2021 18:31:39 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

090177e196ae3d63\Final\Final On: 01-Apr-2021 04:32 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Jan/08/2021

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

Form Version: 10-Oct-2020 16:02

Form Status: Data Complete

Site No: 1214

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

Subject No: 12141039

Subject Initials: ---

Generated By: (b) (4)

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

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1. Lab Panel:

Date	Location	User	Value	Reason
Jan-08-2021 18:31:57 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

2. Laboratory Name and Address

Date	Location	User	Value	Reason
Jan-08-2021 18:31:57 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

3. Collection Date:

Date	Location	User	Value	Reason
Jan-08-2021 18:31:57 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

4. Specimen Type:

Date	Location	User	Value	Reason
Jan-08-2021 18:31:57 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.a

Date	Location	User	Value	Reason
Jan-08-2021 18:31:57 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sponsor-Defined Identifier: Not Applicable Test:: Not Applicable Result:: Not Applicable Not Done:: Not Applicable Lab Normal Range: Not Applicable	Initial Entry

090177e196ae3d63\Final\Final On: 01-Apr-2021 04:32 (GMT)

Header Text: C4591001**Visit:** POT_COVID_ILL 1 - Unscheduled Visit on Jan/08/2021**Form:** LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History**Form Version:** 10-Oct-2020 16:02**Form Status:** Data Complete**Site No:** 1214**Site Name:** (1214) ISTANBUL UNIVERSITY MEDICAL FACULTY CARDIOLOGY INSTITUTE**Subject No:** 12141039**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 13:11**5.a Sponsor ID:**

Date	Location	User	Value	Reason
Jan-08-2021 18:31:57 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.a Test:

Date	Location	User	Value	Reason
Jan-08-2021 18:31:57 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.a Result:

Date	Location	User	Value	Reason
Jan-08-2021 18:31:57 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.a Not Done:

Date	Location	User	Value	Reason
Jan-08-2021 18:31:57 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.a LNMT

Date	Location	User	Value	Reason
Jan-08-2021 18:31:57 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.b

Date	Location	User	Value	Reason
Jan-08-2021 18:31:57 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sponsor-Defined Identifier: Not Applicable Test:: Not Applicable Result:: Not Applicable	Initial Entry

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Jan/08/2021

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

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Form Status: Data Complete

Site No: 1214

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

Subject No: 12141039

Subject Initials: ---

Generated By: (b) (4)

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

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

5.b Sponsor ID:

Date	Location	User	Value	Reason
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5.b Test:

Date	Location	User	Value	Reason
Jan-08-2021 18:31:57 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.b Result:

Date	Location	User	Value	Reason
Jan-08-2021 18:31:57 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.b Not Done:

Date	Location	User	Value	Reason
Jan-08-2021 18:31:57 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.b LNMT

Date	Location	User	Value	Reason
Jan-08-2021 18:31:57 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.c

Date	Location	User	Value	Reason
Jan-08-2021 18:31:57 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sponsor-Defined Identifier: Not Applicable	Initial Entry

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Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Jan/08/2021

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Site No: 1214

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

Subject No: 12141039

Subject Initials: ---

Generated By: (b) (4)

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

			Test:: Not Applicable Result:: Not Applicable Not Done:: Not Applicable Lab Normal Range: Not Applicable
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5.c Sponsor ID:

Date	Location	User	Value	Reason
Jan-08-2021 18:31:57 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.c Test:

Date	Location	User	Value	Reason
Jan-08-2021 18:31:57 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.c Result:

Date	Location	User	Value	Reason
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5.c Not Done:

Date	Location	User	Value	Reason
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5.c LNMT

Date	Location	User	Value	Reason
Jan-08-2021 18:31:57 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.d

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Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Jan/08/2021

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

Form Version: 10-Oct-2020 16:02

Form Status: Data Complete

Site No: 1214

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Subject No: 12141039

Subject Initials: ---

Generated By: (b) (4)

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

Date	Location	User	Value	Reason
Jan-08-2021 18:31:57 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sponsor-Defined Identifier: Not Applicable Test:: Not Applicable Result:: Not Applicable Not Done:: Not Applicable Lab Normal Range: Not Applicable	Initial Entry

Header Text: C4591001**Visit:** POT_COVID_ILL 1 - Unscheduled Visit on Jan/08/2021**Form:** LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History**Form Version:** 10-Oct-2020 16:02**Form Status:** Data Complete**Site No:** 1214**Site Name:** (1214) ISTANBUL UNIVERSITY MEDICAL FACULTY CARDIOLOGY INSTITUTE**Subject No:** 12141039**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 13:11**5.d Sponsor ID:**

Date	Location	User	Value	Reason
Jan-08-2021 18:31:57 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.d Test:

Date	Location	User	Value	Reason
Jan-08-2021 18:31:57 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.d Result:

Date	Location	User	Value	Reason
Jan-08-2021 18:31:57 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.d Not Done:

Date	Location	User	Value	Reason
Jan-08-2021 18:31:57 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.d LNMT

Date	Location	User	Value	Reason
Jan-08-2021 18:31:57 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.e

Date	Location	User	Value	Reason
Jan-08-2021 18:31:57 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sponsor-Defined Identifier: Not Applicable Test:: Not Applicable Result:: Not Applicable	Initial Entry

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Jan/08/2021

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

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Site No: 1214

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

Subject No: 12141039

Subject Initials: ---

Generated By: (b) (4)

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

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

5.e Sponsor ID:

Date	Location	User	Value	Reason
Jan-08-2021 18:31:57 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.e Test:

Date	Location	User	Value	Reason
Jan-08-2021 18:31:57 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.e Result:

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Date	Location	User	Value	Reason
Jan-08-2021 18:31:57 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.f

Date	Location	User	Value	Reason
Jan-08-2021 18:31:57 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sponsor-Defined Identifier: Not Applicable	Initial Entry

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Generated By: (b) (4)

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

			Test:: Not Applicable Result:: Not Applicable Not Done:: Not Applicable Lab Normal Range: Not Applicable
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5.f Sponsor ID:

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Date	Location	User	Value	Reason
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Jan-08-2021 18:31:57 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sponsor-Defined Identifier: Not Applicable Test:: Not Applicable Result:: Not Applicable Not Done:: Not Applicable Lab Normal Range: Not Applicable	Initial Entry

Header Text: C4591001**Visit:** POT_COVID_ILL 1 - Unscheduled Visit on Jan/08/2021**Form:** LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History**Form Version:** 10-Oct-2020 16:02**Form Status:** Data Complete**Site No:** 1214**Site Name:** (1214) ISTANBUL UNIVERSITY MEDICAL FACULTY CARDIOLOGY INSTITUTE**Subject No:** 12141039**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 13:11**5.g Sponsor ID:**

Date	Location	User	Value	Reason
Jan-08-2021 18:31:57 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

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5.h

Date	Location	User	Value	Reason
Jan-08-2021 18:31:57 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sponsor-Defined Identifier: Not Applicable Test:: Not Applicable Result:: Not Applicable	Initial Entry

Header Text: C4591001

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

5.h Sponsor ID:

Date	Location	User	Value	Reason
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5.h Test:

Date	Location	User	Value	Reason
Jan-08-2021 18:31:57 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.h Result:

Date	Location	User	Value	Reason
Jan-08-2021 18:31:57 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.h Not Done:

Date	Location	User	Value	Reason
Jan-08-2021 18:31:57 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.h LNMT

Date	Location	User	Value	Reason
Jan-08-2021 18:31:57 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.i

Date	Location	User	Value	Reason
Jan-08-2021 18:31:57 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sponsor-Defined Identifier: Not Applicable	Initial Entry

090177e196ae3d63\Final\Final On: 01-Apr-2021 04:32 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Jan/08/2021

Form Version: 10-Oct-2020 16:02

Site No: 1214

Subject No: 12141039

Generated By: (b) (4)

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

Form Status: Data Complete

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

Subject Initials: ---

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

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

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Jan/08/2021

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5.i Sponsor ID:

Date	Location	User	Value	Reason
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5.i Test:

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5.i Not Done:

Date	Location	User	Value	Reason
Jan-08-2021 18:31:57 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.i LNMT

Date	Location	User	Value	Reason
Jan-08-2021 18:31:57 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.j

Date	Location	User	Value	Reason
Jan-08-2021 18:31:57 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sponsor-Defined Identifier: Not Applicable Test:: Not Applicable	Initial Entry

090177e196ae3d63\Final\Final On: 01-Apr-2021 04:32 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Jan/08/2021

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

Form Version: 10-Oct-2020 16:02

Form Status: Data Complete

Site No: 1214

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

Subject No: 12141039

Subject Initials: ---

Generated By: (b) (4)

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

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

5.j Sponsor ID:

Date	Location	User	Value	Reason
Jan-08-2021 18:31:57 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.j Test:

Date	Location	User	Value	Reason
Jan-08-2021 18:31:57 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.j Result:

Date	Location	User	Value	Reason
Jan-08-2021 18:31:57 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.j Not Done:

Date	Location	User	Value	Reason
Jan-08-2021 18:31:57 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.j LNMT

Date	Location	User	Value	Reason
Jan-08-2021 18:31:57 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

090177e196ae3d63\Final\Final On: 01-Apr-2021 04:32 (GMT)

Header Text: C4591001**Visit:** POT_COVID_ILL 1 - Unscheduled Visit **Form:** VITAL SIGNS - COVID - eCRF Audit Trail History
on Jan/08/2021**Form Version:** 10-Oct-2020 15:59**Form Status:** Data Complete**Site No:** 1214**Site Name:** (1214) ISTANBUL UNIVERSITY MEDICAL FACULTY
CARDIOLOGY INSTITUTE**Subject No:** 12141039**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 13:11[Back to Form](#)**I. Date:**

Date	Location	User	Value	Reason
Jan-08-2021 18:32:15 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

2.a

Date	Location	User	Value	Reason
Jan-08-2021 18:32:15 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Record Identifier:: Not Applicable Systolic:: Not Applicable Diastolic:: Not Applicable Respiratory Rate in re Not App spirations/minute: licable Heart Rate in beats/mi Not App minute: licable	Initial Entry

2.a Record Identifier:

Date	Location	User	Value	Reason
Jan-08-2021 18:32:15 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

2.a Systolic:

Date	Location	User	Value	Reason
Jan-08-2021 18:32:15 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

2.a Diastolic:

Date	Location	User	Value	Reason
Jan-08-2021 18:32:15 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** VITAL SIGNS - COVID - eCRF Audit Trail History
on Jan/08/2021

Form Version: 10-Oct-2020 15:59

Form Status: Data Complete

Site No: 1214

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

Subject No: 12141039

Subject Initials: ---

Generated By: (b) (4)

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

2.a Respiratory Rate in respirations/minute:

Date	Location	User	Value	Reason
Jan-08-2021 18:32:15 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

2.a Heart Rate in beats/minute:

Date	Location	User	Value	Reason
Jan-08-2021 18:32:15 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Jan/08/2021

Form Version: 10-Oct-2020 16:04

Site No: 1214

Subject No: 12141039

Generated By: (b) (4)

Form: VITAL SIGNS - PULSE OX ROOM AIR - eCRF Audit Trail History

Form Status: Data Complete

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

Subject Initials: ---

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

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I. Date:

Date	Location	User	Value	Reason
Jan-08-2021 18:32:31 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

2.a

Date	Location	User	Value	Reason
Jan-08-2021 18:32:31 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Record Identifier: Not Applicabl e Oxygen Saturatio Not Applicabl n: e	Initial Entry

2.a Record Identifier:

Date	Location	User	Value	Reason
Jan-08-2021 18:32:31 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

2.a SPO2 Pulse Oximetry %

Date	Location	User	Value	Reason
Jan-08-2021 18:32:31 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

090177e196ae3d63\Final\Final On: 01-Apr-2021 04:32 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** OXYGENATION PARAMETERS - eCRF Audit Trail History on Jan/08/2021

Form Version: 06-Jul-2020 21:52

Form Status: Data Complete

Site No: 1214

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

Subject No: 12141039

Subject Initials: ---

Generated By: (b) (4)

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

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1. Date Time of Assessment:

Date	Location	User	Value	Reason
Jan-08-2021 18:32:47 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

2. Arterial Blood Gases PaO2 (mmHg):

Date	Location	User	Value	Reason
Jan-08-2021 18:32:47 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

3. FiO2 (Fraction of Inhaled Oxygen):

Date	Location	User	Value	Reason
Jan-08-2021 18:32:47 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

090177e196ae3d63\Final\Final On: 01-Apr-2021 04:32 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Jan/08/2021

Form: CONCOMITANT MEDICATIONS - VASOPRESSORS - eCRF Audit Trail History

Form Version: 06-Jul-2020 21:55

Form Status: Data Complete

Site No: 1214

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

Subject No: 12141039

Subject Initials: ---

Generated By: (b) (4)

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

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1. What is the medication identifier?

Date	Location	User	Value	Reason
Jan-08-2021 18:33:02 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

2. Category:

Date	Location	User	Value	Reason
Jan-08-2021 18:33:02 (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-08-2021 18:33:02 (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
Jan-08-2021 18:33:02 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5. Start Date:

Date	Location	User	Value	Reason
Jan-08-2021 18:33:02 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

6. Ongoing?

Date	Location	User	Value	Reason
Jan-08-2021 18:33:02 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

090177e196ae3d63\Final\Final On: 01-Apr-2021 04:32 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** IMAGING - eCRF Audit Trail History
on Jan/08/2021

Form Version: 06-Jul-2020 21:53

Form Status: Data Complete

Site No: 1214

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

Subject No: 12141039

Subject Initials: ---

Generated By: (b) (4)

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

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1. Date of Assessment:

Date	Location	User	Value	Reason
Jan-08-2021 18:33:17 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

2. Location of Assessment:

Date	Location	User	Value	Reason
Jan-08-2021 18:33:17 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

3. Type of Imaging Exam:

Date	Location	User	Value	Reason
Jan-08-2021 18:33:17 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

4. Assessment:

Date	Location	User	Value	Reason
Jan-08-2021 18:33:17 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

090177e196ae3d63\Final\Final On: 01-Apr-2021 04:32 (GMT)

Header Text: C4591001

Visit: POT_COVID_CONVA 1 - Unscheduled
Visit on Feb/08/2021

Form: DATE OF VISIT - ILLNESS CONVALESCENT - eCRF Audit
Trail History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Frozen, Verified

Site No: 1214

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

Subject No: 12141039

Subject Initials: ---

Generated By: (b) (4)

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

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1. Date of Visit

Date	Location	User	Value	Reason
Feb-08-2021 12:19:30 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Feb/8/2021	Initial Entry

3. COVID-19 Illness Visit:

Date	Location	User	Value	Reason
Feb-08-2021 12:19:30 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: COVID_A1	Initial Entry

090177e196ae3d63\Final\Final On: 01-Apr-2021 04:32 (GMT)

Header Text: C4591001**Visit:** POT_COVID_CONVA 1 - Unscheduled
Visit on Feb/08/2021**Form Version:** 22-Apr-2020 21:03**Site No:** 1214**Subject No:** 12141039**Generated By:** (b) (4)**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY -
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. Data Origin**

Date	Location	User	Value	Reason
Feb-08-2021 12:19:43 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Feb-08-2021 12:19:43 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SERUM	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Feb-08-2021 15:39:02 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Feb-08-2021 15:06:13 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Feb-08-2021 12:19:43 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Feb-08-2021 12:19:43 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Date of Collection: Feb/8/2021	Initial Entry

5.a

Date	Location	User	Value	Reason
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Header Text: C4591001

Visit: POT_COVID_CONVA 1 - Unscheduled Visit on Feb/08/2021

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: 12141039

Subject Initials: ---

Generated By: (b) (4)

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

Feb-08-2021 15:39:02 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BR5CXW	Initial Entry
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5.a Sample ID

Date	Location	User	Value	Reason
Feb-09-2021 18:03:07 (UTC+03:00) Istanbul	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (b) (4)	Query 1: Closed	Auto closed by Validation Check: VC_BEETRK001_01
Feb-09-2021 14:21:35 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	It was updated
Feb-09-2021 11:54:08 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reissued: Opened	DM: Per CCG, in case a scheduled visit occurs at the same time as V101_VAX3, sample collection date and barcodes should be recorded on original visit. Sample collected=No on SAMP TRK in V101VAX Visit. please review and update. Else, clarify.
Feb-09-2021 09:38:30 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	V101 and POT_COVID_CONVA were done simultaneously
Feb-08-2021 23:48:56 (UTC+03:00) Istanbul	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (b) (4)	Query 1: Opened	DMW7188831;This Barcode is already recorded more than once (for the same subject). Please review and update as appropriate.
Feb-08-2021 15:39:02 (UTC+03:00)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry :	Initial Entry

090177e196ae3d63\Final\Final On: 01-Apr-2021 04:32 (GMT)

Header Text: C4591001

Visit: POT_COVID_CONVA 1 - Unscheduled
Visit on Feb/08/2021

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: 12141039

Subject Initials: ---

Generated By: (b) (4)

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

Istanbul			BR5C XW	
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5.b

Date	Location	User	Value	Reason
Feb-08-2021 15:39:13 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BR5CXX	Initial Entry

Header Text: C4591001

Visit: POT_COVID_CONVA 1 - Unscheduled Visit on Feb/08/2021

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: 12141039

Subject Initials: ---

Generated By: (b) (4)

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

5.b Sample ID

Date	Location	User	Value	Reason
Feb-09-2021 18:03:07 (UTC+03:00) Istanbul	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (b) (4)	Query 1: Closed	Auto closed by Validation Check: VC_BEETRK001_01
Feb-09-2021 14:21:46 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	It was updated
Feb-09-2021 11:53:28 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reissued: Opened	DM: Per CCG, in case a scheduled visit occurs at the same time as V101_VAX3, sample collection date and barcodes should be recorded on original visit. Sample collected=No on SAMP TRK in V101VAX Visit. please review and update. Else, clarify.
Feb-09-2021 09:37:42 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	V101 and POT_COVID_CONVA were done simultaneously
Feb-08-2021 23:48:56 (UTC+03:00) Istanbul	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (b) (4)	Query 1: Opened	DMW7188832;This Barcode is already recorded more than once (for the same subject). Please review and update as appropriate.
Feb-08-2021 15:39:13 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry BR5C XX	Initial Entry

090177e196ae3d63\Final\Final On: 01-Apr-2021 04:32 (GMT)

Header Text: C4591001

Visit: POT_COVID_CONVA 1 - Unscheduled
Visit on Feb/08/2021

Form Version: 22-Apr-2020 21:03

Site No: 1214

Subject No: 12141039

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY -
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

5.c

Date	Location	User	Value	Reason
Feb-08-2021 15:39:22 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BSHD05	Initial Entry

Header Text: C4591001

Visit: POT_COVID_CONVA 1 - Unscheduled Visit on Feb/08/2021

Form Version: 22-Apr-2020 21:03

Site No: 1214

Subject No: 12141039

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - 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

5.c Sample ID

Date	Location	User	Value	Reason
Feb-09-2021 18:03:07 (UTC+03:00) Istanbul	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (b) (4)	Query 1: Closed	Auto closed by Validation Check: VC_BEETRK001_01
Feb-09-2021 14:21:56 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	It was updated
Feb-09-2021 11:54:52 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reissued: Opened	DM: Per CCG, in case a scheduled visit occurs at the same time as V101_VAX3, sample collection date and barcodes should be recorded on original visit. Sample collected=No on SAMP TRK in V101VAX Visit. please review and update. Else, clarify.
Feb-09-2021 09:37:57 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	V101 and POT_COVID_CONVA were done simultaneously
Feb-08-2021 23:48:56 (UTC+03:00) Istanbul	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (b) (4)	Query 1: Opened	DMW7188833;This Barcode is already recorded more than once (for the same subject). Please review and update as appropriate.
Feb-08-2021 15:39:22 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry BSH D05	Initial Entry

090177e196ae3d63\Final\Final On: 01-Apr-2021 04:32 (GMT)

Header Text: C4591001

Visit: POT_COVID_CONVA 1 - Unscheduled
Visit on Feb/08/2021

Form Version: 22-Apr-2020 21:03

Site No: 1214

Subject No: 12141039

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY -
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

5.d

Date	Location	User	Value	Reason
Feb-08-2021 15:39:31 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BSHD06	Initial Entry

Header Text: C4591001

Visit: POT_COVID_CONVA 1 - Unscheduled Visit on Feb/08/2021

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: 12141039

Subject Initials: ---

Generated By: (b) (4)

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

5.d Sample ID

Date	Location	User	Value	Reason
Feb-09-2021 18:03:07 (UTC+03:00) Istanbul	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (b) (4)	Query 1: Closed	Auto closed by Validation Check: VC_BEETRK001_01
Feb-09-2021 14:22:05 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	It was updated
Feb-09-2021 11:52:32 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reissued: Opened	DM: Per CCG, in case a scheduled visit occurs at the same time as V101_VAX3, sample collection date and barcodes should be recorded on original visit. Sample collected=No on SAMP TRK in V101VAX Visit. please review and update. Else, clarify.
Feb-09-2021 09:38:14 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	V101 and POT_COVID_CONVA were done simultaneously
Feb-08-2021 23:48:56 (UTC+03:00) Istanbul	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (b) (4)	Query 1: Opened	DMW7188834;This Barcode is already recorded more than once (for the same subject). Please review and update as appropriate.
Feb-08-2021 15:39:31 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry BSH D06	Initial Entry

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Header Text: C4591001

Visit: Logs - Unscheduled

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Site No: 1214

Subject No: 12141039

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - Audit Trail

Form Status:

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Dec-08-2020 14:18:33 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Created	

Header Text: C4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

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Subject No: 12141039

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Date	Location	User	Value	Reason
Jan-11-2021 16:13:35 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Created	

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Date	Location	User	Value	Reason
Mar-03-2021 12:33:57 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Created	

Header Text: C4591001

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Site No: 1214

Subject No: 12141039

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - Audit Trail

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Date	Location	User	Value	Reason
Mar-12-2021 14:57:41 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Created	

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Generated By: (b) (4)

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1. Category:

Date	Location	User	Value	Reason
Dec-08-2020 14:18:33 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: ADVERSE EVENT	Initial Entry

2. AE ID:

Date	Location	User	Value	Reason
Dec-08-2020 14:18:33 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 1	Initial Entry

3. Adverse Event:

(If possible specify diagnosis, not individual symptoms)

Date	Location	User	Value	Reason
Dec-31-2020 18:54:29 (UTC+03:00) Istanbul	ACV0PFEINFP6000	Salim Bouguermouh (b) (4)	Query 2: Closed	Response satisfies query
Dec-30-2020 16:43:39 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Answered	This is not PD. Patient has not COVID-19.
Dec-29-2020 22:29:28 (UTC+03:00) Istanbul	ACV0PFEINFP6000	Salim Bouguermouh (b) (4)	Query 2: Reissued:Opened	Clin: Thank you. A protocol deviation will be documented.
Dec-27-2020 18:38:41 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Answered	COVID-19 visit was not applied to subject by PI decision because subject had not COVID-19 symptom.
Dec-26-2020 07:30:16 (UTC+03:00) Istanbul	ACV0PFEINFP6000	Salim Bouguermouh (b) (4)	Query 2: Reissued:Opened	Clin: Please the data should still be captured on the potential COVID-19 visit. Please move the barcode from Visit-2 to the COVID-19 visit.

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				Please add a comment on Visit-2 CRF form stating why the nasal swab was moved to COVID-19 visit
Dec-23-2020 20:44:41 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Answered	The patient's diarrhea was caused by ready-made food and nasal sample was collected for visit 2 and no positive result was obtained. PI and SI saw the patient and stated that they had no COVID symptoms and did not require a visit.
Dec-23-2020 10:10:33 (UTC+03:00) Istanbul	ACV0PFEINFP6000	Salim Bouguermouh (b) (4)	Query 2: Reissued:Opened	Medical monitor: During this study every symptoms listed Per Prot Sect 8.1. should have please triggered a potential COVID Illness Visit irrespective of perceived etiology or clinical significance. A protocol deviation will be documented
Dec-22-2020 14:32:54 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Answered	PI confirmed that this subject had only diarrhea due to eating foods that upset the digestive system and evaluated diarrhea as not COVID symptoms. This patient is not COVID-19.Not

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				every symptom is COVID-19.
Dec-22-2020 00:29:25 (UTC+03:00) Istanbul	ACV0PFEINFP6000	Salim Bouguermouh (b) (4)	Query 2: Reissued:Opened	Clin: Thank you. A protocol deviation will be documented.
Dec-19-2020 21:59:53 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Answered	PI confirmed that this subject had only diarrhea due to eating foods that upset the digestive system and evaluated diarrhea as not COVID symptoms.
Dec-18-2020 19:55:45 (UTC+03:00) Istanbul	ACV0PFEINFP6000	Salim Bouguermouh (b) (4)	Query 2: Reissued:Opened	Medical monitor: Per Prot Sect 8.1., COVID-19 listed symptom DIARRHEA should have please triggered a potential COVID Illness Visit irrespective of perceived etiology or clinical significance. A SWAB will not be collected and captured on the SOD form only
Dec-17-2020 09:17:08 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Answered	Patient came to center for V2 on 27NOV2020 when reported COVID-19 symptom and said that diarrhea resulted from prepared foods and continued very shortly.
Dec-16-2020 18:46:31 (UTC+03:00) Istanbul	ACV0PFEINFP6000	Salim Bouguermouh (b) (4)	Query 2: Reissued:Opened	Medical monitor: Per Prot Sect 8.1., COVID-19 listed

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				symptom DIARRHEA should have please triggered a potential COVID Illness Visit irrespective of perceived etiology or clinical significance. A SWAB will not be collected and captured on the SOD form only
Dec-16-2020 18:44:37 (UTC+03:00) Istanbul	ACV0PFEINFP6000	Salim Bouguermouh (b) (4)	Query 1: Closed	Response satisfies query
Dec-16-2020 17:48:59 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Answered	The patient reported diarrhea on November 26, 2020. and came to center on 27Nov2020. For this reason, no phone call was required.
Dec-16-2020 17:46:16 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	COVID-19 Visit was not performed. Because It has been decided by the Investigator that there is no need for a COVID-19 visit.
Dec-16-2020 13:40:44 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Opened	Clin: Despite telehealth visit was not done, please complete the potential COVID-19 Illness Visit CRF forms with all information available. Should be captured only on the SOD CRF form and a NASAL SWAB

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				will not be collected
Dec-16-2020 13:40:44 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	Clin: Per protocol section 8.1., COVID-19 listed symptom DIARRHEA should have please triggered a potential COVID Illness Visit irrespective of perceived etiology or clinical significance. A SWAB will not be collected and captured on the SOD form only
Dec-16-2020 00:02:05 (UTC+03:00) Istanbul	ACV0PFEINFP6000	Salim Bouguermouh (b) (4)	Query 2: Candidate	Clin: Despite telehealth visit was not done, please complete the potential COVID-19 Illness Visit CRF forms with all information available. Should be captured only on the SOD CRF form and a NASAL SWAB will not be collected
Dec-16-2020 00:00:01 (UTC+03:00) Istanbul	ACV0PFEINFP6000	Salim Bouguermouh (b) (4)	Query 1: Candidate	Clin: Per protocol section 8.1., COVID-19 listed symptom DIARRHEA should have please triggered a potential COVID Illness Visit irrespective of perceived etiology or clinical significance. A SWAB will not be collected and

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				captured on the SOD form only
Dec-08-2020 14:18:33 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: diarrhea	Initial Entry

4. Start Date Time:

Date	Location	User	Value	Reason
Dec-08-2020 14:18:33 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Nov/26/2020 17:00	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Dec-08-2020 14:18:33 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO End Date Time: Nov/27/2020 11:00	Initial Entry

6. Toxicity Grade:

Date	Location	User	Value	Reason
Dec-08-2020 14:18:33 (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
Dec-08-2020 14:18:33 (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.

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Date	Location	User	Value	Reason
Dec-08-2020 14:18:33 (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-08-2020 14:18:33 (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 <i>If Other, specify:</i> prepared foods	Initial Entry

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Dec-08-2020 14:18:33 (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-08-2020 14:18:33 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Dec-08-2020 14:18:33 (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
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Generated By: (b) (4)

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Dec-08-2020 14:18:33 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: RECOVERED/RESOLVED	Initial Entry
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14. Did the adverse event cause the subject to be discontinued from the study?

Date	Location	User	Value	Reason
Dec-08-2020 14:18:33 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

Header Text: C4591001

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Site No: 1214

Subject No: 12141039

Generated By: (b) (4)

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1. Category:

Date	Location	User	Value	Reason
Jan-11-2021 16:13:35 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: ADVERSE EVENT	Initial Entry

2. AE ID:

Date	Location	User	Value	Reason
Jan-11-2021 16:13:35 (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-11-2021 16:13:35 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: lymphadenomegaly in the right sub mandibular	Initial Entry

4. Start Date Time:

Date	Location	User	Value	Reason
Jan-11-2021 16:13:35 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Jan/6/2021 UNK:UNK	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Jan-18-2021 13:04:43 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO End Date Time: Jan/15/2021 UNK:UNK	New Information
Jan-11-2021 16:13:35 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

6. Toxicity Grade:

Date	Location	User	Value	Reason
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Jan-11-2021 16:13:35 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 1	Initial Entry
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7. Is the adverse event serious?

If Yes, NOTIFY PFIZER IMMEDIATELY.

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

Date	Location	User	Value	Reason
Jan-11-2021 16:13:35 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

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

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

Date	Location	User	Value	Reason
Jan-11-2021 16:13:35 (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-26-2021 02:21:40 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: C losed	Response satisfies query
Jan-25-2021 16:08:28 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto query (autoquery)	Query 1: A nswered	Transcription Error
Jan-25-2021 16:08:28 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entr y: NOT REL ATED If Not Re lated to st udy treat ment(s), t his event is due to:	Transcription Error

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			OTHE R <i>If Other, specify:</i> Bact eria	
Jan-22-2021 15:39:43 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: R eissued:Op ened	DM: Per CRF, 'If not related to study treatment other' field, in the comment field', 'Orofarengal infection' is entered. Please confirm if any related symptoms, AEs or MEDHX should be updated. If yes then update CRF. Else clarify.
Jan-20-2021 16:32:23 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: A nswered	There are no other symptoms.
Jan-20-2021 08:24:54 (UTC+03:00) Istanbul	ACV0PFEINFP6000.InFormAdapter.Discrepancy	PFE SDQ PROD (b) (4)	Query 1: O pened	Please review "If not related to study treatment other" field, the following text was indicated in the comment field [Orofarengal infection]. Any symptoms, AEs

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				or other key data should be collected on the appropriate page. Please review and update as necessary. (b) (4)
Jan-11-2021 16:21:25 (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 <i>If Other, specify:</i> Orofaryngeal infection	Transcription Error
Jan-11-2021 16:13:35 (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

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Header Text: C4591001

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				R
				If Other, specify:
				Unknown

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Jan-11-2021 16:13:35 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NOT APPLICABLE	Initial Entry

11. Was a Concomitant Medication given?

Date	Location	User	Value	Reason
Jan-11-2021 16:13:35 (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
Jan-11-2021 16:13:35 (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
Jan-18-2021 13:04:59 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Jan-18-2021 13:04:59 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: RECOVERED/RESOLVED	New Information
Jan-18-2021 13:04:43 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	For AE lymphadenomegaly in the right submandibular: Response to "What was the outcome of this adverse event?" is

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				'Recovering/Resolving' but AE End Date/Time is present.
Jan-11-2021 16:13:35 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: RECOVERING/RESOLVING	Initial Entry

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

Date	Location	User	Value	Reason
Jan-11-2021 16:13:35 (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: 12141039

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

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1. Category:

Date	Location	User	Value	Reason
Mar-03-2021 12:33:57 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: ADVERSE EVENT	Initial Entry

2. AE ID:

Date	Location	User	Value	Reason
Mar-03-2021 12:33:57 (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
Mar-03-2021 12:33:57 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: pain at the injection site	Initial Entry

4. Start Date Time:

Date	Location	User	Value	Reason
Mar-03-2021 12:33:57 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Feb/8/2021 18:00	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Mar-03-2021 12:33:57 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO End Date Time: Feb/10/2021 10:00	Initial Entry

6. Toxicity Grade:

Date	Location	User	Value	Reason
Mar-03-2021 12:33:57 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 2	Initial Entry

090177e196ae3d63\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: 12141039

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

7. Is the adverse event serious?

If Yes, NOTIFY PFIZER IMMEDIATELY.

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

Date	Location	User	Value	Reason
Mar-03-2021 12:33:57 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NO	Initial Entry

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

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

Date	Location	User	Value	Reason
Mar-03-2021 12:33:57 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NO	Initial Entry

9. Is this event related to study treatment:

Date	Location	User	Value	Reason
Mar-03-2021 12:33:57 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> RELATED	Initial Entry

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Mar-03-2021 12:33:57 (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
Mar-03-2021 12:33:57 (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
Mar-03-2021 12:33:57 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NO	Initial Entry

090177e196ae3d63\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: 12141039

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

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

Date	Location	User	Value	Reason
Mar-03-2021 12:33:57 (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
Mar-03-2021 12:33:57 (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: 12141039

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete

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

Subject Initials: ---

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

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1. Category:

Date	Location	User	Value	Reason
Mar-12-2021 14:57:41 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: ADVERSE EVENT	Initial Entry

2. AE ID:

Date	Location	User	Value	Reason
Mar-12-2021 14:57:41 (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
Mar-12-2021 14:57:41 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: pain at the injection site	Initial Entry

4. Start Date Time:

Date	Location	User	Value	Reason
Mar-12-2021 14:57:41 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Mar/3/2021 17:00	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Mar-12-2021 14:57:41 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO End Date Time: Mar/5/2021 12:00	Initial Entry

6. Toxicity Grade:

Date	Location	User	Value	Reason
Mar-12-2021 14:57:41 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 2	Initial Entry

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Header Text: C4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1214

Subject No: 12141039

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete

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

Subject Initials: ---

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

7. Is the adverse event serious?

If Yes, NOTIFY PFIZER IMMEDIATELY.

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

Date	Location	User	Value	Reason
Mar-12-2021 14:57:41 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NO	Initial Entry

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

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

Date	Location	User	Value	Reason
Mar-12-2021 14:57:41 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NO	Initial Entry

9. Is this event related to study treatment:

Date	Location	User	Value	Reason
Mar-12-2021 14:57:41 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> RELATED	Initial Entry

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Mar-12-2021 14:57:41 (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
Mar-12-2021 14:57:41 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NO	Initial Entry

12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Mar-12-2021 14:57:41 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NO	Initial Entry

090177e196ae3d63\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: 12141039

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete

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

Subject Initials: ---

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

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

Date	Location	User	Value	Reason
Mar-12-2021 14:57:41 (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
Mar-12-2021 14:57:41 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

Header Text: C4591001

Visit: Logs - Unscheduled

Form Version: 17-Jul-2020 21:54

Site No: 1214

Subject No: 12141039

Generated By: (b) (4)

Form: MEDICATION ERROR - 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

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1. Category:

Date	Location	User	Value	Reason
Dec-08-2020 14:18:48 (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
Dec-08-2020 14:18:48 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

3. Start Date:

Date	Location	User	Value	Reason
Dec-08-2020 14:18:48 (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
Dec-08-2020 14:18:48 (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
Dec-08-2020 14:18:48 (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
Dec-08-2020 14:18:48 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

090177e196ae3d63\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: 12141039

Generated By: (b) (4)

Form: MEDICATION ERROR - 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

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

7. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Dec-08-2020 14:18:48 (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
Dec-08-2020 14:18:48 (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
Dec-08-2020 14:18:48 (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
Dec-08-2020 14:18:48 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

090177e196ae3d63\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, Frozen, Verified

Site No: 1214

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

Subject No: 12141039

Subject Initials: ---

Generated By: (b) (4)

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

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1. What is the medication identifier?

Date	Location	User	Value	Reason
Dec-08-2020 14:19:04 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

2. Category:

Date	Location	User	Value	Reason
Dec-08-2020 14:19:04 (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
Dec-08-2020 14:19:04 (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
Dec-08-2020 14:19:04 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5. Date:

Date	Location	User	Value	Reason
Dec-08-2020 14:19:04 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

090177e196ae3d63\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:** 12141039**Generated By:** (b) (4)**Form:** CONCOMITANT MEDICATIONS - PROHIBITED - 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. What is the medication identifier?**

Date	Location	User	Value	Reason
Dec-08-2020 14:19:19 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

2. Category:

Date	Location	User	Value	Reason
Dec-08-2020 14:19:19 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

3. Concomitant Medications Pre-specified:

Date	Location	User	Value	Reason
Dec-08-2020 14:19:19 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

4. Medication:

Provide the complete generic drug name (including salt form, where applicable). Where generic name is unknown, enter the full trade or proprietary name. Include clarifying information in the Medication text (e.g., Ingredient(s), route, use, formulation).

Date	Location	User	Value	Reason
Dec-08-2020 14:19:19 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5. Dose:

Date	Location	User	Value	Reason
Dec-08-2020 14:19:19 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

Header Text: C4591001

Visit: Logs - Unscheduled

Form: CONCOMITANT MEDICATIONS - PROHIBITED - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1214

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

Subject No: 12141039

Subject Initials: ---

Generated By: (b) (4)

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

6. Dose Unit:

Date	Location	User	Value	Reason
Dec-08-2020 14:19:19 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

7. Dose Frequency:

Date	Location	User	Value	Reason
Dec-08-2020 14:19:19 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

8. Route:

Date	Location	User	Value	Reason
Dec-08-2020 14:19:19 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

9. Start Date:

Date	Location	User	Value	Reason
Dec-08-2020 14:19:19 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

10. Ongoing?

Date	Location	User	Value	Reason
Dec-08-2020 14:19:19 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

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Header Text: C4591001

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Form Version: 22-Apr-2020 21:02

Site No: 1214

Subject No: 12141039

Generated By: (b) (4)

Form: RADIATION 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

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1. Category:

Date	Location	User	Value	Reason
Dec-08-2020 14:19:36 (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
Dec-08-2020 14:19:36 (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
Dec-08-2020 14:19:36 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

4. Treatment:

Date	Location	User	Value	Reason
Dec-08-2020 14:19:36 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5. Start Date:

Date	Location	User	Value	Reason
Dec-08-2020 14:19:36 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

6. Ongoing?

Date	Location	User	Value	Reason
Dec-08-2020 14:19:36 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

090177e196ae3d63\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: 12141039

Generated By: (b) (4)

Form: RADIATION 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

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

090177e196ae3d63\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: 12141039

Generated By: (b) (4)

Form: TRANSFUSIONS - 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

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1. Transfusion Type:

Date	Location	User	Value	Reason
Dec-08-2020 14:19:54 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

2. Date of Transfusion:

Date	Location	User	Value	Reason
Dec-08-2020 14:19:54 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

090177e196ae3d63\Final\Final On: 01-Apr-2021 04:32 (GMT)

Header Text: C4591001

Visit: Unplanned 1 - Unscheduled Visit on
Jan/06/2021

Form: DATE OF VISIT - eCRF Audit Trail History

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: 12141039

Subject Initials: ---

Generated By: (b) (4)

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

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1. Date of Visit

Date	Location	User	Value	Reason
Jan-06-2021 10:03:44 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Jan/6/2021	Initial Entry

090177e196ae3d63\Final\Final On: 01-Apr-2021 04:32 (GMT)

Header Text: C4591001

Visit: Unplanned 1 - Unscheduled Visit on
Jan/06/2021

Form: UNPLANNED VISIT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Frozen, Verified

Site No: 1214

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

Subject No: 12141039

Subject Initials: ---

Generated By: (b) (4)

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

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I. Assessments

Date	Location	User	Value	Reason
Jan-06-2021 10:04:56 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Jan-06-2021 10:03:51 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Contact Outcome is ticked however 'CONTACT OUTCOME' form is not entered. Please review and update as appropriate.
Jan-06-2021 10:03:51 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: CONTACT OUTCOME	Initial Entry

090177e196ae3d63\Final\Final On: 01-Apr-2021 04:32 (GMT)

Header Text: C4591001

Visit: Unplanned 1 - Unscheduled Visit on Jan/06/2021

Form Version: 22-Apr-2020 21:04

Site No: 1214

Subject No: 12141039

Generated By: (b) (4)

Form: CONTACT OUTCOME - UNPLANNED - 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

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I. Contact Type:

Date	Location	User	Value	Reason
Jan-06-2021 10:04:56 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: TELEPHONE VISIT	Initial Entry

2. Was contact made?

Date	Location	User	Value	Reason
Jan-11-2021 16:31:04 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Deleted	NA
Jan-08-2021 17:15:02 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	Contact Outcome' is selected as 'VISIT ARRANGED' but no 'VITAL SIGNS' and/or 'UNPLANNED ASSESSMENT OF LOCAL REACTION' form(s) is/are entered. Please review and update as appropriate.
Jan-08-2021 08:03:41 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reissued:Opened	DM : Thanks for response. Please review and update 'VITAL SIGNS' and/or 'UNPLANNED ASSESSMENT OF LOCAL REACTION' forms. Else, clarify.
Jan-07-2021 15:57:47 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	The visit will be made on 08/JAN /2021. Vital signs page will be entered on 08.JAN.2021.

090177e196ae3d63\Final\Final On: 01-Apr-2021 04:32 (GMT)

Header Text: C4591001

Visit: Unplanned 1 - Unscheduled Visit on Jan/06/2021

Form Version: 22-Apr-2020 21:04

Site No: 1214

Subject No: 12141039

Generated By: (b) (4)

Form: CONTACT OUTCOME - UNPLANNED - 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

Jan-07-2021 11:22:25 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	Contact Outcome' is selected as 'VISIT ARRANGED' but no 'VITAL SIGNS' and/or 'UNPLANNED ASSESSMENT OF LOCAL REACTION' form(s) is/are entered. Please review and update as appropriate.
Jan-06-2021 10:04:56 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	Contact Outcome' is selected as 'VISIT ARRANGED' but no 'VITAL SIGNS' and/or 'UNPLANNED ASSESSMENT OF LOCAL REACTION' form(s) is/are entered. Please review and update as appropriate.
Jan-06-2021 10:04:56 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Date of Contact: Jan/6/2021 Contact Outcome: VISIT ARRANGED	Initial Entry

3. Comments:

Date	Location	User	Value	Reason
Jan-06-2021 10:04:56 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: PI contacted with subject	Initial Entry

Header Text: C4591001

Visit: Unplanned 1 - Unscheduled Visit on
Jan/06/2021

Form: VITAL SIGNS - TEMP - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:27

Form Status: Data Complete, Frozen, Verified

Site No: 1214

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

Subject No: 12141039

Subject Initials: ---

Generated By: (b) (4)

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

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I. Date:

Date	Location	User	Value	Reason
Jan-12-2021 09:20:16 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Jan-11-2021 16:40:14 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	The subject came to the site on 8/JAN/2021 for the potential covid illness visit.
Jan-11-2021 12:27:39 (UTC+03:00) Istanbul	ACV0PFEINFP6000.InFormAdapter.Discrepancy	PFE SDQ PROD (b) (4)	Query 1: Opened	Date of Vital signs 08 Jan 2021 is not same as Date of Assessment None in UNPLANNED ASSESSMENT form. Please verify and update appropriately or provide clarification (b) (4)
Jan-08-2021 17:15:02 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Ent ry: Jan/8/202 1	Initial Entry

2.a

Date	Location	User	Value	Reason
Jan-08-2021 17:15:02 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Record Identifier:: 1	Initial Entry

090177e196ae3d63\Final\Final On: 01-Apr-2021 04:32 (GMT)

Header Text: C4591001

Visit: Unplanned 1 - Unscheduled Visit on Jan/06/2021

Form: VITAL SIGNS - TEMP - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:27

Form Status: Data Complete, Frozen, Verified

Site No: 1214

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

Subject No: 12141039

Subject Initials: ---

Generated By: (b) (4)

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

			Temperature: 36.1	
			Temperature Unit: C	
			Temperature Location: FOREHEAD	

2.a Record Identifier:

Date	Location	User	Value	Reason
Jan-08-2021 17:15:02 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 1	Initial Entry

2.a Temperature:

Date	Location	User	Value	Reason
Jan-08-2021 17:15:02 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 36.1	Initial Entry

2.a Unit:

Date	Location	User	Value	Reason
Jan-08-2021 17:15:02 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: C	Initial Entry

2.a Temperature Location:

Date	Location	User	Value	Reason
Jan-08-2021 17:15:02 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: FOREHEAD	Initial Entry

090177e196ae3d63\Final\Final On: 01-Apr-2021 04:32 (GMT)

Header Text: C4591001**Visit:** Unplanned 1 - Unscheduled Visit on
Jan/06/2021**Form Version:** 10-Dec-2020 02:22**Site No:** 1214**Subject No:** 12141039**Generated By:** (b) (4)**Form:** UNPLANNED ASSESSMENT OF LOCAL REACTION -
SYSTEMIC EVENT - 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 Assessment:**

Date	Location	User	Value	Reason
Jan-12-2021 13:19:29 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1 : Closed	Closed per site response - contact was made for the COVID visit.
Jan-11-2021 10:58:52 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1 : Answered	This contact was made for the COVID visit.
Jan-11-2021 09:21:43 (UTC+03:00) Istanbul	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (b) (4)	Query 1 : Opened	DMW6741602;Date of Assessment is not expected to be Unknown or Not Applicable. Please review and update appropriately or clarify
Jan-08-2021 17:15:14 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

2. Injection Site Location

Date	Location	User	Value	Reason
Jan-08-2021 17:15:14 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

3. Injection Site Body Side:

Date	Location	User	Value	Reason
Jan-08-2021 17:15:14 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

4.a

Date	Location	User	Value	Reason
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Header Text: C4591001

Visit: Unplanned 1 - Unscheduled Visit on Jan/06/2021

Form: UNPLANNED ASSESSMENT OF LOCAL REACTION - SYSTEMIC EVENT - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:22

Form Status: Data Complete, Verified

Site No: 1214

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

Subject No: 12141039

Subject Initials: ---

Generated By: (b) (4)

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

Jan-08-2021 17:15:14 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Reaction:: Not Applicabl e Reaction Present: Not Applicabl :	Initial Entry
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4.a Reaction:

Date	Location	User	Value	Reason
Jan-08-2021 17:15:14 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

4.a Reaction Present:

Date	Location	User	Value	Reason
Jan-08-2021 17:15:14 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

4.b

Date	Location	User	Value	Reason
Jan-08-2021 17:15:14 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Reaction:: Not Applicabl e Reaction Present: Not Applicabl :	Initial Entry

4.b Reaction:

Date	Location	User	Value	Reason
Jan-08-2021 17:15:14 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

4.b Reaction Present:

Date	Location	User	Value	Reason
Jan-08-2021 17:15:14 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.a

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Header Text: C4591001

Visit: Unplanned 1 - Unscheduled Visit on Jan/06/2021

Form: UNPLANNED ASSESSMENT OF LOCAL REACTION - SYSTEMIC EVENT - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:22

Form Status: Data Complete, Verified

Site No: 1214

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

Subject No: 12141039

Subject Initials: ---

Generated By: (b) (4)

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

Date	Location	User	Value	Reason
Jan-08-2021 17:15:14 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom:: Not Applicable Symptom Present :: Not Applicable	Initial Entry

5.a Symptom:

Date	Location	User	Value	Reason
Jan-08-2021 17:15:14 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.a Symptom Present:

Date	Location	User	Value	Reason
Jan-08-2021 17:15:14 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.b

Date	Location	User	Value	Reason
Jan-08-2021 17:15:14 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom:: Not Applicable Symptom Present :: Not Applicable	Initial Entry

5.b Symptom:

Date	Location	User	Value	Reason
Jan-08-2021 17:15:14 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.b Symptom Present:

Date	Location	User	Value	Reason
Jan-08-2021 17:15:14 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

090177e196ae3d63\Final\Final On: 01-Apr-2021 04:32 (GMT)

Header Text: C4591001

Visit: Unplanned 1 - Unscheduled Visit on Jan/06/2021

Form: UNPLANNED ASSESSMENT OF LOCAL REACTION - SYSTEMIC EVENT - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:22

Form Status: Data Complete, Verified

Site No: 1214

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

Subject No: 12141039

Subject Initials: ---

Generated By: (b) (4)

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

5.c

Date	Location	User	Value	Reason
Jan-08-2021 17:15:14 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom:: Not Applicabl e Symptom Present Not Applicabl :: e	Initial Entry

5.c Symptom:

Date	Location	User	Value	Reason
Jan-08-2021 17:15:14 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.c Symptom Present:

Date	Location	User	Value	Reason
Jan-08-2021 17:15:14 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.d

Date	Location	User	Value	Reason
Jan-08-2021 17:15:14 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom:: Not Applicabl e Symptom Present Not Applicabl :: e	Initial Entry

5.d Symptom:

Date	Location	User	Value	Reason
Jan-08-2021 17:15:14 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.d Symptom Present:

Date	Location	User	Value	Reason
Jan-08-2021 17:15:14 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

090177e196ae3d63\Final\Final On: 01-Apr-2021 04:32 (GMT)

Header Text: C4591001

Visit: Unplanned 1 - Unscheduled Visit on Jan/06/2021

Form Version: 10-Dec-2020 02:22

Site No: 1214

Subject No: 12141039

Generated By: (b) (4)

Form: UNPLANNED ASSESSMENT OF LOCAL REACTION - SYSTEMIC EVENT - 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

5.e

Date	Location	User	Value	Reason
Jan-08-2021 17:15:14 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom:: Not Applicabl e Symptom Present Not Applicabl :: e	Initial Entry

5.e Symptom:

Date	Location	User	Value	Reason
Jan-08-2021 17:15:14 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.e Symptom Present:

Date	Location	User	Value	Reason
Jan-08-2021 17:15:14 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.f

Date	Location	User	Value	Reason
Jan-08-2021 17:15:14 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom:: Not Applicabl e Symptom Present Not Applicabl :: e	Initial Entry

5.f Symptom:

Date	Location	User	Value	Reason
Jan-08-2021 17:15:14 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.f Symptom Present:

Date	Location	User	Value	Reason
Jan-08-2021 17:15:14 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

090177e196ae3d63\Final\Final On: 01-Apr-2021 04:32 (GMT)

Header Text: C4591001

Visit: Unplanned 1 - Unscheduled Visit on Jan/06/2021

Form Version: 10-Dec-2020 02:22

Site No: 1214

Subject No: 12141039

Generated By: (b) (4)

Form: UNPLANNED ASSESSMENT OF LOCAL REACTION - SYSTEMIC EVENT - 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

5.g

Date	Location	User	Value	Reason
Jan-08-2021 17:15:14 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom:: Not Applicabl e Symptom Present Not Applicabl :: e	Initial Entry

5.g Symptom:

Date	Location	User	Value	Reason
Jan-08-2021 17:15:14 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.g Symptom Present:

Date	Location	User	Value	Reason
Jan-08-2021 17:15:14 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.h

Date	Location	User	Value	Reason
Jan-08-2021 17:15:14 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom:: Not Applicabl e Symptom Present Not Applicabl :: e	Initial Entry

5.h Symptom:

Date	Location	User	Value	Reason
Jan-08-2021 17:15:14 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.h Symptom Present:

Date	Location	User	Value	Reason
Jan-08-2021 17:15:14 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

090177e196ae3d63\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: 12141039

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

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1. Date of Completion/Discontinuation/Death :

Date	Location	User	Value	Reason
Dec-28-2020 13:27:29 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Dec/28/2020	Initial Entry

2. Phase of Disposition:

Date	Location	User	Value	Reason
Dec-28-2020 13:27:29 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: VACCINATION	Initial Entry

3. Status:

Date	Location	User	Value	Reason
Dec-28-2020 13:27:29 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: COMPLETED	Initial Entry

090177e196ae3d63\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: 12141039

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

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1. Date of Visit

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

Header Text: C4591001

Visit: Potential ReVax Initial Contact -
Unscheduled

Form Version: 10-Dec-2020 02:25

Site No: 1214

Subject No: 12141039

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

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

Date	Location	User	Value	Reason
Dec-31-2020 11:23:03 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Dec-31-2020 11:22:42 (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-31-2020 11:22:42 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Participant is willing to return for Vaccination 3 Participant is: eligible per local/national recommendations and confirmed to have received only placebo at Vaccination 1/2	Initial Entry

090177e196ae3d63\Final\Final On: 01-Apr-2021 04:32 (GMT)

Header Text: C4591001

Visit: V101_VAX3

Form Version: 22-Apr-2020 21:02

Site No: 1214

Subject No: 12141039

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

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1. Date of Visit

Date	Location	User	Value	Reason
Feb-08-2021 12:17:30 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Feb/8/2021	Initial Entry

Header Text: C4591001

Visit: V101_VAX3

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

Form Version: 10-Dec-2020 02:31

Form Status: Data Complete, Frozen, Verified

Site No: 1214

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

Subject No: 12141039

Subject Initials: ---

Generated By: (b) (4)

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

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I. Consent Was:

Date	Location	User	Value	Reason
Feb-08-2021 12:17:42 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: OBTAINED Date Written Consent Obtained Feb/8/2021	Initial Entry

Header Text: C4591001

Visit: V101_VAX3

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

Form Version: 10-Dec-2020 02:31

Form Status: Data Complete, Frozen, Verified

Site No: 1214

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

Subject No: 12141039

Subject Initials: ---

Generated By: (b) (4)

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

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1. Date of Completion/Discontinuation/Death :

Date	Location	User	Value	Reason
Feb-08-2021 12:18:11 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Feb/8/2021	Initial Entry

2. Phase of Disposition:

Date	Location	User	Value	Reason
Feb-08-2021 12:18:11 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: REPEAT SCREENING 1	Initial Entry

3. Status:

Date	Location	User	Value	Reason
Feb-08-2021 12:18:11 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: COMPLETED	Initial Entry

090177e196ae3d63\Final\Final On: 01-Apr-2021 04:32 (GMT)

Header Text: C4591001

Visit: V101_VAX3

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1214

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

Subject No: 12141039

Subject Initials: ---

Generated By: (b) (4)

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

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1. Data Origin

Date	Location	User	Value	Reason
Feb-08-2021 12:18:24 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Feb-08-2021 12:18:24 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SERUM	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Feb-09-2021 14:17:32 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto query (autoquery)	Query 3: Closed	Close Auto Query
Feb-09-2021 12:15:04 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto query (autoquery)	Query 3: Opened	'Sample Collected?' is marked as No and 'If no sample was collected or sample was not collected according to protocol, please provide reason' is missing. Please review and update as appropriate.
Feb-09-2021 12:15:04 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Deleted	Close Auto Query
Feb-09-2021 12:15:04 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Transcription Error
Feb-09-2021 12:14:51 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.

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Header Text: C4591001

Visit: V101_VAX3

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1214

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

Subject No: 12141039

Subject Initials: ---

Generated By: (b) (4)

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

Feb-08-2021 13:05:02 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Feb-08-2021 12:18:24 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Feb-08-2021 12:18:24 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Date of Collection: Feb/8/2021	Initial Entry

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

Date	Location	User	Value	Reason
Feb-09-2021 14:17:32 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Since the V101_VAX3 visit occurs at the same time as the Potential COVID-19 Convalescent visit, the sample collection date and barcodes were recorded at the original visit(Covid-19 Convalescent visit)	Initial Entry

5.a

Date	Location	User	Value	Reason
Feb-09-2021 14:18:05 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID:	Transcription Error (DELETED)
Feb-09-2021 12:14:30 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID:	Transcription Error
Feb-09-2021 12:14:18 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BR5CXW	Transcription Error
Feb-09-2021 12:13:40 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BR5CXW	Transcription Error (DELETED)
Feb-08-2021 13:05:02 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BR5CXW	Initial Entry

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Header Text: C4591001

Visit: V101_VAX3

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1214

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

Subject No: 12141039

Subject Initials: ---

Generated By: (b) (4)

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

5.a Sample ID

Date	Location	User	Value	Reason
Feb-09-2021 22:49:48 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Feb-09-2021 14:18:05 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry</u> :	Transcription Error (DELETED)
Feb-09-2021 12:14:30 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry</u> :	Transcription Error
Feb-09-2021 12:14:18 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry</u> : BR5C XW	Transcription Error
Feb-09-2021 12:13:40 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry</u> : BR5C XW	Transcription Error (DELETED)
Feb-09-2021 12:13:40 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Transcription Error
Feb-09-2021 11:55:56 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reissued: Opened	DM: Per CCG, in case a scheduled visit occurs at the same time as V101_VAX3, sample collection date and barcodes should be recorded on original visit. In this visit, 'Sample Collected' should be 'No'. Kindly review and update.

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Header Text: C4591001

Visit: V101_VAX3

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1214

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

Subject No: 12141039

Subject Initials: ---

Generated By: (b) (4)

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

Feb-09-2021 09:39:27 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	V101 and POT_COVID_CONVA were done simultaneously
Feb-08-2021 23:48:56 (UTC+03:00) Istanbul	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (b) (4)	Query 1: Opened	DMW7188835; This Barcode is already recorded more than once (for the same subject). Please review and update as appropriate.
Feb-08-2021 13:05:02 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry : BR5C XW	Initial Entry

5.b

Date	Location	User	Value	Reason
Feb-09-2021 14:23:06 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID:	Transcription Error (DELETED)
Feb-09-2021 14:19:00 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID:	Transcription Error
Feb-09-2021 14:18:16 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID:	Transcription Error (DELETED)
Feb-09-2021 12:14:01 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID:	Transcription Error
Feb-08-2021 13:05:14 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BR5CXX	Initial Entry

090177e196ae3d63\Final\Final On: 01-Apr-2021 04:32 (GMT)

Header Text: C4591001

Visit: V101_VAX3

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1214

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

Subject No: 12141039

Subject Initials: ---

Generated By: (b) (4)

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

5.b Sample ID

Date	Location	User	Value	Reason
Feb-09-2021 22:49:48 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Feb-09-2021 14:23:06 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry :	Transcription Error (DELETED)
Feb-09-2021 14:22:47 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	The comment was added
Feb-09-2021 14:19:00 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry :	Transcription Error
Feb-09-2021 14:18:16 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry :	Transcription Error (DELETED)
Feb-09-2021 12:24:48 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reissued: Opened	DM: Please add comment in eCRF as sampling done on CONVA accordingly. Thank you.
Feb-09-2021 12:14:01 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry :	Transcription Error
Feb-09-2021 09:39:01 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	V101 and POT_COVID_CONVA were done simultaneously
Feb-08-2021 23:48:56 (UTC+03:00)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (b) (4)	Query 1: Opened	DMW7188836;This Barcode is already recorded more than

090177e196ae3d63\Final\Final On: 01-Apr-2021 04:32 (GMT)

Header Text: C4591001

Visit: V101_VAX3

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

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Form Status: Data Complete, Frozen, Verified

Site No: 1214

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

Subject No: 12141039

Subject Initials: ---

Generated By: (b) (4)

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Istanbul				once (for the same subject). Please review and update as appropriate.
Feb-08-2021 13:05:14 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry</u> : BR5C XX	Initial Entry

5.c

Date	Location	User	Value	Reason
Feb-09-2021 14:18:26 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> <u>Sample ID:</u>	Transcription Error (DELETED)
Feb-09-2021 12:14:41 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> <u>Sample ID:</u>	Transcription Error
Feb-08-2021 13:05:27 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> <u>Sample ID:</u> BSHD05	Initial Entry

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Header Text: C4591001

Visit: V101_VAX3

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1214

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

Subject No: 12141039

Subject Initials: ---

Generated By: (b) (4)

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

5.c Sample ID

Date	Location	User	Value	Reason
Feb-09-2021 14:18:26 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry	Transcription Error (DELETED)
Feb-09-2021 13:36:49 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Feb-09-2021 12:14:41 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry	Transcription Error
Feb-09-2021 09:39:14 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	V101 and POT_COVID_CONVA were done simultaneously
Feb-08-2021 23:48:56 (UTC+03:00) Istanbul	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (b) (4)	Query 1: Opened	DMW7188837;This Barcode is already recorded more than once (for the same subject). Please review and update as appropriate.
Feb-08-2021 13:05:27 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry	Initial Entry

5.d

Date	Location	User	Value	Reason
Feb-09-2021 14:18:36 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID:	Transcription Error (DELETED)
Feb-09-2021 12:14:51 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID:	Transcription Error

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Header Text: C4591001

Visit: V101_VAX3

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1214

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

Subject No: 12141039

Subject Initials: ---

Generated By: (b) (4)

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

Feb-08-2021 13:05:35 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BSHD06	Initial Entry
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5.d Sample ID

Date	Location	User	Value	Reason
Feb-09-2021 14:18:36 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry :	Transcription Error (DELETED)
Feb-09-2021 13:23:46 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Feb-09-2021 12:14:51 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry :	Transcription Error
Feb-09-2021 09:38:45 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	V101 and POT_COVID_CONVA were done simultaneously
Feb-08-2021 23:48:56 (UTC+03:00) Istanbul	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (b) (4)	Query 1: Opened	DMW7188838;This Barcode is already recorded more than once (for the same subject). Please review and update as appropriate.
Feb-08-2021 13:05:35 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry : BSH D06	Initial Entry

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Header Text: C4591001**Visit:** V101_VAX3**Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB - eCRF
Audit Trail History**Form Version:** 22-Apr-2020 21:03**Form Status:** Data Complete, Frozen, Verified**Site No:** 1214**Site Name:** (1214) ISTANBUL UNIVERSITY MEDICAL FACULTY
CARDIOLOGY INSTITUTE**Subject No:** 12141039**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 13:11[Back to Form](#)**1. Data Origin**

Date	Location	User	Value	Reason
Feb-08-2021 12:18:36 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Feb-08-2021 12:18:36 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: NASAL_SWAB	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Feb-08-2021 13:04:44 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Feb-08-2021 12:18:36 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Feb-08-2021 12:18:36 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Date of Collection: Feb/8/2021	Initial Entry

5.a

Date	Location	User	Value	Reason
Feb-08-2021 13:04:44 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BR5CXV	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
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Header Text: C4591001

Visit: V101_VAX3

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1214

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

Subject No: 12141039

Subject Initials: ---

Generated By: (b) (4)

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

Feb-08-2021 13:04:44 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BR5CXV	Initial Entry
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Header Text: C4591001

Visit: V101_VAX3

Form Version: 10-Dec-2020 02:26

Site No: 1214

Subject No: 12141039

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

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1. Was there a temporary delay of vaccination?

Date	Location	User	Value	Reason
Feb-08-2021 12:18:58 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2. Treatment Name

Date	Location	User	Value	Reason
Feb-08-2021 12:18:58 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: BNT162b2	Initial Entry

3. Formulation:

Date	Location	User	Value	Reason
Feb-08-2021 12:18:58 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: INJECTION	Initial Entry

4. Dose Date Time:

Date	Location	User	Value	Reason
Feb-08-2021 12:18:58 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Feb/8/2021 10:40	Initial Entry

5. Anatomical Location:

Date	Location	User	Value	Reason
Feb-08-2021 12:18:58 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: DELTOID MUSCLE	Initial Entry

6. Body Side:

Date	Location	User	Value	Reason
Feb-08-2021 12:18:58 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: RIGHT	Initial Entry

7. Route:

090177e196ae3d63\Final\Final On: 01-Apr-2021 04:32 (GMT)

Header Text: C4591001

Visit: V101_VAX3

Form Version: 10-Dec-2020 02:26

Site No: 1214

Subject No: 12141039

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

Date	Location	User	Value	Reason
Feb-08-2021 12:18:58 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: INTRAMUSCULAR	Initial Entry

8. Actual Dose:

Date	Location	User	Value	Reason
Feb-08-2021 12:18:58 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 30.0	Initial Entry

9. Unit:

Date	Location	User	Value	Reason
Feb-08-2021 12:18:58 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: ug	Initial Entry

10. Timeframe Subject Was Observed

Date	Location	User	Value	Reason
Feb-08-2021 12:18:58 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 30 MINUTES	Initial Entry

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

Date	Location	User	Value	Reason
Feb-08-2021 12:18:58 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

090177e196ae3d63\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: 12141039

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

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1. Date Treatment Unblinded :

Date	Location	User	Value	Reason
Dec-31-2020 11:23:03 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Dec/31/2020	Initial Entry

2. Primary Reason for Unblinding:

Date	Location	User	Value	Reason
Dec-31-2020 11:23:03 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: ASSESS ELIGIBILITY FOR ADD ITIONAL VACCINATION	Initial Entry

090177e196ae3d63\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: 12141039

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

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I. Withdrawal of Consent Date :

Date	Location	User	Value	Reason
Dec-31-2020 11:23:17 (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: 12141039

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

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I. Date of Collection / Notification of Death:

Date	Location	User	Value	Reason
Jan-05-2021 11:04:54 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Query closed as per site response
Jan-04-2021 11:19:12 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Changed data per query
Jan-04-2021 11:18:57 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry
Jan-04-2021 08:25:25 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: 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 18:03:58 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Initial Entry
Dec-31-2020 11:23:37 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

090177e196ae3d63\Final\Final On: 01-Apr-2021 04:32 (GMT)

Header Text: C4591001

Visit: V102_VAX4

Form Version: 22-Apr-2020 21:02

Site No: 1214

Subject No: 12141039

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

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1. Date of Visit

Date	Location	User	Value	Reason
Mar-03-2021 12:30:18 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Mar/3/2021	Initial Entry

Header Text: C4591001

Visit: V102_VAX4

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1214

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

Subject No: 12141039

Subject Initials: ---

Generated By: (b) (4)

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

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1. Data Origin

Date	Location	User	Value	Reason
Mar-03-2021 12:30:30 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Mar-03-2021 12:30:30 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: NASAL_SWAB	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Mar-03-2021 12:31:35 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Mar-03-2021 12:30:30 (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.
Mar-03-2021 12:30:30 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Date of Collection: Mar/3/2021	Initial Entry

5.a

Date	Location	User	Value	Reason
Mar-03-2021 12:31:35 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BR5CYZ	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
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090177e196ae3d63\Final\Final On: 01-Apr-2021 04:32 (GMT)

Header Text: C4591001

Visit: V102_VAX4

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1214

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

Subject No: 12141039

Subject Initials: ---

Generated By: (b) (4)

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

Mar-03-2021 12:31:35 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BR5CYZ	Initial Entry
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Header Text: C4591001

Visit: V102_VAX4

Form Version: 10-Dec-2020 02:26

Site No: 1214

Subject No: 12141039

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

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1. Was there a temporary delay of vaccination?

Date	Location	User	Value	Reason
Mar-03-2021 12:30:53 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2. Treatment Name

Date	Location	User	Value	Reason
Mar-03-2021 12:30:53 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: BNT162b2	Initial Entry

3. Formulation:

Date	Location	User	Value	Reason
Mar-03-2021 12:30:53 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: INJECTION	Initial Entry

4. Dose Date Time:

Date	Location	User	Value	Reason
Mar-03-2021 12:30:53 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Mar/3/2021 10:45	Initial Entry

5. Anatomical Location:

Date	Location	User	Value	Reason
Mar-03-2021 12:30:53 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: DELTOID MUSCLE	Initial Entry

6. Body Side:

Date	Location	User	Value	Reason
Mar-03-2021 12:30:53 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: RIGHT	Initial Entry

7. Route:

Date	Location	User	Value	Reason
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090177e196ae3d63\Final\Final On: 01-Apr-2021 04:32 (GMT)

Header Text: C4591001

Visit: V102_VAX4

Form Version: 10-Dec-2020 02:26

Site No: 1214

Subject No: 12141039

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

Mar-03-2021 12:30:53 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: INTRAMUSCULAR	Initial Entry
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8. Actual Dose:

Date	Location	User	Value	Reason
Mar-03-2021 12:30:53 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 30.0	Initial Entry

9. Unit:

Date	Location	User	Value	Reason
Mar-03-2021 12:30:53 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: ug	Initial Entry

10. Timeframe Subject Was Observed

Date	Location	User	Value	Reason
Mar-03-2021 12:30:53 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 30 MINUTES	Initial Entry

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

Date	Location	User	Value	Reason
Mar-03-2021 12:30:53 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

090177e196ae3d63\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: 12141039

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

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1. Subject Status

Date	Location	User	Value	Reason
Dec-28-2020 13:27:29 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: FOLLOW-UP	Initial Entry
Nov-06-2020 15:17:32 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: ENROLLED/RANDOMIZED	Initial Entry
Nov-06-2020 15:15:36 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SCREENED	Initial Entry

2. Subject Status Date

Date	Location	User	Value	Reason
Dec-28-2020 13:27:29 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Dec/28/2020	Initial Entry
Nov-06-2020 15:17:32 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Nov/6/2020	Initial Entry
Nov-06-2020 15:15:36 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Nov/6/2020	Initial Entry

090177e196ae3d63\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: 12141039

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

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1. Casebook Signature

Date	Location	User	Value	Reason
Nov-20-2020 15:35:42 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Click Here to Enable	Initial Entry