

Header Text: C4591001

Visit: COHORT_SELECTION

Form Version: 10-Oct-2020 16:01

Site No: 1209

Subject No: 12091014

Generated By: (b) (4)

Form: COHORT_SELECTION

Form Status: Data Complete, Frozen, Verified

Site Name: (1209) Turkish MoH Yedikule Chest Diseases and Chest Surgery Training and Application Center

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

090177e196ae30cb\Final\Final On: 01-Apr-2021 04:17 (GMT)

Header Text: C4591001

Visit: COHORT_SELECTION

Form Version: 22-Apr-2020 21:02

Site No: 1209

Subject No: 12091014

Generated By: (b) (4)

Form: MAIN INFORMED CONSENT

Form Status: Data Complete, Frozen, Verified

Site Name: (1209) Turkish MoH Yedikule Chest Diseases and Chest Surgery Training and Application Center

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/3/2020
----	--------------	---

Header Text: C4591001

Visit: COHORT_SELECTION

Form Version: 15-Sep-2020 21:54

Site No: 1209

Subject No: 12091014

Generated By: (b) (4)

Form: DEMOGRAPHY

Form Status: Data Complete, Frozen, Verified

Site Name: (1209) Turkish MoH Yedikule Chest Diseases and Chest Surgery Training and Application Center

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Demography

1.	Subject ID	[12091014]
2.	Birth Date:	(b) (6) 1960
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:	

090177e196ae30cb\Final\Final On: 01-Apr-2021 04:17 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:02

Site No: 1209

Subject No: 12091014

Generated By: (b) (4)

Form: DATE OF VISIT

Form Status: Data Complete, Frozen, Verified

Site Name: (1209) Turkish MoH Yedikule Chest Diseases and Chest Surgery Training and Application Center

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Date of Visit

1.	Date of Visit	Nov/3/2020
2.	Erroneous Visit	

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 10-Oct-2020 16:00

Site No: 1209

Subject No: 12091014

Generated By: (b) (4)

Form: INCLUSION/EXCLUSION CRITERIA

Form Status: Data Complete, Frozen, Verified

Site Name: (1209) Turkish MoH Yedikule Chest Diseases and Chest Surgery Training and Application Center

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

090177e196ae30cb\Final\Final On: 01-Apr-2021 04:17 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 15-Sep-2020 21:52

Site No: 1209

Subject No: 12091014

Generated By: (b) (4)

Form: DISPOSITION - SCREENING

Form Status: Data Complete, Frozen, Verified

Site Name: (1209) Turkish MoH Yedikule Chest Diseases and Chest Surgery Training and Application Center

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Disposition - Screening

1.	Date of Completion/Discontinuation /Death	Nov/3/2020
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: 1209

Subject No: 12091014

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY

Form Status: Data Complete, Frozen, Verified

Site Name: (1209) Turkish MoH Yedikule Chest Diseases and Chest Surgery Training and Application Center

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 _____

090177e196ae30cb\Final\Final On: 01-Apr-2021 04:17 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 15-Sep-2020 21:57

Site No: 1209

Subject No: 12091014

Generated By: (b) (4)

Form: HIV STATUS

Form Status: Data Complete, Frozen, Verified

Site Name: (1209) Turkish MoH Yedikule Chest Diseases and Chest Surgery Training and Application Center

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: 1209

Subject No: 12091014

Generated By: (b) (4)

Form: VITAL SIGNS - BASELINE

Form Status: Data Complete, Frozen, Verified

Site Name: (1209) Turkish MoH Yedikule Chest Diseases and Chest Surgery Training and Application Center

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Vital Signs

1.	Date:	Nov/3/2020
2.	Weight:	[90.0]
3.	Unit:	kg
4.	Height:	[175.0]
5.	Unit:	cm
6.	Body Mass Index:	[29.4]

Vital Signs Details

7.a	Record Identifier:	1
	Temperature:	[36.6]
	Unit:	C
	Temperature Location:	FOREHEAD

090177e196ae30cb\Final\Final On: 01-Apr-2021 04:17 (GMT)

Header Text: C4591001
Visit: V1_DAY1_VAX1_L
Form Version: 22-Apr-2020 21:03
Site No: 1209
Subject No: 12091014
Generated By: (b) (4)

Form: RANDOMIZATION
Form Status: Data Complete, Frozen, Verified
Site Name: (1209) Turkish MoH Yedikule Chest Diseases and Chest Surgery Training and Application Center
Subject Initials: ---
Generated Time (GMT): 29-Mar-2021 13:11

[eCRF Audit Trail History](#)

Disposition		
1.	Randomization Date :	Nov/3/2020
2.	Randomization Number:	[272972]
3.	Randomization Group:	[]

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1209

Subject No: 12091014

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Status: Data Complete, Frozen, Verified

Site Name: (1209) Turkish MoH Yedikule Chest Diseases and Chest Surgery Training and Application Center

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/3/2020
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	[BPZBMH]
5.b	Sample ID	[BPZBMJ]
5.c	Sample ID	[BRZDN7]
5.d	Sample ID	[BRZDN8]

090177e196ae30cb\Final\Final On: 01-Apr-2021 04:17 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1209

Subject No: 12091014

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB

Form Status: Data Complete, Frozen, Verified

Site Name: (1209) Turkish MoH Yedikule Chest Diseases and Chest Surgery Training and Application Center

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/3/2020
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	[BPZBMC]
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090177e196ae30cb\Final\Final On: 01-Apr-2021 04:17 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:04

Site No: 1209

Subject No: 12091014

Generated By: (b) (4)

Form: VACCINATION

Form Status: Data Complete, Frozen, Verified

Site Name: (1209) Turkish MoH Yedikule Chest Diseases and Chest Surgery Training and Application Center

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/3/2020 10:07
5.	Anatomical Location:	DELTOID MUSCLE
6.	Body Side:	LEFT
7.	Route:	INTRAMUSCULAR
8.	Actual Dose:	[]
9.	Unit:	
10.	Timeframe Subject Was Observed	THE PROTOCOL SPECIFIED OBSERVATION PERIOD
11.	Was the subject observed for at least the protocol specified observation period after investigational product administration?	YES

090177e196ae30cb\Final\Final On: 01-Apr-2021 04:17 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 06-Jul-2020 21:53

Site No: 1209

Subject No: 12091014

Generated By: (b) (4)

Form: REACTOGENICITY DIARY

Form Status: Data Complete, Frozen, Verified

Site Name: (1209) Turkish MoH Yedikule Chest Diseases and Chest Surgery Training and Application Center

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: 1209

Subject No: 12091014

Generated By: (b) (4)

Form: DATE OF VISIT

Form Status: Data Complete, Frozen, Verified

Site Name: (1209) Turkish MoH Yedikule Chest Diseases and Chest Surgery Training and Application Center

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Date of Visit

1.	Date of Visit	Nov/24/2020
2.	Erroneous Visit	

090177e196ae30cb\Final\Final On: 01-Apr-2021 04:17 (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: 1209

Site Name: (1209) Turkish MoH Yedikule Chest Diseases and Chest Surgery Training and Application Center

Subject No: 12091014

Subject Initials: ---

Generated By: (b) (4)

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

[eCRF Audit Trail History](#)

Vaccination Symptoms Diary - Symptom Resolved Dates

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

090177e196ae30cb\Final\Final On: 01-Apr-2021 04:17 (GMT)

Header Text: C4591001

Visit: V2_VAX2_L

Form Version: 10-Oct-2020 16:03

Site No: 1209

Subject No: 12091014

Generated By: (b) (4)

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES

Form Status: Data Complete, Frozen, Verified

Site Name: (1209) Turkish MoH Yedikule Chest Diseases and Chest Surgery Training and Application Center

Subject Initials: ---

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

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

090177e196ae30cb\Final\Final On: 01-Apr-2021 04:17 (GMT)

Header Text: C4591001

Visit: V2_VAX2_L

Form Version: 10-Oct-2020 16:01

Site No: 1209

Subject No: 12091014

Generated By: (b) (4)

Form: VITAL SIGNS - TEMP

Form Status: Data Complete, Frozen, Verified

Site Name: (1209) Turkish MoH Yedikule Chest Diseases and Chest Surgery Training and Application Center

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Vital Signs

1.	Date:	Nov/24/2020
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Vital Signs Details

2.a	Record Identifier:	1
	Temperature:	[36.6]
	Unit:	C
	Temperature Location:	FOREHEAD

Header Text: C4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:03

Site No: 1209

Subject No: 12091014

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB

Form Status: Data Complete, Frozen, Verified

Site Name: (1209) Turkish MoH Yedikule Chest Diseases and Chest Surgery Training and Application Center

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/24/2020
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	[BPZBNT]
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090177e196ae30cb\Final\Final On: 01-Apr-2021 04:17 (GMT)

Header Text: C4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:04

Site No: 1209

Subject No: 12091014

Generated By: (b) (4)

Form: VACCINATION

Form Status: Data Complete, Frozen, Verified

Site Name: (1209) Turkish MoH Yedikule Chest Diseases and Chest Surgery Training and Application Center

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/24/2020 09:32
5.	Anatomical Location:	DELTOID MUSCLE
6.	Body Side:	LEFT
7.	Route:	INTRAMUSCULAR
8.	Actual Dose:	[]
9.	Unit:	
10.	Timeframe Subject Was Observed	THE PROTOCOL SPECIFIED OBSERVATION PERIOD
11.	Was the subject observed for at least the protocol specified observation period after investigational product administration?	YES

090177e196ae30cb\Final\Final On: 01-Apr-2021 04:17 (GMT)

Header Text: C4591001

Visit: V3_MONTH1_POSTVAX2_L

Form Version: 22-Apr-2020 21:02

Site No: 1209

Subject No: 12091014

Generated By: (b) (4)

Form: DATE OF VISIT

Form Status: Data Complete, Frozen, Verified

Site Name: (1209) Turkish MoH Yedikule Chest Diseases and Chest Surgery Training and Application Center

Subject Initials: ---

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	

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: 1209

Site Name: (1209) Turkish MoH Yedikule Chest Diseases and Chest Surgery Training and Application Center

Subject No: 12091014

Subject Initials: ---

Generated By: (b) (4)

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

[eCRF Audit Trail History](#)

Vaccination Symptoms Diary - Symptom Resolved Dates

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

090177e196ae30cb\Final\Final On: 01-Apr-2021 04:17 (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: 1209

Site Name: (1209) Turkish MoH Yedikule Chest Diseases and Chest Surgery Training and Application Center

Subject No: 12091014

Subject Initials: ---

Generated By: (b) (4)

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

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

090177e196ae30cb\Final\Final On: 01-Apr-2021 04:17 (GMT)

Header Text: C4591001

Visit: V3_MONTH1_POSTVAX2_L

Form Version: 22-Apr-2020 21:03

Site No: 1209

Subject No: 12091014

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Status: Data Complete, Frozen, Verified

Site Name: (1209) Turkish MoH Yedikule Chest Diseases and Chest Surgery Training and Application Center

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/31/2020
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	[BPZBR8]
5.b	Sample ID	[BPZBR9]
5.c	Sample ID	[BRZDR5]
5.d	Sample ID	[BRZDR6]

090177e196ae30cb\Final\Final On: 01-Apr-2021 04:17 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Dec/21/2020 **Form:** DATE OF VISIT - ILLNESS ONSET

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1209

Site Name: (1209) Turkish MoH Yedikule Chest Diseases and Chest Surgery Training and Application Center

Subject No: 12091014

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/21/2020
2.	Erroneous Visit	

COVID-19 Illness Visit

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

090177e196ae30cb\Final\Final On: 01-Apr-2021 04:17 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Dec/21/2020 **Form:** SIGNS AND SYMPTOMS OF POTENTIAL COVID-19

Form Version: 10-Dec-2020 02:29

Form Status: Data Complete

Site No: 1209

Site Name: (1209) Turkish MoH Yedikule Chest Diseases and Chest Surgery Training and Application Center

Subject No: 12091014

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:	Dec/21/2020
2.	Date of First Symptom Started:	Dec/19/2020
3.	Symptoms Ongoing?	NO Date of Last Symptom Resolved: Dec/20/2020

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?	NO
4.f	Symptoms:	NEW LOSS OF TASTE OR SMELL
	Was symptom present?	NO
4.g	Symptoms:	NEW OR INCREASED SORE THROAT
	Was symptom present?	NO
4.h	Symptoms:	DIARRHEA
	Was symptom present?	NO
4.i	Symptoms:	VOMITING
	Was symptom present?	NO

Symptoms - Other

090177e196ae30cb\Final\Final On: 01-Apr-2021 04:17 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Dec/21/2020

Form: SIGNS AND SYMPTOMS OF POTENTIAL COVID-19

Form Version: 10-Dec-2020 02:29

Form Status: Data Complete

Site No: 1209

Site Name: (1209) Turkish MoH Yedikule Chest Diseases and Chest Surgery Training and Application Center

Subject No: 12091014

Subject Initials: ---

Generated By: (b) (4)

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

5.	Symptoms - Other Text:	[]
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090177e196ae30cb\Final\Final On: 01-Apr-2021 04:17 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1

Form: MICROBIOLOGY SPECIMEN

Form Version: 06-Jul-2020 21:54

Site No: 1209

Site Name: (1209) Turkish MoH Yedikule Chest Diseases and Chest Surgery Training and Application Center

Subject No: 12091014

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.	Dec/18/2020	SWABBED MATERIAL	NASOPHARYNX	SEVERE ACUTE RESPIRATORY SYNDROME CORONAVIRUS 2	SARS-COV-2 DIAGNOSTIC TEST	Repeating Pages

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Dec/21/2020 **Form:** MICROBIOLOGY SPECIMEN

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete

Site No: 1209

Site Name: (1209) Turkish MoH Yedikule Chest Diseases and Chest Surgery Training and Application Center

Subject No: 12091014

Subject Initials: ---

Generated By: (b) (4)

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

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[Form Audit Trail](#)

Microbiology Specimen

1.	Actual Date of Collection:	Dec/18/2020
2.	Specimen Type:	SWABBED MATERIAL
3.	Specimen Collection Location:	NASOPHARYNX
4.	Assay Code and Description:	SEVERE ACUTE RESP SYNDROME CORONAVIRUS 2
5.	Device Type:	SARS-COV-2 DIAGNOSTIC TEST
6.	Trade Name:	OTHER
7.	Test Result:	POSITIVE
8.	Comments/Findings/Details:	[]
9.	Trade Name Other, Specify:	[Bioeksen Bio Speedy Direct RT qPCR SARS CoV 2]

090177e196ae30cb\Final\Final On: 01-Apr-2021 04:17 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Dec/21/2020

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB SELF

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1209

Site Name: (1209) Turkish MoH Yedikule Chest Diseases and Chest Surgery Training and Application Center

Subject No: 12091014

Subject Initials: ---

Generated By: (b) (4)

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

[eCRF Audit Trail History](#)

Electronic Sample Tracking

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB_SELF
3.	Sample Collected?	NO
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[The subject didn't want to use self swab kit]

Aliquot

Please enter barcode for each aliquot.

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

090177e196ae30cb\Final\Final On: 01-Apr-2021 04:17 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Dec/21/2020 **Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1209

Site Name: (1209) Turkish MoH Yedikule Chest Diseases and Chest Surgery Training and Application Center

Subject No: 12091014

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: Dec/31/2020
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[The subject was not available yet to visit the site for nasal swab. They've been discharged from hospital on 25 dec (their pcr result is negative)]

Aliquot

Please enter barcode for each aliquot.

5.a	Sample ID	[BPZBR7]
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090177e196ae30cb\Final\Final On: 01-Apr-2021 04:17 (GMT)

Header Text: C4591001**Visit:** POT_COVID_ILL 1 - Unscheduled Visit on Dec/21/2020 **Form:** HEALTH CARE UTILIZATION**Form Version:** 10-Dec-2020 02:26**Form Status:** Data Complete**Site No:** 1209**Site Name:** (1209) Turkish MoH Yedikule Chest Diseases and Chest Surgery Training and Application Center**Subject No:** 12091014**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:	YES Number of Visits or Contacts: [3]	
1.f	Physician or Healthcare Professional:	OTHER	
	Occurrence of Visits or Contacts:	NO	

Health Care Utilization Other

2.	Other Type of Practitioner Specify:	Not Done []	Comments
----	-------------------------------------	-----------------	--------------------------

Health Care Utilization

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

Header Text: C4591001

Visit: POT_COVID_ILL 1

Form: HOSPITALIZATION DETAILS

Form Version: 22-Apr-2020 21:02

Site No: 1209

Site Name: (1209) Turkish MoH Yedikule Chest Diseases and Chest Surgery Training and Application Center

Subject No: 12091014

Subject Initials: ---

Generated By: (b) (4)

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

#	Hospitalization Category	Hospitalization Term	Admission Date	Ongoing	Form Instance
1.	HOSPITALIZATION STATUS	HOSPITAL	Dec/18/2020	NO Discharge Date: Dec/25/2020	Repeating Pages

090177e196ae30cb\Final\Final On: 01-Apr-2021 04:17 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Dec/21/2020 **Form:** HOSPITALIZATION DETAILS

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete

Site No: 1209

Site Name: (1209) Turkish MoH Yedikule Chest Diseases and Chest Surgery Training and Application Center

Subject No: 12091014

Subject Initials: ---

Generated By: (b) (4)

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

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[Form Audit Trail](#)

Hospitalization Details

1.	Hospitalization Category:	HOSPITALIZATION STATUS
2.	Hospitalization Term:	HOSPITAL
3.	Admission Date:	Dec/18/2020
4.	Ongoing?	NO Discharge Date: Dec/25/2020

Header Text: C4591001

Visit: POT_COVID_ILL 1

Form: RESPIRATORY TREATMENT

Form Version: 06-Jul-2020 21:53

Site No: 1209

Site Name: (1209) Turkish MoH Yedikule Chest Diseases and Chest Surgery Training and Application Center

Subject No: 12091014

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 Done	Not Done	Not Done	Not Done	Not Done	Repeating Pages

090177e196ae30cb\Final\Final On: 01-Apr-2021 04:17 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Dec/21/2020 **Form:** RESPIRATORY TREATMENT

Form Version: 06-Jul-2020 21:53

Form Status: Data Complete

Site No: 1209

Site Name: (1209) Turkish MoH Yedikule Chest Diseases and Chest Surgery Training and Application Center

Subject No: 12091014

Subject Initials: ---

Generated By: (b) (4)

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

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[eCRF Audit Trail History](#)

Respiratory Treatment

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

090177e196ae30cb\Final\Final On: 01-Apr-2021 04:17 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Dec/21/2020 **Form:** ILLNESS DETAILS

Form Version: 06-Jul-2020 21:52

Form Status: Data Complete

Site No: 1209

Site Name: (1209) Turkish MoH Yedikule Chest Diseases and Chest Surgery Training and Application Center

Subject No: 12091014

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?	YES Respiratory Illness Diagnosis: [COVID-19 pneumonia] Date of Diagnosis: Dec/18/2020
3.	Toxicity Grade:	1

090177e196ae30cb\Final\Final On: 01-Apr-2021 04:17 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1

Form: ILLNESS DETAILS - SEVERE

Form Version: 17-Jul-2020 21:55

Site No: 1209

Site Name: (1209) Turkish MoH Yedikule Chest Diseases and Chest Surgery Training and Application Center

Subject No: 12091014

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 Done	Not Done	Not Done	Not Done	Repeating Pages

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Dec/21/2020 **Form:** ILLNESS DETAILS - SEVERE

Form Version: 17-Jul-2020 21:55

Form Status: Data Complete

Site No: 1209

Site Name: (1209) Turkish MoH Yedikule Chest Diseases and Chest Surgery Training and Application Center

Subject No: 12091014

Subject Initials: ---

Generated By: (b) (4)

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

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[eCRF Audit Trail History](#)

Illness Details

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

090177e196ae30cb\Final\Final On: 01-Apr-2021 04:17 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY

Form Version: 10-Oct-2020 15:58

Site No: 1209

Site Name: (1209) Turkish MoH Yedikule Chest Diseases and Chest Surgery Training and Application Center

Subject No: 12091014

Subject Initials: ---

Generated By: (b) (4)

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

#	Category for Lab Test	Vendor Name	Collection Date	Specimen Type	Lab Result			Form Instance
1.	CLINICAL CHEMISTRY	American Hospital (Amerikan Hastanesi) Tesvi kiye, Guzelbahce St. No:20, 34365 Sisli/Istanbul/Turkey	Dec/25/2020	BLOOD	Sponsor-Defined Identifier	Test:	Result:	Repeating Pages
					329	Not Done	11,6	
					30	Not Done	93	
					28	Not Done	74	
					35	Not Done		
					21	Not Done		
					47	Not Done		
					48	Not Done	0,8	

090177e196ae30cb\Final\Final On: 01-Apr-2021 04:17 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Dec/21/2020 **Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY

Form Version: 10-Oct-2020 15:58

Form Status: Data Complete

Site No: 1209

Site Name: (1209) Turkish MoH Yedikule Chest Diseases and Chest Surgery Training and Application Center

Subject No: 12091014

Subject Initials: ---

Generated By: (b) (4)

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

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Lab Chemistry Details

1.	Lab Panel:	CLINICAL CHEMISTRY	Comments
2.	Laboratory Name and Address	[American Hospital (Amerikan Hastanesi) Tesvikiye, Guzelbahce St. No:20, 34365 Sisli/Istanbul/Turkey]	Comments
3.	Collection Date:	Dec/25/2020	Comments
4.	Specimen Type:	BLOOD	Comments

Lab Result

5.a	Sponsor ID:	[329]	Comments
	Test:	C Reactive Protein_PX329	
	Result:	[11,6]	Comments
	Not Done:		Comments
	LNMT	Low [0] High [5] Unit mg/L	Comments
5.b	Sponsor ID:	[30]	Comments
	Test:	Alanine Aminotransferase_PX30	
	Result:	[93]	Comments
	Not Done:		Comments
	LNMT	Low [0] High [41] Unit U/L	Comments

090177e196ae30cb\Final\Final On: 01-Apr-2021 04:17 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Dec/21/2020 **Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY

Form Version: 10-Oct-2020 15:58

Form Status: Data Complete

Site No: 1209

Site Name: (1209) Turkish MoH Yedikule Chest Diseases and Chest Surgery Training and Application Center

Subject No: 12091014

Subject Initials: ---

Generated By: (b) (4)

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

5.c	Sponsor ID:	[28]	Comments
	Test:	Aspartate Aminotransferase_PX28	
	Result:	[74]	Comments
	Not Done:		Comments
	LNMT	Low [0] High [40] Unit U/L	Comments
5.d	Sponsor ID:	[35]	Comments
	Test:	Alkaline Phosphatase_PX35	
	Result:	[]	Comments
	Not Done:	NOT DONE	Comments
	LNMT	Low [] High [] Unit	Comments
5.e	Sponsor ID:	[21]	Comments
	Test:	Bilirubin_PX21	
	Result:	[]	Comments
	Not Done:	NOT DONE	Comments
	LNMT	Low [] High [] Unit	Comments
5.f	Sponsor ID:	[47]	Comments
	Test:	Blood Urea Nitrogen_PX47	
	Result:	[]	Comments
	Not Done:	NOT DONE	Comments
	LNMT	Low [] High [] Unit	Comments

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Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Dec/21/2020

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY

Form Version: 10-Oct-2020 15:58

Form Status: Data Complete

Site No: 1209

Site Name: (1209) Turkish MoH Yedikule Chest Diseases and Chest Surgery Training and Application Center

Subject No: 12091014

Subject Initials: ---

Generated By: (b) (4)

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

5.g	Sponsor ID:	[48]	Comments
	Test:	Creatinine_PX48	
	Result:	[0,8]	Comments
	Not Done:		Comments
	LNMT	Low [0,8] High [1,3] Unit mg/dL	Comments

090177e196ae30cb\Final\Final On: 01-Apr-2021 04:17 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1

Form: LOCAL LABORATORY DATA - REPEATING Hematology

Form Version: 10-Oct-2020 16:02

Site No: 1209

Site Name: (1209) Turkish MoH Yedikule Chest Diseases and Chest Surgery Training and Application Center

Subject No: 12091014

Subject Initials: ---

Generated By: (b) (4)

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

#	Category for Lab Test	Vendor Name (DERIVED)	Collection Date	Specimen Type	Lab Result	Form Instance																																	
1.	HEMATOLOGY	American Hospital (Amerikan Hastanesi) Tesvikiye, Guzelbahce St. No:20, 34365 Sisli/Istanbul/Turkey	Dec/18/2020	BLOOD	<table border="1"> <thead> <tr> <th>Sponsor-Defined Identifier</th> <th>Test:</th> <th>Result:</th> </tr> </thead> <tbody> <tr> <td>1</td> <td>Hemoglobin_PX1</td> <td>15,4</td> </tr> <tr> <td>2</td> <td>Hematocrit_PX2</td> <td>45</td> </tr> <tr> <td>3</td> <td>Erythrocytes_PX3</td> <td>5,15</td> </tr> <tr> <td>5</td> <td>Platelets_PX5</td> <td>[]</td> </tr> <tr> <td>7</td> <td>Leukocytes_PX7</td> <td>7,68</td> </tr> <tr> <td>608</td> <td>Neutrophils_PX608</td> <td>4,3</td> </tr> <tr> <td>609</td> <td>Eosinophils_PX609</td> <td>0</td> </tr> <tr> <td>612</td> <td>Monocytes_PX612</td> <td>1,1</td> </tr> <tr> <td>610</td> <td>Basophils_PX610</td> <td>0,0</td> </tr> <tr> <td>611</td> <td>Lymphocytes_PX611</td> <td>2,2</td> </tr> </tbody> </table>	Sponsor-Defined Identifier	Test:	Result:	1	Hemoglobin_PX1	15,4	2	Hematocrit_PX2	45	3	Erythrocytes_PX3	5,15	5	Platelets_PX5	[]	7	Leukocytes_PX7	7,68	608	Neutrophils_PX608	4,3	609	Eosinophils_PX609	0	612	Monocytes_PX612	1,1	610	Basophils_PX610	0,0	611	Lymphocytes_PX611	2,2	Repeating Pages
Sponsor-Defined Identifier	Test:	Result:																																					
1	Hemoglobin_PX1	15,4																																					
2	Hematocrit_PX2	45																																					
3	Erythrocytes_PX3	5,15																																					
5	Platelets_PX5	[]																																					
7	Leukocytes_PX7	7,68																																					
608	Neutrophils_PX608	4,3																																					
609	Eosinophils_PX609	0																																					
612	Monocytes_PX612	1,1																																					
610	Basophils_PX610	0,0																																					
611	Lymphocytes_PX611	2,2																																					

090177e196ae30cb\Final\Final On: 01-Apr-2021 04:17 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Dec/21/2020 **Form:** LOCAL LABORATORY DATA - REPEATING Hematology

Form Version: 10-Oct-2020 16:02

Form Status: Data Complete

Site No: 1209

Site Name: (1209) Turkish MoH Yedikule Chest Diseases and Chest Surgery Training and Application Center

Subject No: 12091014

Subject Initials: ---

Generated By: (b) (4)

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

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Laboratory Data Hematology

1.	Lab Panel:	HEMATOLOGY
2.	Laboratory Name and Address	[American Hospital (Amerikan Hastanesi) Tesvikiye, Guzelbahce St. No:20, 34365 Sisli/Istanbul/Turkey]
3.	Collection Date:	Dec/18/2020
4.	Specimen Type:	BLOOD

Lab Result

5.a	Sponsor ID:	[1]
	Test:	Hemoglobin_PX1
	Result:	[15,4]
	Not Done:	
	LNMT	Low [13,1] High [17,2] Unit g/dL
5.b	Sponsor ID:	[2]
	Test:	Hematocrit_PX2
	Result:	[45]
	Not Done:	
	LNMT	Low [38] High [51] Unit %

090177e196ae30cb\Final\Final On: 01-Apr-2021 04:17 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Dec/21/2020

Form: LOCAL LABORATORY DATA - REPEATING Hematology

Form Version: 10-Oct-2020 16:02

Form Status: Data Complete

Site No: 1209

Site Name: (1209) Turkish MoH Yedikule Chest Diseases and Chest Surgery Training and Application Center

Subject No: 12091014

Subject Initials: ---

Generated By: (b) (4)

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

5.c	Sponsor ID:	[3]
	Test:	Erythrocytes_PX3
	Result:	[5,15]
	Not Done:	
	LNMT	Low [4,5] High [6,1] Unit /uL
5.d	Sponsor ID:	[5]
	Test:	Platelets_PX5
	Result:	[]
	Not Done:	NOT DONE
	LNMT	Low [] High [] Unit
5.e	Sponsor ID:	[7]
	Test:	Leukocytes_PX7
	Result:	[7,68]
	Not Done:	
	LNMT	Low [4,1] High [11,1] Unit /uL

090177e196ae30cb\Final\Final On: 01-Apr-2021 04:17 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Dec/21/2020

Form: LOCAL LABORATORY DATA - REPEATING Hematology

Form Version: 10-Oct-2020 16:02

Form Status: Data Complete

Site No: 1209

Site Name: (1209) Turkish MoH Yedikule Chest Diseases and Chest Surgery Training and Application Center

Subject No: 12091014

Subject Initials: ---

Generated By: (b) (4)

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

5 f	Sponsor ID:	[608]
	Test:	Neutrophils_PX608
	Result:	[4,3]
	Not Done:	
	LNMT	Low [1,8] High [7,5] Unit /uL
5.g	Sponsor ID:	[609]
	Test:	Eosinophils_PX609
	Result:	[0]
	Not Done:	
	LNMT	Low [0,0] High [0,5] Unit /uL
5.h	Sponsor ID:	[612]
	Test:	Monocytes_PX612
	Result:	[1,1]
	Not Done:	
	LNMT	Low [0,0] High [1,0] Unit /uL

090177e196ae30cb\Final\Final On: 01-Apr-2021 04:17 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Dec/21/2020

Form: LOCAL LABORATORY DATA - REPEATING Hematology

Form Version: 10-Oct-2020 16:02

Form Status: Data Complete

Site No: 1209

Site Name: (1209) Turkish MoH Yedikule Chest Diseases and Chest Surgery Training and Application Center

Subject No: 12091014

Subject Initials: ---

Generated By: (b) (4)

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

5.i	Sponsor ID:	[610]
	Test:	Basophils_PX610
	Result:	[0,0]
	Not Done:	
	LNMT	Low [0,0] High [0,1] Unit /uL
5.j	Sponsor ID:	[611]
	Test:	Lymphocytes_PX611
	Result:	[2,2]
	Not Done:	
	LNMT	Low [1,2] High [5,8] Unit /uL

090177e196ae30cb\Final\Final On: 01-Apr-2021 04:17 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1

Form: VITAL SIGNS - COVID

Form Version: 10-Oct-2020 15:59

Site No: 1209

Site Name: (1209) Turkish MoH Yedikule Chest Diseases and Chest Surgery Training and Application Center

Subject No: 12091014

Subject Initials: ---

Generated By: (b) (4)

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

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

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Dec/21/2020 **Form:** VITAL SIGNS - COVID

Form Version: 10-Oct-2020 15:59

Form Status: Data Complete

Site No: 1209

Site Name: (1209) Turkish MoH Yedikule Chest Diseases and Chest Surgery Training and Application Center

Subject No: 12091014

Subject Initials: ---

Generated By: (b) (4)

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

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Vital Signs

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

Vital Signs Details

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

090177e196ae30cb\Final\Final On: 01-Apr-2021 04:17 (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: 1209

Site Name: (1209) Turkish MoH Yedikule Chest Diseases and Chest Surgery Training and Application Center

Subject No: 12091014

Subject Initials: ---

Generated By: (b) (4)

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

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

090177e196ae30cb\Final\Final On: 01-Apr-2021 04:17 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Dec/21/2020 **Form:** VITAL SIGNS - PULSE OX ROOM AIR

Form Version: 10-Oct-2020 16:04

Form Status: Data Complete

Site No: 1209

Site Name: (1209) Turkish MoH Yedikule Chest Diseases and Chest Surgery Training and Application Center

Subject No: 12091014

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 Done _____ //	Comments
----	-------	-------------------------	--------------------------

Vital Signs Details

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

090177e196ae30cb\Final\Final On: 01-Apr-2021 04:17 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1

Form: OXYGENATION PARAMETERS

Form Version: 06-Jul-2020 21:52

Site No: 1209

Site Name: (1209) Turkish MoH Yedikule Chest Diseases and Chest Surgery Training and Application Center

Subject No: 12091014

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 Done	Not Done	Not Done	Repeating Pages

090177e196ae30cb\Final\Final On: 01-Apr-2021 04:17 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Dec/21/2020 **Form:** OXYGENATION PARAMETERS

Form Version: 06-Jul-2020 21:52

Form Status: Data Complete

Site No: 1209

Site Name: (1209) Turkish MoH Yedikule Chest Diseases and Chest Surgery Training and Application Center

Subject No: 12091014

Subject Initials: ---

Generated By: (b) (4)

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

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[Form Comments](#)

[eCRF Audit Trail History](#)

Oxygenation Parameters

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

Header Text: C4591001

Visit: POT_COVID_ILL 1

Form: CONCOMITANT MEDICATIONS - VASOPRESSORS

Form Version: 06-Jul-2020 21:55

Site No: 1209

Site Name: (1209) Turkish MoH Yedikule Chest Diseases and Chest Surgery Training and Application Center

Subject No: 12091014

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
2.	Not Applicable	Not Applicable	Not Applicable	Not Applicable	Not Applicable	Repeating Pages
3.	Not Applicable	Not Applicable	Not Applicable	Not Applicable	Not Applicable	Repeating Pages

090177e196ae30cb\Final\Final On: 01-Apr-2021 04:17 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Dec/21/2020

Form: CONCOMITANT MEDICATIONS - VASOPRESSORS

Form Version: 06-Jul-2020 21:55

Form Status: Data Complete

Site No: 1209

Site Name: (1209) Turkish MoH Yedikule Chest Diseases and Chest Surgery Training and Application Center

Subject No: 12091014

Subject Initials: ---

Generated By: (b) (4)

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

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[Form Audit Trail](#)

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

090177e196ae30cb\Final\Final On: 01-Apr-2021 04:17 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Dec/21/2020

Form: CONCOMITANT MEDICATIONS - VASOPRESSORS

Form Version: 06-Jul-2020 21:55

Form Status: Data Complete

Site No: 1209

Site Name: (1209) Turkish MoH Yedikule Chest Diseases and Chest Surgery Training and Application Center

Subject No: 12091014

Subject Initials: ---

Generated By: (b) (4)

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

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[Form Audit Trail](#)

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

090177e196ae30cb\Final\Final On: 01-Apr-2021 04:17 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Dec/21/2020

Form: CONCOMITANT MEDICATIONS - VASOPRESSORS

Form Version: 06-Jul-2020 21:55

Form Status: Data Complete

Site No: 1209

Site Name: (1209) Turkish MoH Yedikule Chest Diseases and Chest Surgery Training and Application Center

Subject No: 12091014

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

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Header Text: C4591001

Visit: POT_COVID_ILL 1

Form: IMAGING

Form Version: 06-Jul-2020 21:53

Site No: 1209

Site Name: (1209) Turkish MoH Yedikule Chest Diseases and Chest Surgery Training and Application Center

Subject No: 12091014

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.	Dec/18/2020	CHEST	CT SCAN	ABNORMAL <i>If abnormal, specify findings:</i> there is icy glass appearance of the upper and down lobe of left lung	Repeating Pages

090177e196ae30cb\Final\Final On: 01-Apr-2021 04:17 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Dec/21/2020 **Form:** IMAGING

Form Version: 06-Jul-2020 21:53

Form Status: Data Complete

Site No: 1209

Site Name: (1209) Turkish MoH Yedikule Chest Diseases and Chest Surgery Training and Application Center

Subject No: 12091014

Subject Initials: ---

Generated By: (b) (4)

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

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Imaging

1.	Date of Assessment:	Dec/18/2020	Comments
2.	Location of Assessment:	CHEST	Comments
3.	Type of Imaging Exam:	CT SCAN	Comments
4.	Assessment:	ABNORMAL If abnormal, specify findings: [there is icy glass appearance of the upper and down lobe of left lung]	Comments

Header Text: C4591001

Visit: POT_COVID_CONVA 1 - Unscheduled Visit **Form:** DATE OF VISIT - ILLNESS CONVALESCENT
on Feb/02/2021

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Frozen, Verified

Site No: 1209

Site Name: (1209) Turkish MoH Yedikule Chest Diseases and Chest Surgery
Training and Application Center

Subject No: 12091014

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	Feb/2/2021
2.	Erroneous Visit	

COVID-19 Illness Visit

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

090177e196ae30cb\Final\Final On: 01-Apr-2021 04:17 (GMT)

Header Text: C4591001

Visit: POT_COVID_CONVA 1 - Unscheduled Visit **Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY
on Feb/02/2021

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1209

Site Name: (1209) Turkish MoH Yedikule Chest Diseases and Chest Surgery
Training and Application Center

Subject No: 12091014

Subject Initials: ---

Generated By: (b) (4)

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

[eCRF Audit Trail History](#)

Electronic Sample Tracking

1.	Data Origin	SITE
2.	Sample Type	SERUM
3.	Sample Collected?	YES Date of Collection: Feb/2/2021
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	[BPZBS5]
5.b	Sample ID	[BPZBS6]
5.c	Sample ID	[BRZDRV]
5.d	Sample ID	[BRZDRW]

090177e196ae30cb\Final\Final On: 01-Apr-2021 04:17 (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: 1209

Site Name: (1209) Turkish MoH Yedikule Chest Diseases and Chest Surgery
Training and Application Center

Subject No: 12091014

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:	
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090177e196ae30cb\Final\Final On: 01-Apr-2021 04:17 (GMT)

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: 1209

Site Name: (1209) Turkish MoH Yedikule Chest Diseases and Chest Surgery
Training and Application Center

Subject No: 12091014

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: 1209

Site Name: (1209) Turkish MoH Yedikule Chest Diseases and Chest Surgery Training and Application Center

Subject No: 12091014

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	COVID-19 Illness	Dec/18/2020 UNK:UNK	NO End Date Time: Dec/23/2020 UNK:UNK	Repeating Pages

090177e196ae30cb\Final\Final On: 01-Apr-2021 04:17 (GMT)

Header Text: C4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1209

Subject No: 12091014

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Frozen

Site Name: (1209) Turkish MoH Yedikule Chest Diseases and Chest Surgery Training and Application Center

Subject Initials: ---

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

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Adverse Event Report

1.	Category:	ADVERSE EVENT
2.	AE ID:	[1]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[COVID-19 Illness]
4.	Start Date Time:	Dec/18/2020 UNK:UNK
5.	Is the adverse event still ongoing?	NO End Date Time: Dec/23/2020 UNK:UNK
6.	Toxicity Grade:	1
7.	Is the adverse event serious? If Yes, NOTIFY PFIZER IMMEDIATELY. Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).	YES Is this serious event associated with congenital anomaly or birth defect? NO Did this serious event result in death? NO Did this serious event require or prolong hospitalization? YES Did this serious event result in persistent or significant disability/incapacity? NO Is this serious event life threatening? NO Other medically important serious event NO
8.	Is this adverse event the result of a study Medication Error? If Yes, record the type of medication error on the Medication Error Log.	NO
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: [Covid-19 pandemic]

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Header Text: C4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1209

Subject No: 12091014

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Frozen

Site Name: (1209) Turkish MoH Yedikule Chest Diseases and Chest Surgery Training and Application Center

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?	YES	Comments
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	[2020506841]	

090177e196ae30cb\Final\Final On: 01-Apr-2021 04:17 (GMT)

Header Text: C4591001

Visit: Logs

Form: MEDICATION ERROR

Form Version: 17-Jul-2020 21:54

Site No: 1209

Site Name: (1209) Turkish MoH Yedikule Chest Diseases and Chest Surgery Training and Application Center

Subject No: 12091014

Subject Initials: ---

Generated By: (b) (4)

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

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

Header Text: C4591001

Visit: Logs - Unscheduled

Form Version: 17-Jul-2020 21:54

Site No: 1209

Subject No: 12091014

Generated By: (b) (4)

Form: MEDICATION ERROR

Form Status: Not Started

Site Name: (1209) Turkish MoH Yedikule Chest Diseases and Chest Surgery Training and Application Center

Subject Initials: ---

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

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Medication Error

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

090177e196ae30cb\Final\Final On: 01-Apr-2021 04:17 (GMT)

Header Text: C4591001

Visit: Logs

Form: CONCOMITANT MEDICATIONS - NON STUDY VACCINATIONS

Form Version: 22-Apr-2020 21:03

Site No: 1209

Site Name: (1209) Turkish MoH Yedikule Chest Diseases and Chest Surgery Training and Application Center

Subject No: 12091014

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.	1	VACCINATIONS	NO	SKY Cellflu Quadri valent	Dec/16/2020	Repeating Pages

Header Text: C4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1209

Subject No: 12091014

Generated By: (b) (4)

Form: CONCOMITANT MEDICATIONS - NON STUDY VACCINATIONS

Form Status: Data Complete, Frozen, Verified

Site Name: (1209) Turkish MoH Yedikule Chest Diseases and Chest Surgery Training and Application Center

Subject Initials: ---

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

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Concomitant Medications

1.	What is the medication identifier?	[1]
2.	Category:	VACCINATIONS
3.	Concomitant Medications Pre-specified:	NO
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).	[SKY Cellflu Quadrivalent]
5.	Date:	Dec/16/2020

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Header Text: C4591001

Visit: Logs

Form: CONCOMITANT MEDICATIONS - PROHIBITED

Form Version: 22-Apr-2020 21:03

Site No: 1209

Site Name: (1209) Turkish MoH Yedikule Chest Diseases and Chest Surgery Training and Application Center

Subject No: 12091014

Subject Initials: ---

Generated By: (b) (4)

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

#	Sponsor-Defined Identifier	Category for Medication	Concomitant Medications Pre-specified	Name of Medication	Dose Description	Form Instance
1.						Repeating Pages

Header Text: C4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1209

Subject No: 12091014

Generated By: (b) (4)

Form: CONCOMITANT MEDICATIONS - PROHIBITED

Form Status: Not Started

Site Name: (1209) Turkish MoH Yedikule Chest Diseases and Chest Surgery Training and Application Center

Subject Initials: ---

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

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Concomitant Medications

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

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Header Text: C4591001

Visit: Logs

Form: RADIATION TREATMENT

Form Version: 22-Apr-2020 21:02

Site No: 1209

Site Name: (1209) Turkish MoH Yedikule Chest Diseases and Chest Surgery Training and Application Center

Subject No: 12091014

Subject Initials: ---

Generated By: (b) (4)

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

#	Category	Treatment Identifier	Con Non-Drug Treatments Pre-specified	Treatment	Start Date	Form Instance
1.						Repeating Pages

Header Text: C4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1209

Subject No: 12091014

Generated By: (b) (4)

Form: RADIATION TREATMENT

Form Status: Not Started

Site Name: (1209) Turkish MoH Yedikule Chest Diseases and Chest Surgery Training and Application Center

Subject Initials: ---

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

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Radiation Treatment

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

Header Text: C4591001

Visit: Logs

Form: TRANSFUSIONS

Form Version: 22-Apr-2020 21:03

Site No: 1209

Site Name: (1209) Turkish MoH Yedikule Chest Diseases and Chest Surgery Training and Application Center

Subject No: 12091014

Subject Initials: ---

Generated By: (b) (4)

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

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

Header Text: C4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1209

Subject No: 12091014

Generated By: (b) (4)

Form: TRANSFUSIONS

Form Status: Not Started

Site Name: (1209) Turkish MoH Yedikule Chest Diseases and Chest Surgery Training and Application Center

Subject Initials: ---

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

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

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Header Text: C4591001

Visit: Unplanned - New Unscheduled Visit

Form: DATE OF VISIT

Form Version: 22-Apr-2020 21:02

Form Status: Not Started

Site No: 1209

Site Name: (1209) Turkish MoH Yedikule Chest Diseases and Chest Surgery Training and Application Center

Subject No: 12091014

Subject Initials: ---

Generated By: (b) (4)

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

Date of Visit

1.	Date of Visit	//
2.	Erroneous Visit	

Header Text: C4591001

Visit: Unplanned - New Unscheduled Visit

Form Version: 22-Apr-2020 21:04

Site No: 1209

Subject No: 12091014

Generated By: (b) (4)

Form: UNPLANNED VISIT

Form Status: Not Started

Site Name: (1209) Turkish MoH Yedikule Chest Diseases and Chest Surgery Training and Application Center

Subject Initials: ---

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

Unplanned Assessments

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

090177e196ae30cb\Final\Final On: 01-Apr-2021 04:17 (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: 1209

Site Name: (1209) Turkish MoH Yedikule Chest Diseases and Chest Surgery Training and Application Center

Subject No: 12091014

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: 1209

Site Name: (1209) Turkish MoH Yedikule Chest Diseases and Chest Surgery Training and Application Center

Subject No: 12091014

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 Version: 10-Dec-2020 02:26

Site No: 1209

Subject No: 12091014

Generated By: (b) (4)

Form: VACCINATION

Form Status: Not Started

Site Name: (1209) Turkish MoH Yedikule Chest Diseases and Chest Surgery Training and Application Center

Subject Initials: ---

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?	

090177e196ae30cb\Final\Final On: 01-Apr-2021 04:17 (GMT)

Header Text: C4591001

Visit: Unplanned Vaccination - Unscheduled

Form Version: 10-Oct-2020 15:57

Site No: 1209

Subject No: 12091014

Generated By: (b) (4)

Form: CONTACT OUTCOME - MONTH 1

Form Status: Not Started

Site Name: (1209) Turkish MoH Yedikule Chest Diseases and Chest Surgery Training and Application Center

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: Unplanned Vaccination - Unscheduled

Form Version: 10-Oct-2020 16:01

Site No: 1209

Subject No: 12091014

Generated By: (b) (4)

Form: CONTACT OUTCOME - MONTH 6

Form Status: Not Started

Site Name: (1209) Turkish MoH Yedikule Chest Diseases and Chest Surgery Training and Application Center

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: End of Treatment - Unscheduled

Form Version: 10-Dec-2020 02:29

Site No: 1209

Subject No: 12091014

Generated By: (b) (4)

Form: DISPOSITION - TREATMENT

Form Status: Data Complete, Frozen, Verified

Site Name: (1209) Turkish MoH Yedikule Chest Diseases and Chest Surgery Training and Application Center

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Disposition - Treatment

1.	Date of Completion/Discontinuation /Death :	Dec/31/2020
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: 1209

Site Name: (1209) Turkish MoH Yedikule Chest Diseases and Chest Surgery Training and Application Center

Subject No: 12091014

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	

Header Text: C4591001

Visit: Potential ReVax Initial Contact - Unscheduled **Form:** FURTHER VACCINATION CONFIRMATION

Form Version: 10-Dec-2020 02:25

Form Status: Data Complete, Frozen, Verified

Site No: 1209

Site Name: (1209) Turkish MoH Yedikule Chest Diseases and Chest Surgery Training and Application Center

Subject No: 12091014

Subject Initials: ---

Generated By: (b) (4)

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

[eCRF Audit Trail History](#)

Further Vaccination Confirmation

1.	Select appropriate response - Is participant willing to return for Vaccination 3?	Participant is willing to return for Vaccination 3 Participant is: eligible per local/national recommendations and confirmed to have received only placebo at Vaccination 1/2
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090177e196ae30cb\Final\Final On: 01-Apr-2021 04:17 (GMT)

Header Text: C4591001

Visit: Follow-Up - Unscheduled

Form Version: 15-Sep-2020 21:53

Site No: 1209

Subject No: 12091014

Generated By: (b) (4)

Form: DISPOSITION - FOLLOW-UP

Form Status: Not Started

Site Name: (1209) Turkish MoH Yedikule Chest Diseases and Chest Surgery Training and Application Center

Subject Initials: ---

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

Disposition - Follow-Up

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

Header Text: C4591001

Visit: Disposition - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1209

Subject No: 12091014

Generated By: (b) (4)

Form: TREATMENT UNBLINDED

Form Status: Data Complete, Frozen, Verified

Site Name: (1209) Turkish MoH Yedikule Chest Diseases and Chest Surgery Training and Application Center

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

090177e196ae30cb\Final\Final On: 01-Apr-2021 04:17 (GMT)

Header Text: C4591001

Visit: Disposition - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1209

Subject No: 12091014

Generated By: (b) (4)

Form: WITHDRAWAL OF CONSENT

Form Status: Data Complete, Verified

Site Name: (1209) Turkish MoH Yedikule Chest Diseases and Chest Surgery Training and Application Center

Subject Initials: ---

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

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

Withdrawal Of Consent

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

Header Text: C4591001

Visit: Disposition - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1209

Subject No: 12091014

Generated By: (b) (4)

Form: DEATH DETAILS CODED

Form Status: Data Complete, Verified

Site Name: (1209) Turkish MoH Yedikule Chest Diseases and Chest Surgery Training and Application Center

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 _____ []

090177e196ae30cb\Final\Final On: 01-Apr-2021 04:17 (GMT)

Header Text: C4591001

Visit: V101_VAX3

Form Version: 22-Apr-2020 21:02

Site No: 1209

Subject No: 12091014

Generated By: (b) (4)

Form: DATE OF VISIT

Form Status: Data Complete, Frozen, Verified

Site Name: (1209) Turkish MoH Yedikule Chest Diseases and Chest Surgery Training and Application Center

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Date of Visit

1.	Date of Visit	Feb/26/2021
2.	Erroneous Visit	

Header Text: C4591001

Visit: V101_VAX3

Form Version: 10-Dec-2020 02:31

Site No: 1209

Subject No: 12091014

Generated By: (b) (4)

Form: INFORMED CONSENT - FURTHER VACCINATION

Form Status: Data Complete, Frozen, Verified

Site Name: (1209) Turkish MoH Yedikule Chest Diseases and Chest Surgery Training and Application Center

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/26/2021
----	--------------	--

090177e196ae30cb\Final\Final On: 01-Apr-2021 04:17 (GMT)

Header Text: C4591001

Visit: V101_VAX3

Form Version: 10-Dec-2020 02:30

Site No: 1209

Subject No: 12091014

Generated By: (b) (4)

Form: INCLUSION/EXCLUSION CRITERIA - FURTHER VACCINATION

Form Status: Data Complete, Frozen, Verified

Site Name: (1209) Turkish MoH Yedikule Chest Diseases and Chest Surgery Training and Application Center

Subject Initials: ---

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

Form Comments

Inclusion Criteria Not Met

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

Exclusion Criteria Met

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

Header Text: C4591001

Visit: V101_VAX3

Form Version: 10-Dec-2020 02:31

Site No: 1209

Subject No: 12091014

Generated By: (b) (4)

Form: DISPOSITION - SCREENING FOR FURTHER VACCINATION

Form Status: Data Complete, Frozen, Verified

Site Name: (1209) Turkish MoH Yedikule Chest Diseases and Chest Surgery Training and Application Center

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/26/2021
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: 1209

Subject No: 12091014

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Status: Data Complete, Frozen, Verified

Site Name: (1209) Turkish MoH Yedikule Chest Diseases and Chest Surgery Training and Application Center

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: Feb/26/2021
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	[BPZBSW]
5.b	Sample ID	[BPZBSX]
5.c	Sample ID	[BRZDRZ]
5.d	Sample ID	[BRZDS0]

090177e196ae30cb\Final\Final On: 01-Apr-2021 04:17 (GMT)

Header Text: C4591001

Visit: V101_VAX3

Form Version: 22-Apr-2020 21:03

Site No: 1209

Subject No: 12091014

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB

Form Status: Data Complete, Frozen, Verified

Site Name: (1209) Turkish MoH Yedikule Chest Diseases and Chest Surgery Training and Application Center

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/26/2021
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	[BPZBSV]
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090177e196ae30cb\Final\Final On: 01-Apr-2021 04:17 (GMT)

Header Text: C4591001

Visit: V101_VAX3

Form Version: 10-Dec-2020 02:26

Site No: 1209

Subject No: 12091014

Generated By: (b) (4)

Form: VACCINATION

Form Status: Data Complete, Frozen, Verified

Site Name: (1209) Turkish MoH Yedikule Chest Diseases and Chest Surgery Training and Application Center

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/26/2021 10:00
5.	Anatomical Location:	DELTOID MUSCLE
6.	Body Side:	LEFT
7.	Route:	INTRAMUSCULAR
8.	Actual Dose:	[30.0]
9.	Unit:	ug
10.	Timeframe Subject Was Observed	30 MINUTES
11.	Was the subject observed for at least the protocol specified observation period after investigational product administration?	YES

090177e196ae30cb\Final\Final On: 01-Apr-2021 04:17 (GMT)

Header Text: C4591001

Visit: V102_VAX4

Form Version: 22-Apr-2020 21:02

Site No: 1209

Subject No: 12091014

Generated By: (b) (4)

Form: DATE OF VISIT

Form Status: Not Started

Site Name: (1209) Turkish MoH Yedikule Chest Diseases and Chest Surgery Training and Application Center

Subject Initials: ---

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

Date of Visit

1.	Date of Visit	//
2.	Erroneous Visit	

090177e196ae30cb\Final\Final On: 01-Apr-2021 04:17 (GMT)

Header Text: C4591001

Visit: V102_VAX4

Form Version: 22-Apr-2020 21:03

Site No: 1209

Subject No: 12091014

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB

Form Status: Not Started

Site Name: (1209) Turkish MoH Yedikule Chest Diseases and Chest Surgery Training and Application Center

Subject Initials: ---

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

Electronic Sample Tracking

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

Aliquot

Please enter barcode for each aliquot.

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

Header Text: C4591001

Visit: V102_VAX4

Form Version: 10-Dec-2020 02:26

Site No: 1209

Subject No: 12091014

Generated By: (b) (4)

Form: VACCINATION

Form Status: Not Started

Site Name: (1209) Turkish MoH Yedikule Chest Diseases and Chest Surgery Training and Application Center

Subject Initials: ---

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?	

090177e196ae30cb\Final\Final On: 01-Apr-2021 04:17 (GMT)

Header Text: C4591001

Visit: V103_MONTH1

Form Version: 22-Apr-2020 21:02

Site No: 1209

Subject No: 12091014

Generated By: (b) (4)

Form: DATE OF VISIT

Form Status: Not Started

Site Name: (1209) Turkish MoH Yedikule Chest Diseases and Chest Surgery Training and Application Center

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: 1209

Subject No: 12091014

Generated By: (b) (4)

Form: CONTACT OUTCOME

Form Status: Not Started

Site Name: (1209) Turkish MoH Yedikule Chest Diseases and Chest Surgery Training and Application Center

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: 1209

Subject No: 12091014

Generated By: (b) (4)

Form: DATE OF VISIT

Form Status: Not Started

Site Name: (1209) Turkish MoH Yedikule Chest Diseases and Chest Surgery Training and Application Center

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: 1209

Subject No: 12091014

Generated By: (b) (4)

Form: CONTACT OUTCOME

Form Status: Not Started

Site Name: (1209) Turkish MoH Yedikule Chest Diseases and Chest Surgery Training and Application Center

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: 1209

Subject No: 12091014

Generated By: (b) (4)

Form: DATE OF VISIT

Form Status: Not Started

Site Name: (1209) Turkish MoH Yedikule Chest Diseases and Chest Surgery Training and Application Center

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: 1209

Subject No: 12091014

Generated By: (b) (4)

Form: CONTACT OUTCOME

Form Status: Not Started

Site Name: (1209) Turkish MoH Yedikule Chest Diseases and Chest Surgery Training and Application Center

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: 1209

Site Name: (1209) Turkish MoH Yedikule Chest Diseases and Chest Surgery
Training and Application Center

Subject No: 12091014

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: 1209

Subject No: 12091014

Generated By: (b) (4)

Form: SUBJECT STATUS

Form Status: Data Complete, Verified

Site Name: (1209) Turkish MoH Yedikule Chest Diseases and Chest Surgery Training and Application Center

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/31/2020

Header Text: C4591001

Visit: Investigator Signature - Unscheduled

Form Version: 22-Apr-2020 21:04

Site No: 1209

Subject No: 12091014

Generated By: (b) (4)

Form: CASEBOOK SIGNATURE FORM

Form Status: Data Complete, Signed, Verified

Site Name: (1209) Turkish MoH Yedikule Chest Diseases and Chest Surgery Training and Application Center

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 Version: 22-Apr-2020 21:04

Site No: 1209

Subject No: 12091014

Generated By: (b) (4)

Form: CASEBOOK SIGNATURE FORM

Form Status: Data Complete, Signed, Verified

Site Name: (1209) Turkish MoH Yedikule Chest Diseases and Chest Surgery Training and Application Center

Subject Initials: ---

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

[Audit Trail](#)

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

- CRF_Sign

Name	Signature Meaning	Date	Type	Action
(b) (6)	Approved	Mar-11-2021 13:54:14 (UTC+03:00) Istanbul	BOOK	Signed

Affidavit:

By my dated signature below, I, (b) (6), verify that all case report form pages accurately display the results of the examinations, tests, evaluations and treatments performed on this subject.

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

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

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 10-Oct-2020 16:00

Site No: 1209

Subject No: 12091014

Generated By: (b) (4)

Form: INCLUSION/EXCLUSION CRITERIA - Comments

Form Status: Data Complete, Frozen, Verified

Site Name: (1209) Turkish MoH Yedikule Chest Diseases and Chest Surgery Training and Application Center

Subject Initials: ---

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

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Item	Date	User	Comment
Form	Nov-03-2020 14:25:25 (UTC+03:00) Istanbul	(b) (4), (b) (6)	Not Applicable

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1209

Subject No: 12091014

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - Comments

Form Status: Data Complete, Frozen, Verified

Site Name: (1209) Turkish MoH Yedikule Chest Diseases and Chest Surgery Training and Application Center

Subject Initials: ---

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

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Item	Date	User	Comment
Form	Nov-03-2020 14:31:11 (UTC+03:00) Istanbul	(b) (4), (b) (6)	Not Applicable

090177e196ae30cb\Final\Final On: 01-Apr-2021 04:17 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1

Form Version: 10-Dec-2020 02:26

Site No: 1209

Subject No: 12091014

Generated By: (b) (4)

Form: HEALTH CARE UTILIZATION - Comments

Form Status: Data Complete

Site Name: (1209) Turkish MoH Yedikule Chest Diseases and Chest Surgery Training and Application Center

Subject Initials: ---

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

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Item	Date	User	Comment
2	Jan-07-2021 16:08:03 (UTC+03:00) Istanbul	(b) (4), (b) (6)	Not Done

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Dec/21/2020 **Form:** RESPIRATORY TREATMENT - Comments

Form Version: 06-Jul-2020 21:53

Form Status: Data Complete

Site No: 1209

Site Name: (1209) Turkish MoH Yedikule Chest Diseases and Chest Surgery Training and Application Center

Subject No: 12091014

Subject Initials: ---

Generated By: (b) (4)

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

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Item	Date	User	Comment
Form	Dec-29-2020 20:11:48 (UTC+03:00) Istanbul	(b) (4), (b) (6)	Not Done

090177e196ae30cb\Final\Final On: 01-Apr-2021 04:17 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Dec/21/2020 **Form:** RESPIRATORY TREATMENT - Comments

Form Version: 06-Jul-2020 21:53

Form Status: Data Complete

Site No: 1209

Site Name: (1209) Turkish MoH Yedikule Chest Diseases and Chest Surgery Training and Application Center

Subject No: 12091014

Subject Initials: ---

Generated By: (b) (4)

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

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Item	Date	User	Comment
1	Dec-29-2020 20:11:48 (UTC+03:00) Istanbul	(b) (4), (b) (6)	Not Done

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Dec/21/2020 **Form:** RESPIRATORY TREATMENT - Comments

Form Version: 06-Jul-2020 21:53

Form Status: Data Complete

Site No: 1209

Site Name: (1209) Turkish MoH Yedikule Chest Diseases and Chest Surgery Training and Application Center

Subject No: 12091014

Subject Initials: ---

Generated By: (b) (4)

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

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Item	Date	User	Comment
2	Dec-29-2020 20:11:48 (UTC+03:00) Istanbul	(b) (4), (b) (6)	Not Done

090177e196ae30cb\Final\Final On: 01-Apr-2021 04:17 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Dec/21/2020 **Form:** RESPIRATORY TREATMENT - Comments

Form Version: 06-Jul-2020 21:53

Form Status: Data Complete

Site No: 1209

Site Name: (1209) Turkish MoH Yedikule Chest Diseases and Chest Surgery Training and Application Center

Subject No: 12091014

Subject Initials: ---

Generated By: (b) (4)

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

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Item	Date	User	Comment
3	Dec-29-2020 20:11:48 (UTC+03:00) Istanbul	(b) (4), (b) (6)	Not Done

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Dec/21/2020 **Form:** RESPIRATORY TREATMENT - Comments

Form Version: 06-Jul-2020 21:53

Form Status: Data Complete

Site No: 1209

Site Name: (1209) Turkish MoH Yedikule Chest Diseases and Chest Surgery Training and Application Center

Subject No: 12091014

Subject Initials: ---

Generated By: (b) (4)

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

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Item	Date	User	Comment
4	Dec-29-2020 20:11:48 (UTC+03:00) Istanbul	(b) (4), (b) (6)	Not Done

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Dec/21/2020 **Form:** RESPIRATORY TREATMENT - Comments

Form Version: 06-Jul-2020 21:53

Form Status: Data Complete

Site No: 1209

Site Name: (1209) Turkish MoH Yedikule Chest Diseases and Chest Surgery Training and Application Center

Subject No: 12091014

Subject Initials: ---

Generated By: (b) (4)

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

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Item	Date	User	Comment
5	Dec-29-2020 20:11:48 (UTC+03:00) Istanbul	(b) (4), (b) (6)	Not Done

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Dec/21/2020 **Form:** RESPIRATORY TREATMENT - Comments

Form Version: 06-Jul-2020 21:53

Form Status: Data Complete

Site No: 1209

Site Name: (1209) Turkish MoH Yedikule Chest Diseases and Chest Surgery Training and Application Center

Subject No: 12091014

Subject Initials: ---

Generated By: (b) (4)

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

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Item	Date	User	Comment
6	Dec-29-2020 20:11:48 (UTC+03:00) Istanbul	(b) (4), (b) (6)	Not Done

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Dec/21/2020 **Form:** ILLNESS DETAILS - SEVERE - Comments

Form Version: 17-Jul-2020 21:55

Form Status: Data Complete

Site No: 1209

Site Name: (1209) Turkish MoH Yedikule Chest Diseases and Chest Surgery Training and Application Center

Subject No: 12091014

Subject Initials: ---

Generated By: (b) (4)

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

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Item	Date	User	Comment
Form	Dec-29-2020 20:12:42 (UTC+03:00) Istanbul	(b) (4), (b) (6)	Not Done

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Dec/21/2020 **Form:** ILLNESS DETAILS - SEVERE - Comments

Form Version: 17-Jul-2020 21:55

Form Status: Data Complete

Site No: 1209

Site Name: (1209) Turkish MoH Yedikule Chest Diseases and Chest Surgery Training and Application Center

Subject No: 12091014

Subject Initials: ---

Generated By: (b) (4)

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

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Item	Date	User	Comment
1	Dec-29-2020 20:12:42 (UTC+03:00) Istanbul	(b) (4), (b) (6)	Not Done

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Dec/21/2020 **Form:** ILLNESS DETAILS - SEVERE - Comments

Form Version: 17-Jul-2020 21:55

Form Status: Data Complete

Site No: 1209

Site Name: (1209) Turkish MoH Yedikule Chest Diseases and Chest Surgery Training and Application Center

Subject No: 12091014

Subject Initials: ---

Generated By: (b) (4)

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

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Item	Date	User	Comment
2	Dec-29-2020 20:12:42 (UTC+03:00) Istanbul	(b) (4), (b) (6)	Not Done

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Dec/21/2020 **Form:** ILLNESS DETAILS - SEVERE - Comments

Form Version: 17-Jul-2020 21:55

Form Status: Data Complete

Site No: 1209

Site Name: (1209) Turkish MoH Yedikule Chest Diseases and Chest Surgery Training and Application Center

Subject No: 12091014

Subject Initials: ---

Generated By: (b) (4)

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

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Item	Date	User	Comment
3	Dec-29-2020 20:12:42 (UTC+03:00) Istanbul	(b) (4), (b) (6)	Not Done

090177e196ae30cb\Final\Final On: 01-Apr-2021 04:17 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Dec/21/2020 **Form:** ILLNESS DETAILS - SEVERE - Comments

Form Version: 17-Jul-2020 21:55

Form Status: Data Complete

Site No: 1209

Site Name: (1209) Turkish MoH Yedikule Chest Diseases and Chest Surgery Training and Application Center

Subject No: 12091014

Subject Initials: ---

Generated By: (b) (4)

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

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Item	Date	User	Comment
4	Dec-29-2020 20:12:42 (UTC+03:00) Istanbul	(b) (4), (b) (6)	Not Done

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Dec/21/2020

Form Version: 10-Oct-2020 15:58

Site No: 1209

Subject No: 12091014

Generated By: (b) (4)

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY - Comments

Form Status: Data Complete

Site Name: (1209) Turkish MoH Yedikule Chest Diseases and Chest Surgery Training and Application Center

Subject Initials: ---

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5.g	Dec-29-2020 20:15:29 (UTC+03:00) Istanbul	(b) (4), (b) (6)	Not Done

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Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Dec/21/2020 **Form:** VITAL SIGNS - COVID - Comments

Form Version: 10-Oct-2020 15:59

Form Status: Data Complete

Site No: 1209

Site Name: (1209) Turkish MoH Yedikule Chest Diseases and Chest Surgery Training and Application Center

Subject No: 12091014

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Visit: POT_COVID_ILL 1 - Unscheduled Visit on Dec/21/2020 **Form:** VITAL SIGNS - PULSE OX ROOM AIR - Comments

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Form Status: Data Complete

Site No: 1209

Site Name: (1209) Turkish MoH Yedikule Chest Diseases and Chest Surgery Training and Application Center

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Header Text: C4591001

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3	Dec-29-2020 20:34:54 (UTC+03:00) Istanbul	(b) (4), (b) (6)	Not Done

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Dec/21/2020 **Form:** IMAGING - Comments

Form Version: 06-Jul-2020 21:53

Form Status: Data Complete

Site No: 1209

Site Name: (1209) Turkish MoH Yedikule Chest Diseases and Chest Surgery Training and Application Center

Subject No: 12091014

Subject Initials: ---

Generated By: (b) (4)

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

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Item	Date	User	Comment
4	Jan-08-2021 14:21:37 (UTC+03:00) Istanbul	(b) (4), (b) (6)	
4	Dec-29-2020 20:34:54 (UTC+03:00) Istanbul	(b) (4), (b) (6)	Not Done

Header Text: C4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1209

Subject No: 12091014

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - Comments

Form Status: Data Complete, Frozen

Site Name: (1209) Turkish MoH Yedikule Chest Diseases and Chest Surgery Training and Application Center

Subject Initials: ---

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

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Item	Date	User	Comment
11	Feb-04-2021 10:46:23 (UTC+03:00) Istanbul	(b) (4), (b) (6)	Remdesivir, Enoxaparin sodium and, Pantoprazole.

090177e196ae30cb\Final\Final On: 01-Apr-2021 04:17 (GMT)

Header Text: C4591001

Visit: Disposition - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1209

Subject No: 12091014

Generated By: (b) (4)

Form: WITHDRAWAL OF CONSENT - Comments

Form Status: Data Complete, Verified

Site Name: (1209) Turkish MoH Yedikule Chest Diseases and Chest Surgery Training and Application Center

Subject Initials: ---

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

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Item	Date	User	Comment
Form	Jan-20-2021 14:09:02 (UTC+03:00) Istanbul	(b) (4), (b) (6)	Not Applicable

Header Text: C4591001

Visit: Disposition

Form Version: 22-Apr-2020 21:03

Site No: 1209

Subject No: 12091014

Generated By: (b) (4)

Form: WITHDRAWAL OF CONSENT - Comments

Form Status: Data Complete, Verified

Site Name: (1209) Turkish MoH Yedikule Chest Diseases and Chest Surgery Training and Application Center

Subject Initials: ---

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

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Item	Date	User	Comment
1	Jan-20-2021 14:09:02 (UTC+03:00) Istanbul	(b) (4), (b) (6)	Not Applicable

090177e196ae30cb\Final\Final On: 01-Apr-2021 04:17 (GMT)

Header Text: C4591001

Visit: Disposition - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1209

Subject No: 12091014

Generated By: (b) (4)

Form: DEATH DETAILS CODED - Comments

Form Status: Data Complete, Verified

Site Name: (1209) Turkish MoH Yedikule Chest Diseases and Chest Surgery Training and Application Center

Subject Initials: ---

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

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Item	Date	User	Comment
Form	Jan-20-2021 14:09:28 (UTC+03:00) Istanbul	(b) (4), (b) (6)	Not Applicable

Header Text: C4591001

Visit: Disposition

Form Version: 22-Apr-2020 21:03

Site No: 1209

Subject No: 12091014

Generated By: (b) (4)

Form: DEATH DETAILS CODED - Comments

Form Status: Data Complete, Verified

Site Name: (1209) Turkish MoH Yedikule Chest Diseases and Chest Surgery Training and Application Center

Subject Initials: ---

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

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Item	Date	User	Comment
1	Jan-20-2021 14:09:28 (UTC+03:00) Istanbul	(b) (4), (b) (6)	Not Applicable

090177e196ae30cb\Final\Final On: 01-Apr-2021 04:17 (GMT)

Header Text: C4591001

Visit: V101_VAX3

Form Version: 10-Dec-2020 02:30

Site No: 1209

Subject No: 12091014

Generated By: (b) (4)

Form: INCLUSION/EXCLUSION CRITERIA - FURTHER VACCINATION - Comments

Form Status: Data Complete, Frozen, Verified

Site Name: (1209) Turkish MoH Yedikule Chest Diseases and Chest Surgery Training and Application Center

Subject Initials: ---

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

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Item	Date	User	Comment
Form	Feb-26-2021 09:55:17 (UTC+03:00) Istanbul	(b) (4), (b) (6)	Not Applicable

Header Text: C4591001

Visit: Investigator Signature - Unscheduled

Form Version: 22-Apr-2020 21:04

Site No: 1209

Subject No: 12091014

Generated By: (b) (4)

Form: CASEBOOK SIGNATURE FORM - Signature History

Form Status: Data Complete, Signed, Verified

Site Name: (1209) Turkish MoH Yedikule Chest Diseases and Chest Surgery Training and Application Center

Subject Initials: ---

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
(b) (6)	Approved	Mar-11-2021 13:54:14 (UTC+03:00) Istanbul	BOOK	Signed

Affidavit:

By my dated signature below, I, (b) (6), verify that all case report form pages accurately display the results of the examinations, tests, evaluations and treatments performed on this subject.

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

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

(b) (6)	N/A	Feb-02-2021 09:13:20 (UTC+03:00) Istanbul		Edit - All signatures invalidated
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Affidavit:

N/A

(b) (6)	Approved	Jan-21-2021 13:59:29 (UTC+03:00) Istanbul	BOOK	Signed
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Affidavit:

By my dated signature below, I, (b) (6), verify that all case report form pages accurately display the results of the examinations, tests, evaluations and treatments performed on this subject.

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

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

090177e196ae30cb\Final\Final On: 01-Apr-2021 04:17 (GMT)

Header Text: C4591001

Visit: COHORT_SELECTION

Form Version: 10-Oct-2020 16:01

Site No: 1209

Subject No: 12091014

Generated By: (b) (4)

Form: COHORT_SELECTION - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1209) Turkish MoH Yedikule Chest Diseases and Chest Surgery Training and Application Center

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-03-2020 14:20:20 (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-03-2020 14:20:20 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: STAGE 3 COHORTS	Initial Entry

Header Text: C4591001

Visit: COHORT_SELECTION

Form Version: 22-Apr-2020 21:02

Site No: 1209

Subject No: 12091014

Generated By: (b) (4)

Form: MAIN INFORMED CONSENT - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1209) Turkish MoH Yedikule Chest Diseases and Chest Surgery Training and Application Center

Subject Initials: ---

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

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I. Consent Was:

Date	Location	User	Value	Reason
Nov-03-2020 14:20:32 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: OBTAINED Date Written Consent Obtained Nov/3/2020	Initial Entry

Header Text: C4591001

Visit: COHORT_SELECTION

Form Version: 15-Sep-2020 21:54

Site No: 1209

Subject No: 12091014

Generated By: (b) (4)

Form: DEMOGRAPHY - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1209) Turkish MoH Yedikule Chest Diseases and Chest Surgery Training and Application Center

Subject Initials: ---

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

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1. Subject ID

Date	Location	User	Value	Reason
Nov-03-2020 14:20:08 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 12091014	Item copied from previous form

2. Birth Date:

Date	Location	User	Value	Reason
Nov-03-2020 14:19:51 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: (b) (6)/1960	Enrollment Entry

3. Sex:

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

4. Ethnicity:

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

090177e196ae30cb\Final\Final On: 01-Apr-2021 04:17 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:02

Site No: 1209

Subject No: 12091014

Generated By: (b) (4)

Form: DATE OF VISIT - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1209) Turkish MoH Yedikule Chest Diseases and Chest Surgery Training and Application Center

Subject Initials: ---

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

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1. Date of Visit

Date	Location	User	Value	Reason
Nov-03-2020 14:25:06 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Nov/3/2020	Initial Entry

090177e196ae30cb\Final\Final On: 01-Apr-2021 04:17 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 15-Sep-2020 21:52

Site No: 1209

Subject No: 12091014

Generated By: (b) (4)

Form: DISPOSITION - SCREENING - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1209) Turkish MoH Yedikule Chest Diseases and Chest Surgery Training and Application Center

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-03-2020 14:25:52 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Nov/3/2020	Initial Entry

2. Phase of Disposition:

Date	Location	User	Value	Reason
Nov-03-2020 14:25:52 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SCREENING	Initial Entry

3. Status:

Date	Location	User	Value	Reason
Nov-03-2020 14:25:52 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: COMPLETED	Initial Entry

090177e196ae30cb\Final\Final On: 01-Apr-2021 04:17 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 15-Sep-2020 21:57

Site No: 1209

Subject No: 12091014

Generated By: (b) (4)

Form: HIV STATUS - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1209) Turkish MoH Yedikule Chest Diseases and Chest Surgery Training and Application Center

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-03-2020 14:32:18 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: The subject is NOT known to be HIV POSITIVE	Initial Entry

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 10-Oct-2020 16:04

Site No: 1209

Subject No: 12091014

Generated By: (b) (4)

Form: VITAL SIGNS - BASELINE - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1209) Turkish MoH Yedikule Chest Diseases and Chest Surgery Training and Application Center

Subject Initials: ---

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

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1. Date:

Date	Location	User	Value	Reason
Nov-03-2020 14:35:14 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Nov/3/2020	Initial Entry

2. Weight:

Date	Location	User	Value	Reason
Nov-03-2020 14:35:14 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 90.0	Initial Entry

3. Unit:

Date	Location	User	Value	Reason
Nov-03-2020 14:35:14 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: kg	Initial Entry

4. Height:

Date	Location	User	Value	Reason
Nov-03-2020 14:35:14 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 175.0	Initial Entry

5. Unit:

Date	Location	User	Value	Reason
Nov-03-2020 14:35:14 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: cm	Initial Entry

6. Body Mass Index:

Date	Location	User	Value	Reason
Nov-03-2020 14:35:14 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 29.4	Initial Entry

7.a

Date	Location	User	Value	Reason
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090177e196ae30cb\Final\Final On: 01-Apr-2021 04:17 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 10-Oct-2020 16:04

Site No: 1209

Subject No: 12091014

Generated By: (b) (4)

Form: VITAL SIGNS - BASELINE - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1209) Turkish MoH Yedikule Chest Diseases and Chest Surgery Training and Application Center

Subject Initials: ---

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

Nov-03-2020 14:35:14 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Record Identifier:: 1 Temperature: 36.6 Temperature Unit: C Temperature Location: FOREHEA :	Initial Entry
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7.a Record Identifier:

Date	Location	User	Value	Reason
Nov-03-2020 14:35:14 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 1	Initial Entry

7.a Temperature:

Date	Location	User	Value	Reason
Nov-03-2020 14:35:14 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 36.6	Initial Entry

7.a Unit:

Date	Location	User	Value	Reason
Nov-03-2020 14:35:14 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: C	Initial Entry

7.a Temperature Location:

Date	Location	User	Value	Reason
Nov-03-2020 14:35:14 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: FOREHEAD	Initial Entry

090177e196ae30cb\Final\Final On: 01-Apr-2021 04:17 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1209

Subject No: 12091014

Generated By: (b) (4)

Form: RANDOMIZATION - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1209) Turkish MoH Yedikule Chest Diseases and Chest Surgery Training and Application Center

Subject Initials: ---

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

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1. Randomization Date :

Date	Location	User	Value	Reason
Nov-03-2020 14:35:47 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Nov/3/2020	Initial Entry

2. Randomization Number:

Date	Location	User	Value	Reason
Nov-03-2020 14:35:47 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 272972	Initial Entry

Header Text: C4591001**Visit:** V1_DAY1_VAX1_L**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - eCRF
Audit Trail History**Form Version:** 22-Apr-2020 21:03**Form Status:** Data Complete, Frozen, Verified**Site No:** 1209**Site Name:** (1209) Turkish MoH Yedikule Chest Diseases and Chest Surgery
Training and Application Center**Subject No:** 12091014**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-03-2020 14:36:31 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Nov-03-2020 14:36:31 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SERUM	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Nov-03-2020 14:36:51 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Nov-03-2020 14:36:31 (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-03-2020 14:36:31 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Date of Collection: Nov/3/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Nov-03-2020 14:36:51 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BPZBMH	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Nov-03-2020 14:36:51 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BPZBMH	Initial Entry

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1209

Site Name: (1209) Turkish MoH Yedikule Chest Diseases and Chest Surgery
Training and Application Center

Subject No: 12091014

Subject Initials: ---

Generated By: (b) (4)

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

5.b

Date	Location	User	Value	Reason
Nov-03-2020 14:37:08 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BPZBMJ	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Nov-03-2020 14:37:08 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BPZBMJ	Initial Entry

5.c

Date	Location	User	Value	Reason
Nov-03-2020 14:37:43 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BRZDN7	Initial Entry

5.c Sample ID

Date	Location	User	Value	Reason
Nov-03-2020 14:37:43 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BRZDN7	Initial Entry

5.d

Date	Location	User	Value	Reason
Nov-03-2020 14:37:52 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BRZDN8	Initial Entry

5.d Sample ID

Date	Location	User	Value	Reason
Nov-03-2020 14:37:52 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BRZDN8	Initial Entry

090177e196ae30cb\Final\Final On: 01-Apr-2021 04:17 (GMT)

Header Text: C4591001**Visit:** V1_DAY1_VAX1_L**Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB - eCRF Audit Trail History**Form Version:** 22-Apr-2020 21:03**Form Status:** Data Complete, Frozen, Verified**Site No:** 1209**Site Name:** (1209) Turkish MoH Yedikule Chest Diseases and Chest Surgery Training and Application Center**Subject No:** 12091014**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-03-2020 14:38:14 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Nov-03-2020 14:38:14 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: NASAL_SWAB	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Nov-03-2020 14:38:25 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Nov-03-2020 14:38:14 (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-03-2020 14:38:14 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Date of Collection: Nov/3/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Nov-03-2020 14:38:25 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BPZBMC	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Nov-03-2020 14:38:25 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BPZBMC	Initial Entry

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:04

Site No: 1209

Subject No: 12091014

Generated By: (b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1209) Turkish MoH Yedikule Chest Diseases and Chest Surgery Training and Application Center

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-03-2020 14:39:04 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2. Treatment Name

Date	Location	User	Value	Reason
Nov-03-2020 14:39:04 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: BLINDED THERAPY	Initial Entry

3. Formulation:

Date	Location	User	Value	Reason
Nov-03-2020 14:39:04 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: INJECTION	Initial Entry

4. Dose Date Time:

Date	Location	User	Value	Reason
Nov-03-2020 14:39:04 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Nov/3/2020 10:07	Initial Entry

5. Anatomical Location:

Date	Location	User	Value	Reason
Nov-03-2020 14:39:04 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: DELTOID MUSCLE	Initial Entry

6. Body Side:

Date	Location	User	Value	Reason
Nov-03-2020 14:39:04 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: LEFT	Initial Entry

7. Route:

Date	Location	User	Value	Reason
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090177e196ae30cb\Final\Final On: 01-Apr-2021 04:17 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:04

Site No: 1209

Subject No: 12091014

Generated By: (b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1209) Turkish MoH Yedikule Chest Diseases and Chest Surgery Training and Application Center

Subject Initials: ---

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

Nov-03-2020 14:39:04 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: INTRAMUSCULAR	Initial Entry
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10. Timeframe Subject Was Observed

Date	Location	User	Value	Reason
Nov-03-2020 14:39:04 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: THE PROTOCOL SPECIFIED OBSER VATION 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-03-2020 14:39:04 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

090177e196ae30cb\Final\Final On: 01-Apr-2021 04:17 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 06-Jul-2020 21:53

Site No: 1209

Subject No: 12091014

Generated By: (b) (4)

Form: REACTOGENICITY DIARY - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1209) Turkish MoH Yedikule Chest Diseases and Chest Surgery Training and Application Center

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-03-2020 19:48:23 (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: 1209

Subject No: 12091014

Generated By: (b) (4)

Form: DATE OF VISIT - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1209) Turkish MoH Yedikule Chest Diseases and Chest Surgery Training and Application Center

Subject Initials: ---

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

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I. Date of Visit

Date	Location	User	Value	Reason
Jan-02-2021 23:30:50 (UTC+03:00) Istanbul	ACV0PFEINFP6000	Salim Bouguermouh (b) (4)	Query 1: Closed	Response satisfies query
Dec-31-2020 11:38:45 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	The subject's potential covid-19 illness visit performed on 31 Dec 2020.
Dec-24-2020 21:59:50 (UTC+03:00) Istanbul	ACV0PFEINFP6000	Salim Bouguermouh (b) (4)	Query 1: Reissued:Opened	Clin: Please this query should remain open until a potential COVID-19 illness visit is conducted and a nasal swab could be obtained from the subject for the central laboratory
Dec-24-2020 09:56:16 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Since the subject is not stable enough to make pot covid illness visit yet and their isolation is still ongoing, this visit will be planned as soon as possible.
Dec-23-2020 18:02:02 (UTC+03:00) Istanbul	ACV0PFEINFP6000	Salim Bouguermouh (b) (4)	Query 1: Opened	Clin: It was stated in the SAE report #2020506841 that the subject had a diagnosis of COVID-19 on 21 Dec 2020 that should have please triggered a potential COVID Illness Visit and a nasal swab collected as soon as possible
Nov-24-2020 09:37:50 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Nov/24/2020	Initial Entry

090177e196ae30cb\Final\Final On: 01-Apr-2021 04:17 (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: 1209

Site Name: (1209) Turkish MoH Yedikule Chest Diseases and Chest Surgery Training and Application Center

Subject No: 12091014

Subject Initials: ---

Generated By: (b) (4)

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

[Back to Form](#)

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

Date	Location	User	Value	Reason
Nov-24-2020 09:38:39 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NO	Initial Entry

2.a

Date	Location	User	Value	Reason
Nov-24-2020 09:38:39 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> <u>Symptom::</u> FE VE R NO Were fever or systemic symptoms present on the last day the Subject Diary was completed?:	Initial Entry

2.a Symptom:

Date	Location	User	Value	Reason
Nov-24-2020 09:38:39 (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
Nov-24-2020 09:38:39 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NO	Initial Entry

2.b

Date	Location	User	Value	Reason
Nov-24-2020 09:38:39 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> <u>Symptom::</u> FAT IGU E NO Were fever or systemic symptoms present on the last day the Subject Diary was completed?:	Initial Entry

090177e196ae30cb\Final\Final On: 01-Apr-2021 04:17 (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: 1209

Site Name: (1209) Turkish MoH Yedikule Chest Diseases and Chest Surgery
Training and Application Center

Subject No: 12091014

Subject Initials: ---

Generated By: (b) (4)

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

2.b Symptom:

Date	Location	User	Value	Reason
Nov-24-2020 09:38:39 (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-24-2020 09:38:39 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NO	Initial Entry

2.c

Date	Location	User	Value	Reason
Nov-24-2020 09:38:39 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> <u>Symptom::</u> HEA DAC HE Were fever or systemic symptoms present on the last day the Subject Diary was completed? : NO	Initial Entry

2.c Symptom:

Date	Location	User	Value	Reason
Nov-24-2020 09:38:39 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> HEADACHE	Initial Entry

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

Date	Location	User	Value	Reason
Nov-24-2020 09:38:39 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NO	Initial Entry

2.d

Date	Location	User	Value	Reason
Nov-24-2020 09:38:39 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (6)	<u>Data Entry:</u> <u>Symptom::</u> CH	Initial Entry

090177e196ae30cb\Final\Final On: 01-Apr-2021 04:17 (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: 1209

Site Name: (1209) Turkish MoH Yedikule Chest Diseases and Chest Surgery
Training and Application Center

Subject No: 12091014

Subject Initials: ---

Generated By: (b) (4)

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

		(b) (4)	ILL S Were fever or systemic symptoms present on the last day the Subject Diary was completed?: NO	
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2.d Symptom:

Date	Location	User	Value	Reason
Nov-24-2020 09:38:39 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> CHILLS	Initial Entry

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

Date	Location	User	Value	Reason
Nov-24-2020 09:38:39 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NO	Initial Entry

2.e

Date	Location	User	Value	Reason
Nov-24-2020 09:38:39 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Symptom:: VO MITI NG 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-24-2020 09:38:39 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> 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-24-2020 09:38:39 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NO	Initial Entry

090177e196ae30cb\Final\Final On: 01-Apr-2021 04:17 (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: 1209

Site Name: (1209) Turkish MoH Yedikule Chest Diseases and Chest Surgery
Training and Application Center

Subject No: 12091014

Subject Initials: ---

Generated By: (b) (4)

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

2.f

Date	Location	User	Value	Reason
Nov-24-2020 09:38:39 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom:: DIA RRH EA Were fever or systemic symptoms present on the last day the Subject Diary was completed?: NO	Initial Entry

2.f Symptom:

Date	Location	User	Value	Reason
Nov-24-2020 09:38:39 (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-24-2020 09:38:39 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2.g

Date	Location	User	Value	Reason
Nov-24-2020 09:38:39 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom:: NEW OR WORSENE D MUSCL E PAIN Were fever or systemic symptoms present on the last day the Subject Diary was completed?: NO	Initial Entry

090177e196ae30cb\Final\Final On: 01-Apr-2021 04:17 (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: 1209

Site Name: (1209) Turkish MoH Yedikule Chest Diseases and Chest Surgery
Training and Application Center

Subject No: 12091014

Subject Initials: ---

Generated By: (b) (4)

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

2.g Symptom:

Date	Location	User	Value	Reason
Nov-24-2020 09:38:39 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NEW OR WORSENER MUSCLE PAI N	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-24-2020 09:38:39 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2.h

Date	Location	User	Value	Reason
Nov-24-2020 09:38:39 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom:: NEW OR WORSENER ED JOINT PAIN Were fever or systemic s NO ymptoms present on the l ast day the Subject Diary was completed?:	Initial Entry

2.h Symptom:

Date	Location	User	Value	Reason
Nov-24-2020 09:38:39 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NEW OR WORSENER JOINT PAIN	Initial Entry

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

Date	Location	User	Value	Reason
Nov-24-2020 09:38:39 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

3. Injection Site Location:

Date	Location	User	Value	Reason
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090177e196ae30cb\Final\Final On: 01-Apr-2021 04:17 (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: 1209

Site Name: (1209) Turkish MoH Yedikule Chest Diseases and Chest Surgery
Training and Application Center

Subject No: 12091014

Subject Initials: ---

Generated By: (b) (4)

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

Nov-24-2020 09:38:39 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: DELTOID MUSCLE	Initial Entry
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4. Injection Site Body Side:

Date	Location	User	Value	Reason
Nov-24-2020 09:38:39 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: LEFT	Initial Entry

5.a

Date	Location	User	Value	Reason
Nov-24-2020 09:38:39 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Injection Site Reaction:: RED NES S Were injection site reactions pr NO esent on the last day the Subjec t Diary was completed?:	Initial Entry

5.a Injection Site Reaction:

Date	Location	User	Value	Reason
Nov-24-2020 09:38:39 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: REDNESS	Initial Entry

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

Date	Location	User	Value	Reason
Nov-24-2020 09:38:39 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

5.b

Date	Location	User	Value	Reason
Nov-24-2020 09:38:39 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Injection Site Reaction:: SWE LLIN G Were injection site reactions p NO resent on the last day the Subj ect Diary was completed?:	Initial Entry

090177e196ae30cb\Final\Final On: 01-Apr-2021 04:17 (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: 1209

Site Name: (1209) Turkish MoH Yedikule Chest Diseases and Chest Surgery
Training and Application Center

Subject No: 12091014

Subject Initials: ---

Generated By: (b) (4)

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

5.b Injection Site Reaction:

Date	Location	User	Value	Reason
Nov-24-2020 09:38:39 (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-24-2020 09:38:39 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

5.c

Date	Location	User	Value	Reason
Nov-24-2020 09:38:39 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Injection Site Reaction:: PAIN AT INJECTI ON SITE Were injection site reactio ns present on the last day t he Subject Diary was com pleted?: NO	Initial Entry

5.c Injection Site Reaction:

Date	Location	User	Value	Reason
Nov-24-2020 09:38:39 (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-24-2020 09:38:39 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

090177e196ae30cb\Final\Final On: 01-Apr-2021 04:17 (GMT)

Header Text: C4591001

Visit: V2_VAX2_L

Form Version: 10-Oct-2020 16:01

Site No: 1209

Subject No: 12091014

Generated By: (b) (4)

Form: VITAL SIGNS - TEMP - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1209) Turkish MoH Yedikule Chest Diseases and Chest Surgery Training and Application Center

Subject Initials: ---

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

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I. Date:

Date	Location	User	Value	Reason
Nov-24-2020 09:39:06 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Nov/24/2020	Initial Entry

2.a

Date	Location	User	Value	Reason
Nov-24-2020 09:39:06 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Record Identifier:: 1 Temperature: 36.6 Temperature Unit: C Temperature Location: FOREHEA : D	Initial Entry

2.a Record Identifier:

Date	Location	User	Value	Reason
Nov-24-2020 09:39:06 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 1	Initial Entry

2.a Temperature:

Date	Location	User	Value	Reason
Nov-24-2020 09:39:06 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 36.6	Initial Entry

2.a Unit:

Date	Location	User	Value	Reason
Nov-24-2020 09:39:06 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: C	Initial Entry

2.a Temperature Location:

Date	Location	User	Value	Reason
Nov-24-2020 09:39:06 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (6)	Data Entry: FOREHEAD	Initial Entry

090177e196ae30cb\Final\Final On: 01-Apr-2021 04:17 (GMT)

Header Text: C4591001

Visit: V2_VAX2_L

Form Version: 10-Oct-2020 16:01

Site No: 1209

Subject No: 12091014

Generated By: (b) (4)

Form: VITAL SIGNS - TEMP - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1209) Turkish MoH Yedikule Chest Diseases and Chest Surgery Training and Application Center

Subject Initials: ---

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

(b) (4)

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:** 1209**Site Name:** (1209) Turkish MoH Yedikule Chest Diseases and Chest Surgery Training and Application Center**Subject No:** 12091014**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-24-2020 16:03:23 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Nov-24-2020 16:03:23 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: NASAL_SWAB	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Nov-24-2020 16:03:41 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Nov-24-2020 16:03:23 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Nov-24-2020 16:03:23 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Date of Collection: Nov/24/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Nov-24-2020 16:03:41 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BPZBNT	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Nov-24-2020 16:03:41 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BPZBNT	Initial Entry

Header Text: C4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:04

Site No: 1209

Subject No: 12091014

Generated By: (b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1209) Turkish MoH Yedikule Chest Diseases and Chest Surgery Training and Application Center

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-24-2020 09:57:54 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2. Treatment Name

Date	Location	User	Value	Reason
Nov-24-2020 09:57:54 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: BLINDED THERAPY	Initial Entry

3. Formulation:

Date	Location	User	Value	Reason
Nov-24-2020 09:57:54 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: INJECTION	Initial Entry

4. Dose Date Time:

Date	Location	User	Value	Reason
Nov-24-2020 09:57:54 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Nov/24/2020 09:32	Initial Entry

5. Anatomical Location:

Date	Location	User	Value	Reason
Nov-24-2020 09:57:54 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: DELTOID MUSCLE	Initial Entry

6. Body Side:

Date	Location	User	Value	Reason
Nov-24-2020 09:57:54 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: LEFT	Initial Entry

7. Route:

Date	Location	User	Value	Reason
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090177e196ae30cb\Final\Final On: 01-Apr-2021 04:17 (GMT)

Header Text: C4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:04

Site No: 1209

Subject No: 12091014

Generated By: (b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1209) Turkish MoH Yedikule Chest Diseases and Chest Surgery Training and Application Center

Subject Initials: ---

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

Nov-24-2020 09:57:54 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: INTRAMUSCULAR	Initial Entry
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10. Timeframe Subject Was Observed

Date	Location	User	Value	Reason
Nov-24-2020 09:57:54 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: THE PROTOCOL SPECIFIED OBSER VATION 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-24-2020 09:57:54 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

090177e196ae30cb\Final\Final On: 01-Apr-2021 04:17 (GMT)

Header Text: C4591001

Visit: V3_MONTH1_POSTVAX2_L

Form: DATE OF VISIT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen, Verified

Site No: 1209

Site Name: (1209) Turkish MoH Yedikule Chest Diseases and Chest Surgery Training and Application Center

Subject No: 12091014

Subject Initials: ---

Generated By: (b) (4)

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

[Back to Form](#)

1. Date of Visit

Date	Location	User	Value	Reason
Jan-05-2021 09:27:13 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	As per site confirmation - updated PD tracker
Jan-04-2021 10:20:46 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	The subject's v3 planned on 22Dec2020 but since they were hospitalized for covid positive on 18dec2020, they couldn't make it to come to the study site until 31dec2020
Jan-04-2021 09:07:39 (UTC+03:00) Istanbul	ACV0PFEINFP6000.InFormAdapter.Discrepancy	PFE SDQ PROD (b) (4)	Query 1: Opened	PDQ: Date of visit at V3_MONTH1_POSTVAX2_L is out of window for 2 days from V2_VAX2_L DOV or V2 Vaccination date. Please verify and update. Else, confirm in query response appropriately. (b) (4)
Dec-31-2020 09:53:56 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry : Dec/31/2020	Initial Entry

090177e196ae30cb\Final\Final On: 01-Apr-2021 04:17 (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: 1209

Site Name: (1209) Turkish MoH Yedikule Chest Diseases and Chest Surgery Training and Application Center

Subject No: 12091014

Subject Initials: ---

Generated By: (b) (4)

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

[Back to Form](#)

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

Date	Location	User	Value	Reason
Dec-31-2020 10:02:31 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NO	Initial Entry

2.a

Date	Location	User	Value	Reason
Dec-31-2020 10:02:31 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> <u>Symptom::</u> FE VE R NO Were fever or systemic symptoms present on the last day the Subject Diary was completed?:	Initial Entry

2.a Symptom:

Date	Location	User	Value	Reason
Dec-31-2020 10:02:31 (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-31-2020 10:02:31 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NO	Initial Entry

2.b

Date	Location	User	Value	Reason
Dec-31-2020 10:02:31 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> <u>Symptom::</u> FAT IGU E NO Were fever or systemic symptoms present on the last day the Subject Diary was completed?:	Initial Entry

090177e196ae30cb\Final\Final On: 01-Apr-2021 04:17 (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: 1209

Site Name: (1209) Turkish MoH Yedikule Chest Diseases and Chest Surgery
Training and Application Center

Subject No: 12091014

Subject Initials: ---

Generated By: (b) (4)

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

2.b Symptom:

Date	Location	User	Value	Reason
Dec-31-2020 10:02:31 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> FATIGUE	Initial Entry

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

Date	Location	User	Value	Reason
Dec-31-2020 10:02:31 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NO	Initial Entry

2.c

Date	Location	User	Value	Reason
Dec-31-2020 10:02:31 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> <u>Symptom::</u> HEA DAC HE Were fever or systemic symptoms present on the last day the Subject Diary was completed? : NO	Initial Entry

2.c Symptom:

Date	Location	User	Value	Reason
Dec-31-2020 10:02:31 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> HEADACHE	Initial Entry

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

Date	Location	User	Value	Reason
Dec-31-2020 10:02:31 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NO	Initial Entry

2.d

Date	Location	User	Value	Reason
Dec-31-2020 10:02:31 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (6)	<u>Data Entry:</u> <u>Symptom::</u> CH	Initial Entry

090177e196ae30cb\Final\Final On: 01-Apr-2021 04:17 (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: 1209

Site Name: (1209) Turkish MoH Yedikule Chest Diseases and Chest Surgery Training and Application Center

Subject No: 12091014

Subject Initials: ---

Generated By: (b) (4)

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

		(b) (4)	ILL S Were fever or systemic symptoms present on the last day the Subject Diary was completed?: NO	
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2.d Symptom:

Date	Location	User	Value	Reason
Dec-31-2020 10:02:31 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> CHILLS	Initial Entry

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

Date	Location	User	Value	Reason
Dec-31-2020 10:02:31 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NO	Initial Entry

2.e

Date	Location	User	Value	Reason
Dec-31-2020 10:02:31 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Symptom:: VO MITI NG 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-31-2020 10:02:31 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> 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-31-2020 10:02:31 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NO	Initial Entry

090177e196ae30cb\Final\Final On: 01-Apr-2021 04:17 (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: 1209

Site Name: (1209) Turkish MoH Yedikule Chest Diseases and Chest Surgery Training and Application Center

Subject No: 12091014

Subject Initials: ---

Generated By: (b) (4)

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

2.f

Date	Location	User	Value	Reason
Dec-31-2020 10:02:31 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom:: DIA RRH EA Were fever or systemic symptoms present on the last day the Subject Diary was completed?: NO	Initial Entry

2.f Symptom:

Date	Location	User	Value	Reason
Dec-31-2020 10:02:31 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: DIARRHEA	Initial Entry

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

Date	Location	User	Value	Reason
Dec-31-2020 10:02:31 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2.g

Date	Location	User	Value	Reason
Dec-31-2020 10:02:31 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom:: NEW OR WORSENE D MUSCL E PAIN Were fever or systemic symptoms present on the last day the Subject Diary was completed?: NO	Initial Entry

090177e196ae30cb\Final\Final On: 01-Apr-2021 04:17 (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: 1209

Site Name: (1209) Turkish MoH Yedikule Chest Diseases and Chest Surgery
Training and Application Center

Subject No: 12091014

Subject Initials: ---

Generated By: (b) (4)

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

2.g Symptom:

Date	Location	User	Value	Reason
Dec-31-2020 10:02:31 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NEW OR WORSENERD MUSCLE PAI N	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-31-2020 10:02:31 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2.h

Date	Location	User	Value	Reason
Dec-31-2020 10:02:31 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom:: NEW OR WORSENERD JOINT PAIN Were fever or systemic s NO ymptoms present on the l ast day the Subject Diary was completed?:	Initial Entry

2.h Symptom:

Date	Location	User	Value	Reason
Dec-31-2020 10:02:31 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NEW OR WORSENERD JOINT PAIN	Initial Entry

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

Date	Location	User	Value	Reason
Dec-31-2020 10:02:31 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

3. Injection Site Location:

Date	Location	User	Value	Reason
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090177e196ae30cb\Final\Final On: 01-Apr-2021 04:17 (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: 1209

Site Name: (1209) Turkish MoH Yedikule Chest Diseases and Chest Surgery Training and Application Center

Subject No: 12091014

Subject Initials: ---

Generated By: (b) (4)

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

Dec-31-2020 10:02:31 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: DELTOID MUSCLE	Initial Entry
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4. Injection Site Body Side:

Date	Location	User	Value	Reason
Dec-31-2020 10:02:31 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: LEFT	Initial Entry

5.a

Date	Location	User	Value	Reason
Dec-31-2020 10:02:31 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Injection Site Reaction:: RED NES S Were injection site reactions pr NO esent on the last day the Subjec t Diary was completed?:	Initial Entry

5.a Injection Site Reaction:

Date	Location	User	Value	Reason
Dec-31-2020 10:02:31 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: REDNESS	Initial Entry

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

Date	Location	User	Value	Reason
Dec-31-2020 10:02:31 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

5.b

Date	Location	User	Value	Reason
Dec-31-2020 10:02:31 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Injection Site Reaction:: SWE LLIN G Were injection site reactions p NO resent on the last day the Subj ect Diary was completed?:	Initial Entry

090177e196ae30cb\Final\Final On: 01-Apr-2021 04:17 (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: 1209

Site Name: (1209) Turkish MoH Yedikule Chest Diseases and Chest Surgery Training and Application Center

Subject No: 12091014

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-31-2020 10:02:31 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> SWELLING	Initial Entry

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

Date	Location	User	Value	Reason
Dec-31-2020 10:02:31 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NO	Initial Entry

5.c

Date	Location	User	Value	Reason
Dec-31-2020 10:02:43 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Injection Site Reaction:: PAIN AT INJECTI ON SITE Were injection site reactio ns present on the last day t he Subject Diary was com pleted?: NO	Initial Entry
Dec-31-2020 10:02:31 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Injection Site Reaction:: PAIN AT INJECTI ON SITE Were injection site reactio ns present on the last day t he Subject Diary was com pleted?:	Initial Entry

090177e196ae30cb\Final\Final On: 01-Apr-2021 04:17 (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: 1209

Site Name: (1209) Turkish MoH Yedikule Chest Diseases and Chest Surgery
Training and Application Center

Subject No: 12091014

Subject Initials: ---

Generated By: (b) (4)

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

5.c Injection Site Reaction:

Date	Location	User	Value	Reason
Dec-31-2020 10:02:31 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: PAIN AT INJECTION SITE	Initial Entry

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

Date	Location	User	Value	Reason
Dec-31-2020 10:02:43 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

Header Text: C4591001**Visit:** V3_MONTH1_POSTVAX2_L**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - eCRF
Audit Trail History**Form Version:** 22-Apr-2020 21:03**Form Status:** Data Complete, Frozen, Verified**Site No:** 1209**Site Name:** (1209) Turkish MoH Yedikule Chest Diseases and Chest Surgery
Training and Application Center**Subject No:** 12091014**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-31-2020 16:01:22 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Dec-31-2020 16:01:22 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SERUM	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Dec-31-2020 16:01:43 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Dec-31-2020 16:01:22 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Dec-31-2020 16:01:22 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Date of Collection: Dec/31/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Dec-31-2020 16:01:43 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BPZBR8	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Dec-31-2020 16:01:43 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BPZBR8	Initial Entry

5.b

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: 1209

Site Name: (1209) Turkish MoH Yedikule Chest Diseases and Chest Surgery
Training and Application Center

Subject No: 12091014

Subject Initials: ---

Generated By: (b) (4)

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

Date	Location	User	Value	Reason
Dec-31-2020 16:02:07 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Sample ID: BPZBR9	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Dec-31-2020 16:02:07 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> BPZBR9	Initial Entry

5.c

Date	Location	User	Value	Reason
Dec-31-2020 16:02:23 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Sample ID: BRZDR5	Initial Entry

5.c Sample ID

Date	Location	User	Value	Reason
Dec-31-2020 16:02:23 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> BRZDR5	Initial Entry

5.d

Date	Location	User	Value	Reason
Dec-31-2020 16:02:37 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Sample ID: BRZDR6	Initial Entry

5.d Sample ID

Date	Location	User	Value	Reason
Dec-31-2020 16:02:37 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> BRZDR6	Initial Entry

090177e196ae30cb\Final\Final On: 01-Apr-2021 04:17 (GMT)

Header Text: C4591001**Visit:** POT_COVID_ILL 1 - Unscheduled Visit on Dec/21/2020 **Form:** DATE OF VISIT - ILLNESS ONSET - eCRF Audit Trail History**Form Version:** 22-Apr-2020 21:03**Form Status:** Data Complete, Frozen, Verified**Site No:** 1209**Site Name:** (1209) Turkish MoH Yedikule Chest Diseases and Chest Surgery Training and Application Center**Subject No:** 12091014**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 13:11[Back to Form](#)**1. Date of Visit**

Date	Location	User	Value	Reason
Dec-31-2020 10:04:11 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Dec-30-2020 14:54:33 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	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.
Dec-29-2020 19:16:22 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Deleted	Close Auto Query
Dec-29-2020 19:15:33 (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.
Dec-29-2020 19:15:33 (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.
Dec-29-2020 19:15:33 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Dec/21/2020	Initial Entry

3. COVID-19 Illness Visit:

Date	Location	User	Value	Reason
Dec-29-2020 19:15:33 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: COVID_A	Initial Entry

Header Text: C4591001**Visit:** POT_COVID_ILL 1 - Unscheduled Visit on Dec/21/2020**Form Version:** 10-Dec-2020 02:29**Site No:** 1209**Subject No:** 12091014**Generated By:** (b) (4)**Form:** SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - eCRF Audit Trail History**Form Status:** Data Complete**Site Name:** (1209) Turkish MoH Yedikule Chest Diseases and Chest Surgery Training and Application Center**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 13:11[Back to Form](#)**1. Date of Assessment:**

Date	Location	User	Value	Reason
Dec-29-2020 19:16:22 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Dec/21/2020	Initial Entry

2. Date of First Symptom Started:

Date	Location	User	Value	Reason
Dec-29-2020 19:16:22 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Dec/19/2020	Initial Entry

3. Symptoms Ongoing?

Date	Location	User	Value	Reason
Dec-29-2020 19:17:07 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO Date of Last Symptom Resolved: Dec/20/2020	Transcription Error
Dec-29-2020 19:16:22 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

4.a

Date	Location	User	Value	Reason
Dec-29-2020 19:16:22 (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
Dec-29-2020 19:16:22 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: FEVER	Initial Entry

4.a Was symptom present?

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Dec/21/2020

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: 1209

Site Name: (1209) Turkish MoH Yedikule Chest Diseases and Chest Surgery Training and Application Center

Subject No: 12091014

Subject Initials: ---

Generated By: (b) (4)

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

Date	Location	User	Value	Reason
Dec-29-2020 19:16:22 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

4.b

Date	Location	User	Value	Reason
Dec-29-2020 19:16:22 (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
Dec-29-2020 19:16:22 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NEW OR INCREASED COUGH	Initial Entry

4.b Was symptom present?

Date	Location	User	Value	Reason
Dec-29-2020 19:16:22 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

4.c

Date	Location	User	Value	Reason
Dec-29-2020 19:16:22 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptoms: NEW OR INCREASED SHORTNESS OF BREATH Symptom Present: NO	Initial Entry

090177e196ae30cb\Final\Final On: 01-Apr-2021 04:17 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Dec/21/2020

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: 1209

Site Name: (1209) Turkish MoH Yedikule Chest Diseases and Chest Surgery Training and Application Center

Subject No: 12091014

Subject Initials: ---

Generated By: (b) (4)

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

4.c Symptoms:

Date	Location	User	Value	Reason
Dec-29-2020 19:16:22 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NEW OR INCREASED SHORTNESS OF BREATH	Initial Entry

4.c Was symptom present?

Date	Location	User	Value	Reason
Dec-29-2020 19:16:22 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

4.d

Date	Location	User	Value	Reason
Dec-29-2020 19:16:22 (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
Dec-29-2020 19:16:22 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: CHILLS	Initial Entry

4.d Was symptom present?

Date	Location	User	Value	Reason
Dec-29-2020 19:16:22 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

4.e

Date	Location	User	Value	Reason
Dec-29-2020 19:16:22 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptoms: NEW OR INCREASED MUSCLE PAIN Symptom Present: NO	Initial Entry

090177e196ae30cb\Final\Final On: 01-Apr-2021 04:17 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Dec/21/2020

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: 1209

Site Name: (1209) Turkish MoH Yedikule Chest Diseases and Chest Surgery Training and Application Center

Subject No: 12091014

Subject Initials: ---

Generated By: (b) (4)

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

4.e Symptoms:

Date	Location	User	Value	Reason
Dec-29-2020 19:16:22 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NEW OR INCREASED MUSCLE PAIN	Initial Entry

4.e Was symptom present?

Date	Location	User	Value	Reason
Dec-29-2020 19:16:22 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

4.f

Date	Location	User	Value	Reason
Dec-29-2020 19:16:22 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptoms: NEW LOSS OF TASTE OR SMELL Symptom Present: NO	Initial Entry

4.f Symptoms:

Date	Location	User	Value	Reason
Dec-29-2020 19:16:22 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NEW LOSS OF TASTE OR SMELL	Initial Entry

4.f Was symptom present?

Date	Location	User	Value	Reason
Dec-29-2020 19:16:22 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

4.g

Date	Location	User	Value	Reason
Dec-29-2020 19:16:22 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptoms: NEW OR INCREASED SORE THROAT	Initial Entry

090177e196ae30cb\Final\Final On: 01-Apr-2021 04:17 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Dec/21/2020

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: 1209

Site Name: (1209) Turkish MoH Yedikule Chest Diseases and Chest Surgery Training and Application Center

Subject No: 12091014

Subject Initials: ---

Generated By: (b) (4)

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

			Symptom Present:	
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4.g Symptoms:

Date	Location	User	Value	Reason
Dec-29-2020 19:16:22 (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
Dec-29-2020 19:16:22 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

4.h

Date	Location	User	Value	Reason
Dec-29-2020 19:16:22 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptoms: DIARRHEA Symptom Present: NO	Initial Entry

4.h Symptoms:

Date	Location	User	Value	Reason
Dec-29-2020 19:16:22 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: DIARRHEA	Initial Entry

4.h Was symptom present?

Date	Location	User	Value	Reason
Dec-29-2020 19:16:22 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

4.i

Date	Location	User	Value	Reason
Dec-29-2020 19:16:22 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptoms: VOMITING Symptom Present: NO	Initial Entry

090177e196ae30cb\Final\Final On: 01-Apr-2021 04:17 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Dec/21/2020

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: 1209

Site Name: (1209) Turkish MoH Yedikule Chest Diseases and Chest Surgery Training and Application Center

Subject No: 12091014

Subject Initials: ---

Generated By: (b) (4)

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

4.i Symptoms:

Date	Location	User	Value	Reason
Dec-29-2020 19:16:22 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> VOMITING	Initial Entry

4.i Was symptom present?

Date	Location	User	Value	Reason
Dec-29-2020 19:16:22 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NO	Initial Entry

090177e196ae30cb\Final\Final On: 01-Apr-2021 04:17 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Dec/21/2020 **Form:** MICROBIOLOGY SPECIMEN - Audit Trail

Form Version: 06-Jul-2020 21:54

Form Status:

Site No: 1209

Site Name: (1209) Turkish MoH Yedikule Chest Diseases and Chest Surgery Training and Application Center

Subject No: 12091014

Subject Initials: ---

Generated By: (b) (4)

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

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Date	Location	User	Value	Reason
Dec-29-2020 19:56:19 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Created	

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Dec/21/2020 Form: MICROBIOLOGY SPECIMEN - eCRF Audit Trail History

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete

Site No: 1209

Site Name: (1209) Turkish MoH Yedikule Chest Diseases and Chest Surgery Training and Application Center

Subject No: 12091014

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
Dec-29-2020 19:56:19 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Dec/18/2020	Initial Entry

2. Specimen Type:

Date	Location	User	Value	Reason
Dec-29-2020 19:56:19 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: SWABBED MATERIAL	Initial Entry

3. Specimen Collection Location:

Date	Location	User	Value	Reason
Dec-29-2020 19:56:19 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NASOPHARYNX	Initial Entry

4. Assay Code and Description:

Date	Location	User	Value	Reason
Dec-29-2020 19:56:19 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SEVERE ACUTE RESP SYNDROME CORONAVIRUS 2	Initial Entry

5. Device Type:

Date	Location	User	Value	Reason
Dec-29-2020 19:56:19 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SARS-COV-2 DIAGNOSTIC TEST	Initial Entry

6. Trade Name:

Date	Location	User	Value	Reason
Dec-29-2020 19:56:19 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: OTHER	Initial Entry

7. Test Result:

Date	Location	User	Value	Reason
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Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Dec/21/2020 **Form:** MICROBIOLOGY SPECIMEN - eCRF Audit Trail History

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete

Site No: 1209

Site Name: (1209) Turkish MoH Yedikule Chest Diseases and Chest Surgery Training and Application Center

Subject No: 12091014

Subject Initials: ---

Generated By: (b) (4)

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

Dec-29-2020 19:56:19 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: POSITIVE	Initial Entry
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9. Trade Name Other, Specify:

Date	Location	User	Value	Reason
Dec-29-2020 19:56:19 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Bioeksen Bio Speedy Direct RT qPCR SARS CoV 2	Initial Entry

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Dec/21/2020

Form Version: 22-Apr-2020 21:03

Site No: 1209

Subject No: 12091014

Generated By: (b) (4)

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

Form Status: Data Complete, Frozen, Verified

Site Name: (1209) Turkish MoH Yedikule Chest Diseases and Chest Surgery Training and Application Center

Subject Initials: ---

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

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1. Data Origin

Date	Location	User	Value	Reason
Dec-29-2020 20:05:31 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Dec-29-2020 20:05:31 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: NASAL_SWAB_SELF	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Dec-29-2020 20:05:31 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

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

Date	Location	User	Value	Reason
Dec-29-2020 20:05:31 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: The subject didn't want to use self swab kit	Initial Entry

090177e196ae30cb\Final\Final On: 01-Apr-2021 04:17 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Dec/21/2020

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1209

Site Name: (1209) Turkish MoH Yedikule Chest Diseases and Chest Surgery Training and Application Center

Subject No: 12091014

Subject Initials: ---

Generated By: (b) (4)

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

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1. Data Origin

Date	Location	User	Value	Reason
Dec-29-2020 20:06:09 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Dec-29-2020 20:06:09 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: NASAL_SWAB	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Jan-07-2021 14:19:48 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Closing as reason of delay is documented on CRF
Jan-04-2021 14:01:59 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Closed	Closed as per site response.
Dec-31-2020 10:42:15 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto query (autoquery)	Query 3: Deleted	Close Auto Query
Dec-31-2020 10:35:40 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	The subject was not available yet to visit the site for nasal swab. They've been discharged from hospital on 25 dec (their pcr result is negative)
Dec-31-2020 10:29:42 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Answered	The subject wasn't available until 31 Dec 2020 since they've been hospitalized for being COVID + between dec 18 and 25. Their pcr test outcome is negative by the dec 25.

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Header Text: C4591001**Visit:** POT_COVID_ILL 1 - Unscheduled Visit on Dec/21/2020**Form Version:** 22-Apr-2020 21:03**Site No:** 1209**Subject No:** 12091014**Generated By:** (b) (4)**Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB - eCRF Audit Trail History**Form Status:** Data Complete, Frozen, Verified**Site Name:** (1209) Turkish MoH Yedikule Chest Diseases and Chest Surgery Training and Application Center**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 13:11

Dec-31-2020 10:04:11 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto query (autoquery)	Query 3: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Dec-31-2020 10:04:11 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Opened	Date of Collection 31/Dec/2020 is different from Date of Visit 21/Dec/2020. Please review and update as appropriate, else clarify.
Dec-31-2020 10:04:11 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	Date of Collection is more than 4 days after Date of Last Symptom Resolved on the Signs and Symptoms form in the same visit. Please review and update as appropriate.
Dec-31-2020 10:04:11 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Date of Collection: Dec/31/2020	New Information
Dec-29-2020 20:06:09 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

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

Date	Location	User	Value	Reason
Dec-31-2020 10:31:30 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: The subject was not available yet to visit the site for nasal swab. They've been discharged from hospital on 25 Dec (the IR PCR result is negative)	New Information
Dec-29-2020 20:06:09 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: The subject is not available yet to visit the site for nasal swab	Initial Entry

5.a

Date	Location	User	Value	Reason
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Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Dec/21/2020

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1209

Site Name: (1209) Turkish MoH Yedikule Chest Diseases and Chest Surgery Training and Application Center

Subject No: 12091014

Subject Initials: ---

Generated By: (b) (4)

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Dec-31-2020 10:42:15 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BPZBR7	Initial Entry
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5.a Sample ID

Date	Location	User	Value	Reason
Dec-31-2020 10:42:15 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BPZBR7	Initial Entry

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Dec/21/2020 Form: HEALTH CARE UTILIZATION - eCRF Audit Trail History

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Form Status: Data Complete

Site No: 1209

Site Name: (1209) Turkish MoH Yedikule Chest Diseases and Chest Surgery Training and Application Center

Subject No: 12091014

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
Dec-29-2020 20:10:35 (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
Dec-29-2020 20:10:35 (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
Dec-29-2020 20:10:35 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

I.b

Date	Location	User	Value	Reason
Dec-29-2020 20:10:35 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Type of Practitioner: EMERGENCY ROOM Occurrence of Visits or Contacts: NO	Initial Entry

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Header Text: C4591001**Visit:** POT_COVID_ILL 1 - Unscheduled Visit on Dec/21/2020 **Form:** HEALTH CARE UTILIZATION - eCRF Audit Trail History**Form Version:** 10-Dec-2020 02:26**Form Status:** Data Complete**Site No:** 1209**Site Name:** (1209) Turkish MoH Yedikule Chest Diseases and Chest Surgery Training and Application Center**Subject No:** 12091014**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 13:11***I.b Physician or Healthcare Professional:***

Date	Location	User	Value	Reason
Dec-29-2020 20:10:35 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: EMERGENCY ROOM	Initial Entry

I.b Occurrence of Visits or Contacts:

Date	Location	User	Value	Reason
Dec-29-2020 20:10:35 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

I.c

Date	Location	User	Value	Reason
Dec-29-2020 20:10:35 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Type of Practitioner: PRIMARY CARE PHYSICIAN Occurrence of Visits or Contacts: NO	Initial Entry

I.c Physician or Healthcare Professional:

Date	Location	User	Value	Reason
Dec-29-2020 20:10:35 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: PRIMARY CARE PHYSICIAN	Initial Entry

I.c Occurrence of Visits or Contacts:

Date	Location	User	Value	Reason
Dec-29-2020 20:10:35 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

I.d

Date	Location	User	Value	Reason
Dec-29-2020 20:10:35 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Type of Practitioner: URGENT CARE	Initial Entry

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Dec/21/2020 Form: HEALTH CARE UTILIZATION - eCRF Audit Trail History

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Form Status: Data Complete

Site No: 1209

Site Name: (1209) Turkish MoH Yedikule Chest Diseases and Chest Surgery Training and Application Center

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Subject Initials: ---

Generated By: (b) (4)

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

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

Date	Location	User	Value	Reason
Dec-29-2020 20:10:35 (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
Dec-29-2020 20:10:35 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

1.e

Date	Location	User	Value	Reason
Dec-29-2020 20:10:35 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Type of Practitioner: TELEPHONE CONSULTATION Occurrence of Visits or Contacts: YES <i>Number of Visits or Contacts:</i> 3	Initial Entry

1.e Physician or Healthcare Professional:

Date	Location	User	Value	Reason
Dec-29-2020 20:10:35 (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
Dec-29-2020 20:10:35 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES <i>Number of Visits or Contacts:</i> 3	Initial Entry

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Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Dec/21/2020 Form: HEALTH CARE UTILIZATION - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:26

Form Status: Data Complete

Site No: 1209

Site Name: (1209) Turkish MoH Yedikule Chest Diseases and Chest Surgery Training and Application Center

Subject No: 12091014

Subject Initials: ---

Generated By: (b) (4)

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

I.f

Date	Location	User	Value	Reason
Dec-29-2020 20:10:35 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Type of Practitioner: OTH R Occurrence of Visits or Cont acts: NO	Initial Entry

I.f Physician or Healthcare Professional:

Date	Location	User	Value	Reason
Dec-29-2020 20:10:35 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: OTHER	Initial Entry

I.f Occurrence of Visits or Contacts:

Date	Location	User	Value	Reason
Dec-29-2020 20:10:35 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2. Other Type of Practitioner Specify:

Date	Location	User	Value	Reason
Jan-07-2021 16:08:03 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

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

Date	Location	User	Value	Reason
Jan-12-2021 16:31:12 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Jan-08-2021 14:56:21 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Changed data per query
Jan-07-2021 22:19:53 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reissued:Opened	Clin: All data from hospitalization should be recorded, eg, vital signs, pulse oxymet,

090177e196ae30cb\Final\Final On: 01-Apr-2021 04:17 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Dec/21/2020

Form: HEALTH CARE UTILIZATION - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:26

Form Status: Data Complete

Site No: 1209

Site Name: (1209) Turkish MoH Yedikule Chest Diseases and Chest Surgery Training and Application Center

Subject No: 12091014

Subject Initials: ---

Generated By: (b) (4)

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

				chemistry, imaging.
Jan-07-2021 16:21:37 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	The subject hospitalized due to isolation. They didn't get any treatment other than covid-19 illness treatment drug (Remdesivir). The subject's laboratory results (such as hematology, coagulation, biochemistry) is filed at site as source document.
Dec-31-2020 19:10:09 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	Clinical Query: As this subject was hospitalized, please enter on the CRF form any available information (vital signs, pulse oxymet, respiratory treatment, lab results, imaging...). Please make every effort to obtain these information.
Dec-29-2020 20:10:35 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Has the subject been in intensive care due to potential COVID-19 illness ? NO	Initial Entry

090177e196ae30cb\Final\Final On: 01-Apr-2021 04:17 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Dec/21/2020 **Form:** HOSPITALIZATION DETAILS - Audit Trail

Form Version: 22-Apr-2020 21:02

Form Status:

Site No: 1209

Site Name: (1209) Turkish MoH Yedikule Chest Diseases and Chest Surgery Training and Application Center

Subject No: 12091014

Subject Initials: ---

Generated By: (b) (4)

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

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Date	Location	User	Value	Reason
Dec-29-2020 20:11:21 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Created	

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Dec/21/2020 Form: HOSPITALIZATION DETAILS - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete

Site No: 1209

Site Name: (1209) Turkish MoH Yedikule Chest Diseases and Chest Surgery Training and Application Center

Subject No: 12091014

Subject Initials: ---

Generated By: (b) (4)

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

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1. Hospitalization Category:

Date	Location	User	Value	Reason
Dec-29-2020 20:11:21 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: HOSPITALIZATION STATUS	Initial Entry

2. Hospitalization Term:

Date	Location	User	Value	Reason
Dec-29-2020 20:11:21 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: HOSPITAL	Initial Entry

3. Admission Date:

Date	Location	User	Value	Reason
Dec-29-2020 20:11:21 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Dec/18/2020	Initial Entry

4. Ongoing?

Date	Location	User	Value	Reason
Dec-29-2020 20:11:21 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO Discharge Date: Dec/25/2020	Initial Entry

090177e196ae30cb\Final\Final On: 01-Apr-2021 04:17 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Dec/21/2020 Form: RESPIRATORY TREATMENT - eCRF Audit Trail History

Form Version: 06-Jul-2020 21:53

Form Status: Data Complete

Site No: 1209

Site Name: (1209) Turkish MoH Yedikule Chest Diseases and Chest Surgery Training and Application Center

Subject No: 12091014

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
Dec-29-2020 20:11:48 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Done	Initial Entry

2. Concomitant Non-drug Treatment Pre-specified:

Date	Location	User	Value	Reason
Dec-29-2020 20:11:48 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Done	Initial Entry

3. Treatment:

Date	Location	User	Value	Reason
Dec-29-2020 20:11:48 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Done	Initial Entry

4. Treatment:

Date	Location	User	Value	Reason
Dec-29-2020 20:11:48 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Done	Initial Entry

5. Start Date:

Date	Location	User	Value	Reason
Dec-29-2020 20:11:48 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Done	Initial Entry

6. Ongoing?

Date	Location	User	Value	Reason
Dec-29-2020 20:11:48 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Done	Initial Entry

090177e196ae30cb\Final\Final On: 01-Apr-2021 04:17 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Dec/21/2020 Form: ILLNESS DETAILS - eCRF Audit Trail History

Form Version: 06-Jul-2020 21:52

Form Status: Data Complete

Site No: 1209

Site Name: (1209) Turkish MoH Yedikule Chest Diseases and Chest Surgery Training and Application Center

Subject No: 12091014

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
Dec-29-2020 20:12:16 (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-06-2021 18:57:32 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Jan-04-2021 10:32:55 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Closed	Close Auto Query
Jan-04-2021 10:32:55 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES <i>Respiratory Illness Diagnosis:</i> COVID-19 pneumonia Date of Diagnosis: Dec/18/2020	New Information
Jan-01-2021 23:58:02 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Opened	Yes is selected, however, either the diagnosis details or date of diagnosis is missing. Please correct.
Jan-01-2021 23:58:02 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Transcription Error
Jan-01-2021 23:58:02 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Date of Diagnosis: Dec/18/2020	Transcription Error
Dec-31-2020 19:08:01 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	Clin: As subject is symptomatic and has a positive local swab collected on

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Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Dec/21/2020 **Form:** ILLNESS DETAILS - eCRF Audit Trail History

Form Version: 06-Jul-2020 21:52

Form Status: Data Complete

Site No: 1209

Site Name: (1209) Turkish MoH Yedikule Chest Diseases and Chest Surgery Training and Application Center

Subject No: 12091014

Subject Initials: ---

Generated By: (b) (4)

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

				18Dec2020, diagnosis of COVID-19 should be recorded.
Dec-29-2020 20:12:16 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

3. Toxicity Grade:

Date	Location	User	Value	Reason
Dec-29-2020 20:12:16 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 1	Initial Entry

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Dec/21/2020 **Form:** ILLNESS DETAILS - SEVERE - eCRF Audit Trail History

Form Version: 17-Jul-2020 21:55

Form Status: Data Complete

Site No: 1209

Site Name: (1209) Turkish MoH Yedikule Chest Diseases and Chest Surgery Training and Application Center

Subject No: 12091014

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
Dec-29-2020 20:12:42 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

2. Subcategory of Clinical Event:

Date	Location	User	Value	Reason
Dec-29-2020 20:12:42 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

3. Was a diagnosis obtained?

Date	Location	User	Value	Reason
Dec-29-2020 20:12:42 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

4. Toxicity Grade:

Date	Location	User	Value	Reason
Dec-29-2020 20:12:42 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

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Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Dec/21/2020

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY - Audit Trail

Form Version: 10-Oct-2020 15:58

Form Status:

Site No: 1209

Site Name: (1209) Turkish MoH Yedikule Chest Diseases and Chest Surgery Training and Application Center

Subject No: 12091014

Subject Initials: ---

Generated By: (b) (4)

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

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Date	Location	User	Value	Reason
Jan-08-2021 14:39:48 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Created	

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Dec/21/2020

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

Form Version: 10-Oct-2020 15:58

Form Status: Data Complete

Site No: 1209

Site Name: (1209) Turkish MoH Yedikule Chest Diseases and Chest Surgery Training and Application Center

Subject No: 12091014

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 14:39:48 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: CLINICAL CHEMISTRY	Initial Entry
Jan-08-2021 14:35:40 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Initial Entry
Dec-29-2020 20:15:29 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

2. Laboratory Name and Address

Date	Location	User	Value	Reason
Jan-08-2021 14:39:48 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: American Hospital (Amerikan Hastanesi) Tesvikiye, Guzelbahce St. No:20, 34 365 Sisli/Istanbul/Turkey	Initial Entry
Jan-08-2021 14:35:40 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Initial Entry
Dec-29-2020 20:15:29 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

3. Collection Date:

Date	Location	User	Value	Reason
Jan-08-2021 14:39:48 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Dec/25/2020	Initial Entry
Jan-08-2021 14:35:40 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Initial Entry
Dec-29-2020 20:15:29 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

4. Specimen Type:

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Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Dec/21/2020

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

Form Version: 10-Oct-2020 15:58

Form Status: Data Complete

Site No: 1209

Site Name: (1209) Turkish MoH Yedikule Chest Diseases and Chest Surgery Training and Application Center

Subject No: 12091014

Subject Initials: ---

Generated By: (b) (4)

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

Date	Location	User	Value	Reason
Jan-08-2021 14:39:48 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: BLOOD	Initial Entry
Jan-08-2021 14:35:40 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Initial Entry
Dec-29-2020 20:15:29 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

5.a

Date	Location	User	Value	Reason
Jan-08-2021 14:40:31 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sponsor-Defined Identifier: 329 Test:: Not Done Result:: 11,6 Not Done:: Lab Normal Range: <i>Low</i> 0 <i>High</i> 5 <i>Unit</i> mg/L	Transcription Error
Jan-08-2021 14:39:48 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sponsor-Defined Identifier: 329 Test:: Not Done Result:: 11,6 Not Done:: Lab Normal Range: <i>High</i> 5 <i>Unit</i> mg/L	Initial Entry
Jan-08-2021 14:35:40 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sponsor-Defined Identifier	Initial Entry

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Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Dec/21/2020

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

Form Version: 10-Oct-2020 15:58

Form Status: Data Complete

Site No: 1209

Site Name: (1209) Turkish MoH Yedikule Chest Diseases and Chest Surgery Training and Application Center

Subject No: 12091014

Subject Initials: ---

Generated By: (b) (4)

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

			: Test:: Not Done Result:: Not Done:: Lab Normal Range:	
Dec-29-2020 20:15:29 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sponsor-Defined Identifier Not Done : Test:: Not Done Result:: Not Done Not Done:: Not Done Lab Normal Range: Not Done	Initial Entry

5.a Sponsor ID:

Date	Location	User	Value	Reason
Jan-08-2021 14:39:48 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 329	Initial Entry
Jan-08-2021 14:35:40 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Initial Entry
Dec-29-2020 20:15:29 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

5.a Test:

Date	Location	User	Value	Reason
Dec-29-2020 20:15:29 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

5.a Result:

Date	Location	User	Value	Reason
Jan-08-2021 14:40:31 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query

090177e196ae30cb\Final\Final On: 01-Apr-2021 04:17 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Dec/21/2020

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

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Form Status: Data Complete

Site No: 1209

Site Name: (1209) Turkish MoH Yedikule Chest Diseases and Chest Surgery Training and Application Center

Subject No: 12091014

Subject Initials: ---

Generated By: (b) (4)

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

Jan-08-2021 14:39:48 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	Result is present, but lab normal range (Low, high or Unit) is missing. Please correct or confirm.
Jan-08-2021 14:39:48 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 11,6	Initial Entry
Jan-08-2021 14:35:40 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Initial Entry
Dec-29-2020 20:15:29 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

5.a Not Done:

Date	Location	User	Value	Reason
Jan-08-2021 14:35:40 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Initial Entry
Dec-29-2020 20:15:29 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

5.a LNMT

Date	Location	User	Value	Reason
Jan-08-2021 14:40:31 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: <i>Low</i> 0 <i>High</i> 5 <i>Unit</i> mg/L	Transcription Error
Jan-08-2021 14:39:48 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: <i>High</i> 5 <i>Unit</i> mg/L	Initial Entry

090177e196ae30cb\Final\Final On: 01-Apr-2021 04:17 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Dec/21/2020

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

Form Version: 10-Oct-2020 15:58

Form Status: Data Complete

Site No: 1209

Site Name: (1209) Turkish MoH Yedikule Chest Diseases and Chest Surgery Training and Application Center

Subject No: 12091014

Subject Initials: ---

Generated By: (b) (4)

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

Jan-08-2021 14:35:40 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Initial Entry
Dec-29-2020 20:15:29 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

5.b

Date	Location	User	Value	Reason
Jan-08-2021 14:40:53 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sponsor-Defined Identifier: 30 Test:: Not Done Result:: 93 Not Done:: Lab Normal Range: Low 0 High 41 Unit U/L	Transcription Error
Jan-08-2021 14:39:48 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sponsor-Defined Identifier: 30 Test:: Not Done Result:: 93 Not Done:: Lab Normal Range: High 41 Unit U/L	Initial Entry
Jan-08-2021 14:35:40 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sponsor-Defined Identifier: : Test:: Not Done Result::	Initial Entry

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Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Dec/21/2020

Form Version: 10-Oct-2020 15:58

Site No: 1209

Subject No: 12091014

Generated By: (b) (4)

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

Form Status: Data Complete

Site Name: (1209) Turkish MoH Yedikule Chest Diseases and Chest Surgery Training and Application Center

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

			Not Done:: Lab Normal Range:	
Dec-29-2020 20:15:29 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sponsor-Defined Identifier Not Done : Test:: Not Done Result:: Not Done Not Done:: Not Done Lab Normal Range: Not Done	Initial Entry

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Dec/21/2020

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

Form Version: 10-Oct-2020 15:58

Form Status: Data Complete

Site No: 1209

Site Name: (1209) Turkish MoH Yedikule Chest Diseases and Chest Surgery Training and Application Center

Subject No: 12091014

Subject Initials: ---

Generated By: (b) (4)

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

5.b Sponsor ID:

Date	Location	User	Value	Reason
Jan-08-2021 14:39:48 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> 30	Initial Entry
Jan-08-2021 14:35:40 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u>	Initial Entry
Dec-29-2020 20:15:29 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Done	Initial Entry

5.b Test:

Date	Location	User	Value	Reason
Dec-29-2020 20:15:29 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Done	Initial Entry

5.b Result:

Date	Location	User	Value	Reason
Jan-08-2021 14:40:53 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Jan-08-2021 14:39:48 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	Result is present, but lab normal range (Low, high or Unit) is missing. Please correct or confirm.
Jan-08-2021 14:39:48 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> 93	Initial Entry
Jan-08-2021 14:35:40 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u>	Initial Entry
Dec-29-2020 20:15:29 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Done	Initial Entry

5.b Not Done:

Date	Location	User	Value	Reason
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090177e196ae30cb\Final\Final On: 01-Apr-2021 04:17 (GMT)

Header Text: C4591001**Visit:** POT_COVID_ILL 1 - Unscheduled Visit on Dec/21/2020**Form Version:** 10-Oct-2020 15:58**Site No:** 1209**Subject No:** 12091014**Generated By:** (b) (4)**Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History**Form Status:** Data Complete**Site Name:** (1209) Turkish MoH Yedikule Chest Diseases and Chest Surgery Training and Application Center**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 13:11

Jan-08-2021 14:35:40 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Initial Entry
Dec-29-2020 20:15:29 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

5.b LNMT

Date	Location	User	Value	Reason
Jan-08-2021 14:40:53 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: <i>Low</i> 0 <i>High</i> 41 <i>Unit</i> U/L	Transcription Error
Jan-08-2021 14:39:48 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: <i>High</i> 41 <i>Unit</i> U/L	Initial Entry
Jan-08-2021 14:35:40 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Initial Entry
Dec-29-2020 20:15:29 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

5.c

Date	Location	User	Value	Reason
Jan-08-2021 14:41:36 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sponsor-Defined Identifier: 28 Test:: Not Done Result:: 74 Not Done::	Transcription Error

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Dec/21/2020

Form Version: 10-Oct-2020 15:58

Site No: 1209

Subject No: 12091014

Generated By: (b) (4)

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

Form Status: Data Complete

Site Name: (1209) Turkish MoH Yedikule Chest Diseases and Chest Surgery Training and Application Center

Subject Initials: ---

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

			Lab Normal Range: <i>Low</i> 0 <i>High</i> 40 <i>Unit</i> U/L	
Jan-08-2021 14:39:48 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sponsor-Defined Identifier: 28 Test:: Not Done Result:: 74 Not Done:: Lab Normal Range: <i>High</i> 40 <i>Unit</i> U/L	Initial Entry
Jan-08-2021 14:35:40 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sponsor-Defined Identifier : Test:: Not Done Result:: Not Done:: Lab Normal Range:	Initial Entry
Dec-29-2020 20:15:29 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sponsor-Defined Identifier Not Done : Test:: Not Done Result:: Not Done Not Done:: Not Done Lab Normal Range: Not Done e	Initial Entry

090177e196ae30cb\Final\Final On: 01-Apr-2021 04:17 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Dec/21/2020

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

Form Version: 10-Oct-2020 15:58

Form Status: Data Complete

Site No: 1209

Site Name: (1209) Turkish MoH Yedikule Chest Diseases and Chest Surgery Training and Application Center

Subject No: 12091014

Subject Initials: ---

Generated By: (b) (4)

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

5.c Sponsor ID:

Date	Location	User	Value	Reason
Jan-08-2021 14:39:48 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> 28	Initial Entry
Jan-08-2021 14:35:40 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u>	Initial Entry
Dec-29-2020 20:15:29 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Done	Initial Entry

5.c Test:

Date	Location	User	Value	Reason
Dec-29-2020 20:15:29 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Done	Initial Entry

5.c Result:

Date	Location	User	Value	Reason
Jan-08-2021 14:41:36 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Jan-08-2021 14:39:48 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	Result is present, but lab normal range (Low, high or Unit) is missing. Please correct or confirm.
Jan-08-2021 14:39:48 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> 74	Initial Entry
Jan-08-2021 14:35:40 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u>	Initial Entry

090177e196ae30cb\Final\Final On: 01-Apr-2021 04:17 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Dec/21/2020

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

Form Version: 10-Oct-2020 15:58

Form Status: Data Complete

Site No: 1209

Site Name: (1209) Turkish MoH Yedikule Chest Diseases and Chest Surgery Training and Application Center

Subject No: 12091014

Subject Initials: ---

Generated By: (b) (4)

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

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5.c Result:

Date	Location	User	Value	Reason
Dec-29-2020 20:15:29 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

5.c Not Done:

Date	Location	User	Value	Reason
Jan-08-2021 14:35:40 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Initial Entry
Dec-29-2020 20:15:29 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

5.c LNMT

Date	Location	User	Value	Reason
Jan-08-2021 14:41:36 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: <i>Low</i> 0 <i>High</i> 40 <i>Unit</i> U/L	Transcription Error
Jan-08-2021 14:39:48 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: <i>High</i> 40 <i>Unit</i> U/L	Initial Entry
Jan-08-2021 14:35:40 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Initial Entry
Dec-29-2020 20:15:29 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

090177e196ae30cb\Final\Final On: 01-Apr-2021 04:17 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Dec/21/2020

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

Form Version: 10-Oct-2020 15:58

Form Status: Data Complete

Site No: 1209

Site Name: (1209) Turkish MoH Yedikule Chest Diseases and Chest Surgery Training and Application Center

Subject No: 12091014

Subject Initials: ---

Generated By: (b) (4)

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

5.d

Date	Location	User	Value	Reason
Jan-08-2021 14:42:22 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sponsor-Defined Identifier: 35 Test:: Not Done Result:: Not Done:: NOT DONE Lab Normal Range:	Initial Entry
Jan-08-2021 14:35:40 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sponsor-Defined Identifier: Test:: Not Done Result:: Not Done:: Lab Normal Range:	Initial Entry
Dec-29-2020 20:15:29 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sponsor-Defined Identifier: Not Done Test:: Not Done Result:: Not Done Not Done:: Not Done Lab Normal Range: Not Done	Initial Entry

090177e196ae30cb\Final\Final On: 01-Apr-2021 04:17 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Dec/21/2020

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

Form Version: 10-Oct-2020 15:58

Form Status: Data Complete

Site No: 1209

Site Name: (1209) Turkish MoH Yedikule Chest Diseases and Chest Surgery Training and Application Center

Subject No: 12091014

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 14:42:22 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> 35	Initial Entry
Jan-08-2021 14:35:40 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u>	Initial Entry
Dec-29-2020 20:15:29 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Done	Initial Entry

5.d Test:

Date	Location	User	Value	Reason
Dec-29-2020 20:15:29 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Done	Initial Entry

5.d Result:

Date	Location	User	Value	Reason
Jan-08-2021 14:35:40 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u>	Initial Entry
Dec-29-2020 20:15:29 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Done	Initial Entry

5.d Not Done:

Date	Location	User	Value	Reason
Jan-08-2021 14:42:22 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NOT DONE	Initial Entry
Jan-08-2021 14:35:40 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u>	Initial Entry
Dec-29-2020 20:15:29 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Done	Initial Entry

5.d LNMT

090177e196ae30cb\Final\Final On: 01-Apr-2021 04:17 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Dec/21/2020

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

Form Version: 10-Oct-2020 15:58

Form Status: Data Complete

Site No: 1209

Site Name: (1209) Turkish MoH Yedikule Chest Diseases and Chest Surgery Training and Application Center

Subject No: 12091014

Subject Initials: ---

Generated By: (b) (4)

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

Date	Location	User	Value	Reason
Jan-08-2021 14:35:40 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Initial Entry
Dec-29-2020 20:15:29 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

5.e

Date	Location	User	Value	Reason
Jan-08-2021 14:42:22 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sponsor-Defined Identifier: 21 Test:: Not Done Result:: Not Done:: NOT DONE Lab Normal Range:	Initial Entry
Jan-08-2021 14:35:40 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sponsor-Defined Identifier: Test:: Not Done Result:: Not Done:: Lab Normal Range:	Initial Entry
Dec-29-2020 20:15:29 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sponsor-Defined Identifier: Not Done Test:: Not Done Result:: Not Done Not Done:: Not Done Lab Normal Range: Not Done	Initial Entry

090177e196ae30cb\Final\Final On: 01-Apr-2021 04:17 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Dec/21/2020

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

Form Version: 10-Oct-2020 15:58

Form Status: Data Complete

Site No: 1209

Site Name: (1209) Turkish MoH Yedikule Chest Diseases and Chest Surgery Training and Application Center

Subject No: 12091014

Subject Initials: ---

Generated By: (b) (4)

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

5.e Sponsor ID:

Date	Location	User	Value	Reason
Jan-08-2021 14:42:22 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> 21	Initial Entry
Jan-08-2021 14:35:40 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u>	Initial Entry
Dec-29-2020 20:15:29 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Done	Initial Entry

5.e Test:

Date	Location	User	Value	Reason
Dec-29-2020 20:15:29 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Done	Initial Entry

5.e Result:

Date	Location	User	Value	Reason
Jan-08-2021 14:35:40 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u>	Initial Entry
Dec-29-2020 20:15:29 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Done	Initial Entry

5.e Not Done:

Date	Location	User	Value	Reason
Jan-08-2021 14:42:22 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NOT DONE	Initial Entry
Jan-08-2021 14:35:40 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u>	Initial Entry
Dec-29-2020 20:15:29 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Done	Initial Entry

5.e LNMT

090177e196ae30cb\Final\Final On: 01-Apr-2021 04:17 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Dec/21/2020

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

Form Version: 10-Oct-2020 15:58

Form Status: Data Complete

Site No: 1209

Site Name: (1209) Turkish MoH Yedikule Chest Diseases and Chest Surgery Training and Application Center

Subject No: 12091014

Subject Initials: ---

Generated By: (b) (4)

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

Date	Location	User	Value	Reason
Jan-08-2021 14:35:40 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Initial Entry
Dec-29-2020 20:15:29 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

5.f

Date	Location	User	Value	Reason
Jan-08-2021 14:42:22 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sponsor-Defined Identifier: 47 Test:: Not Done Result:: Not Done:: NOT DONE Lab Normal Range:	Initial Entry
Jan-08-2021 14:35:40 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sponsor-Defined Identifier : Test:: Not Done Result:: Not Done:: Lab Normal Range:	Initial Entry
Dec-29-2020 20:15:29 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sponsor-Defined Identifier Not Done : Test:: Not Done Result:: Not Done Not Done:: Not Done Lab Normal Range: Not Done	Initial Entry

090177e196ae30cb\Final\Final On: 01-Apr-2021 04:17 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Dec/21/2020

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

Form Version: 10-Oct-2020 15:58

Form Status: Data Complete

Site No: 1209

Site Name: (1209) Turkish MoH Yedikule Chest Diseases and Chest Surgery Training and Application Center

Subject No: 12091014

Subject Initials: ---

Generated By: (b) (4)

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

5.f Sponsor ID:

Date	Location	User	Value	Reason
Jan-08-2021 14:42:22 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> 47	Initial Entry
Jan-08-2021 14:35:40 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u>	Initial Entry
Dec-29-2020 20:15:29 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Done	Initial Entry

5.f Test:

Date	Location	User	Value	Reason
Dec-29-2020 20:15:29 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Done	Initial Entry

5.f Result:

Date	Location	User	Value	Reason
Jan-08-2021 14:35:40 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u>	Initial Entry
Dec-29-2020 20:15:29 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Done	Initial Entry

5.f Not Done:

Date	Location	User	Value	Reason
Jan-08-2021 14:42:22 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NOT DONE	Initial Entry
Jan-08-2021 14:35:40 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u>	Initial Entry
Dec-29-2020 20:15:29 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Done	Initial Entry

5.f LNMT

090177e196ae30cb\Final\Final On: 01-Apr-2021 04:17 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Dec/21/2020

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

Form Version: 10-Oct-2020 15:58

Form Status: Data Complete

Site No: 1209

Site Name: (1209) Turkish MoH Yedikule Chest Diseases and Chest Surgery Training and Application Center

Subject No: 12091014

Subject Initials: ---

Generated By: (b) (4)

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

Date	Location	User	Value	Reason
Jan-08-2021 14:35:40 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Initial Entry
Dec-29-2020 20:15:29 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

5.g

Date	Location	User	Value	Reason
Jan-08-2021 14:39:48 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sponsor-Defined Identifier 48 : Test:: Not Done Result:: 0,8 Not Done:: Lab Normal Range: <i>Low</i> 0,8 <i>High</i> 1,3 <i>Unit</i> mg/dL	Initial Entry

090177e196ae30cb\Final\Final On: 01-Apr-2021 04:17 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Dec/21/2020

Form Version: 10-Oct-2020 15:58

Site No: 1209

Subject No: 12091014

Generated By: (b) (4)

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

Form Status: Data Complete

Site Name: (1209) Turkish MoH Yedikule Chest Diseases and Chest Surgery Training and Application Center

Subject Initials: ---

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

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5.g				
Date	Location	User	Value	Reason
Jan-08-2021 14:35:40 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sponsor-Defined Identifier : Test:: Not Done Result:: Not Done:: Lab Normal Range:	Initial Entry
Dec-29-2020 20:15:29 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sponsor-Defined Identifier Not Done : Test:: Not Done Result:: Not Done Not Done:: Not Done Lab Normal Range: Not Done	Initial Entry

090177e196ae30cb\Final\Final On: 01-Apr-2021 04:17 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Dec/21/2020

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

Form Version: 10-Oct-2020 15:58

Form Status: Data Complete

Site No: 1209

Site Name: (1209) Turkish MoH Yedikule Chest Diseases and Chest Surgery Training and Application Center

Subject No: 12091014

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 14:39:48 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> 48	Initial Entry
Jan-08-2021 14:35:40 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u>	Initial Entry
Dec-29-2020 20:15:29 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Done	Initial Entry

5.g Test:

Date	Location	User	Value	Reason
Dec-29-2020 20:15:29 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Done	Initial Entry

5.g Result:

Date	Location	User	Value	Reason
Jan-08-2021 14:39:48 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> 0,8	Initial Entry
Jan-08-2021 14:35:40 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u>	Initial Entry
Dec-29-2020 20:15:29 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Done	Initial Entry

5.g Not Done:

Date	Location	User	Value	Reason
Jan-08-2021 14:35:40 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u>	Initial Entry
Dec-29-2020 20:15:29 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Done	Initial Entry

5.g LNMT

090177e196ae30cb\Final\Final On: 01-Apr-2021 04:17 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Dec/21/2020

Form Version: 10-Oct-2020 15:58

Site No: 1209

Subject No: 12091014

Generated By: (b) (4)

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

Form Status: Data Complete

Site Name: (1209) Turkish MoH Yedikule Chest Diseases and Chest Surgery Training and Application Center

Subject Initials: ---

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

Date	Location	User	Value	Reason
Jan-08-2021 14:39:48 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: <i>Low</i> 0,8 <i>High</i> 1,3 <i>Unit</i> mg/dL	Initial Entry
Jan-08-2021 14:35:40 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Initial Entry
Dec-29-2020 20:15:29 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

090177e196ae30cb\Final\Final On: 01-Apr-2021 04:17 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Dec/21/2020

Form: LOCAL LABORATORY DATA - REPEATING Hematology - Audit Trail

Form Version: 10-Oct-2020 16:02

Form Status:

Site No: 1209

Site Name: (1209) Turkish MoH Yedikule Chest Diseases and Chest Surgery Training and Application Center

Subject No: 12091014

Subject Initials: ---

Generated By: (b) (4)

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

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Date	Location	User	Value	Reason
Dec-29-2020 20:24:47 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Created	

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Dec/21/2020

Form Version: 10-Oct-2020 16:02

Site No: 1209

Subject No: 12091014

Generated By: (b) (4)

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

Form Status: Data Complete

Site Name: (1209) Turkish MoH Yedikule Chest Diseases and Chest Surgery Training and Application Center

Subject Initials: ---

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

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1. Lab Panel:

Date	Location	User	Value	Reason
Dec-29-2020 20:24:47 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: HEMATOLOGY	Initial Entry

2. Laboratory Name and Address

Date	Location	User	Value	Reason
Jan-06-2021 08:56:55 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Jan-05-2021 10:02:29 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Transcription Error
Jan-05-2021 10:02:29 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: American Hospital (Amerikan Hasta nes) Tesvikiye, Guzelbahce St. No:20, 34365 Sisli/Istanbul/Turkey	Transcription Error
Jan-04-2021 22:25:26 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	DM :A carriage return is identified, please do not press enter key, just type lab name all in single line with comma separated.
Dec-29-2020 20:24:47 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: American Hospital (Amerikan Hasta nes) Tesvikiye, Guzelbahce St. No:20, 34365 Sisli/Istanbul/Turkey	Initial Entry

3. Collection Date:

Date	Location	User	Value	Reason
Dec-31-2020 15:45:48 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Closed as per site response.
Dec-29-2020 20:29:53 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	The subject noticed that they're covid positive during their routine checkup without any covid-19 symptom.

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Header Text: C4591001**Visit:** POT_COVID_ILL 1 - Unscheduled Visit on Dec/21/2020**Form Version:** 10-Oct-2020 16:02**Site No:** 1209**Subject No:** 12091014**Generated By:** (b) (4)**Form:** LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History**Form Status:** Data Complete**Site Name:** (1209) Turkish MoH Yedikule Chest Diseases and Chest Surgery Training and Application Center**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 13:11

Dec-29-2020 20:24:47 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	Collection Date is before Date of First Symptom Started on the Signs and Symptoms form in the same visit. Please review and update as appropriate.
Dec-29-2020 20:24:47 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Dec/18/2020	Initial Entry

4. Specimen Type:

Date	Location	User	Value	Reason
Dec-29-2020 20:24:47 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: BLOOD	Initial Entry

5.a

Date	Location	User	Value	Reason
Dec-29-2020 20:24:47 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sponsor-Defined Identifier: Test:: Hemoglobin_PX1 Result:: 15,4 Not Done:: Lab Normal Range: <i>Low</i> 13,1 <i>High</i> 17,2 <i>Unit</i> g/dL	Initial Entry

5.a Sponsor ID:

Date	Location	User	Value	Reason
Dec-29-2020 20:24:47 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 1	Initial Entry

5.a Test:

Date	Location	User	Value	Reason
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Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Dec/21/2020

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Site No: 1209

Site Name: (1209) Turkish MoH Yedikule Chest Diseases and Chest Surgery Training and Application Center

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Subject Initials: ---

Generated By: (b) (4)

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Dec-29-2020 20:24:47 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Hemoglobin_PX1	Initial Entry
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5.a Result:

Date	Location	User	Value	Reason
Dec-29-2020 20:24:47 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 15,4	Initial Entry

5.a LNMT

Date	Location	User	Value	Reason
Dec-29-2020 20:24:47 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: <i>Low</i> 13,1 <i>High</i> 17,2 <i>Unit</i> g/dL	Initial Entry

5.b

Date	Location	User	Value	Reason
Dec-29-2020 20:24:47 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sponsor-Defined Identifier: Test:: Hematocrit_P X2 Result:: 45 Not Done:: Lab Normal Range: <i>Low</i> 38 <i>High</i> 51 <i>Unit</i> %	Initial Entry

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Site No: 1209

Site Name: (1209) Turkish MoH Yedikule Chest Diseases and Chest Surgery Training and Application Center

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Subject Initials: ---

Generated By: (b) (4)

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5.b Sponsor ID:

Date	Location	User	Value	Reason
Dec-29-2020 20:24:47 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 2	Initial Entry

5.b Test:

Date	Location	User	Value	Reason
Dec-29-2020 20:24:47 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Hematocrit_PX2	Initial Entry

5.b Result:

Date	Location	User	Value	Reason
Dec-29-2020 20:24:47 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 45	Initial Entry

5.b LNMT

Date	Location	User	Value	Reason
Dec-29-2020 20:24:47 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: <i>Low</i> 38 <i>High</i> 51 <i>Unit</i> %	Initial Entry

5.c

Date	Location	User	Value	Reason
Dec-29-2020 20:24:47 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sponsor-Defined Identifier: Test:: Erythrocytes_PX3 Result:: 5,15 Not Done::	Initial Entry

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Header Text: C4591001

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Site No: 1209

Site Name: (1209) Turkish MoH Yedikule Chest Diseases and Chest Surgery Training and Application Center

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Subject Initials: ---

Generated By: (b) (4)

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

			Lab Normal Range: <i>Low</i> 4,5 <i>High</i> 6,1 <i>Unit</i> /uL	
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5.c Sponsor ID:

Date	Location	User	Value	Reason
Dec-29-2020 20:24:47 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 3	Initial Entry

5.c Test:

Date	Location	User	Value	Reason
Dec-29-2020 20:24:47 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Erythrocytes_PX3	Initial Entry

5.c Result:

Date	Location	User	Value	Reason
Dec-29-2020 20:24:47 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 5,15	Initial Entry

5.c LNMT

Date	Location	User	Value	Reason
Dec-29-2020 20:24:47 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: <i>Low</i> 4,5 <i>High</i> 6,1 <i>Unit</i> /uL	Initial Entry

5.d

Date	Location	User	Value	Reason
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090177e196ae30cb\Final\Final On: 01-Apr-2021 04:17 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Dec/21/2020

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Site Name: (1209) Turkish MoH Yedikule Chest Diseases and Chest Surgery Training and Application Center

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Subject Initials: ---

Generated By: (b) (4)

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

Dec-29-2020 20:24:47 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sponsor-Defined Identifier: Test:: Platelets_P X5 Result:: Not Done:: NOT DONE E Lab Normal Range:	Initial Entry
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5.d Sponsor ID:

Date	Location	User	Value	Reason
Dec-29-2020 20:24:47 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 5	Initial Entry

5.d Test:

Date	Location	User	Value	Reason
Dec-29-2020 20:24:47 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Platelets_PX5	Initial Entry

5.d Not Done:

Date	Location	User	Value	Reason
Dec-29-2020 20:24:47 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NOT DONE	Initial Entry

5.e

Date	Location	User	Value	Reason
Dec-29-2020 20:24:47 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sponsor-Defined Identifier: Test:: Leukocytes_P X7 Result:: 7,68 Not Done::	Initial Entry

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Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Dec/21/2020

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Form Status: Data Complete

Site No: 1209

Site Name: (1209) Turkish MoH Yedikule Chest Diseases and Chest Surgery Training and Application Center

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Subject Initials: ---

Generated By: (b) (4)

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

			Lab Normal Range: <i>Low</i> 4,1 <i>High</i> 11,1 <i>Unit</i> /uL	
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5.e Sponsor ID:

Date	Location	User	Value	Reason
Dec-29-2020 20:24:47 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 7	Initial Entry

5.e Test:

Date	Location	User	Value	Reason
Dec-29-2020 20:24:47 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Leukocytes_PX7	Initial Entry

5.e Result:

Date	Location	User	Value	Reason
Dec-29-2020 20:24:47 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 7,68	Initial Entry

5.e LNMT

Date	Location	User	Value	Reason
Dec-29-2020 20:24:47 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: <i>Low</i> 4,1 <i>High</i> 11,1 <i>Unit</i> /uL	Initial Entry

5.f

Date	Location	User	Value	Reason
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Visit: POT_COVID_ILL 1 - Unscheduled Visit on Dec/21/2020

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Subject No: 12091014

Generated By: (b) (4)

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Form Status: Data Complete

Site Name: (1209) Turkish MoH Yedikule Chest Diseases and Chest Surgery Training and Application Center

Subject Initials: ---

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

Dec-29-2020 20:24:47 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sponsor-Defined Identifier: 608 Test:: Neutrophils_P X608 Result:: 4,3 Not Done:: Lab Normal Range: <i>Low</i> 1,8 <i>High</i> 7,5 <i>Unit</i> /uL	Initial Entry
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090177e196ae30cb\Final\Final On: 01-Apr-2021 04:17 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Dec/21/2020

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Form Status: Data Complete

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Site Name: (1209) Turkish MoH Yedikule Chest Diseases and Chest Surgery Training and Application Center

Subject No: 12091014

Subject Initials: ---

Generated By: (b) (4)

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

5.f Sponsor ID:

Date	Location	User	Value	Reason
Dec-29-2020 20:24:47 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 608	Initial Entry

5.f Test:

Date	Location	User	Value	Reason
Dec-29-2020 20:24:47 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Neutrophils_PX608	Initial Entry

5.f Result:

Date	Location	User	Value	Reason
Dec-29-2020 20:24:47 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 4,3	Initial Entry

5.f LNMT

Date	Location	User	Value	Reason
Dec-29-2020 20:24:47 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: <i>Low</i> 1,8 <i>High</i> 7,5 <i>Unit</i> /uL	Initial Entry

5.g

Date	Location	User	Value	Reason
Dec-29-2020 20:24:47 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sponsor-Defined Identifier: 609 Test:: Eosinophils_PX609 Result:: 0 Not Done::	Initial Entry

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Header Text: C4591001

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Form Status: Data Complete

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Subject Initials: ---

Generated By: (b) (4)

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

			Lab Normal Range: <i>Low</i> 0,0 <i>High</i> 0,5 <i>Unit</i> /uL	
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5.g Sponsor ID:

Date	Location	User	Value	Reason
Dec-29-2020 20:24:47 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 609	Initial Entry

5.g Test:

Date	Location	User	Value	Reason
Dec-29-2020 20:24:47 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Eosinophils_PX609	Initial Entry

5.g Result:

Date	Location	User	Value	Reason
Dec-29-2020 20:24:47 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 0	Initial Entry

5.g LNMT

Date	Location	User	Value	Reason
Dec-29-2020 20:24:47 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: <i>Low</i> 0,0 <i>High</i> 0,5 <i>Unit</i> /uL	Initial Entry

5.h

Date	Location	User	Value	Reason
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090177e196ae30cb\Final\Final On: 01-Apr-2021 04:17 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Dec/21/2020

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Subject No: 12091014

Generated By: (b) (4)

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

Form Status: Data Complete

Site Name: (1209) Turkish MoH Yedikule Chest Diseases and Chest Surgery Training and Application Center

Subject Initials: ---

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

Dec-29-2020 20:24:47 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sponsor-Defined Identifier: 612 Test:: Monocytes_P X612 Result:: 1,1 Not Done:: Lab Normal Range: <i>Low</i> 0,0 <i>High</i> 1,0 <i>Unit</i> /uL	Initial Entry
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090177e196ae30cb\Final\Final On: 01-Apr-2021 04:17 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Dec/21/2020

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Form Status: Data Complete

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Site Name: (1209) Turkish MoH Yedikule Chest Diseases and Chest Surgery Training and Application Center

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Subject Initials: ---

Generated By: (b) (4)

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5.h Sponsor ID:

Date	Location	User	Value	Reason
Dec-29-2020 20:24:47 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 612	Initial Entry

5.h Test:

Date	Location	User	Value	Reason
Dec-29-2020 20:24:47 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Monocytes_PX612	Initial Entry

5.h Result:

Date	Location	User	Value	Reason
Dec-29-2020 20:24:47 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 1,1	Initial Entry

5.h LNMT

Date	Location	User	Value	Reason
Dec-29-2020 20:24:47 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: <i>Low</i> 0,0 <i>High</i> 1,0 <i>Unit</i> /uL	Initial Entry

5.i

Date	Location	User	Value	Reason
Dec-29-2020 20:24:47 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sponsor-Defined Identifier: 610 Test:: Basophils_PX 610 Result:: 0,0 Not Done::	Initial Entry

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Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Dec/21/2020

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			Lab Normal Range: <i>Low</i> 0,0 <i>High</i> 0,1 <i>Unit</i> /uL	
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5.i Sponsor ID:

Date	Location	User	Value	Reason
Dec-29-2020 20:24:47 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 610	Initial Entry

5.i Test:

Date	Location	User	Value	Reason
Dec-29-2020 20:24:47 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Basophils_PX610	Initial Entry

5.i Result:

Date	Location	User	Value	Reason
Dec-29-2020 20:24:47 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 0,0	Initial Entry

5.i LNMT

Date	Location	User	Value	Reason
Dec-29-2020 20:24:47 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: <i>Low</i> 0,0 <i>High</i> 0,1 <i>Unit</i> /uL	Initial Entry

5.j

Date	Location	User	Value	Reason
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Visit: POT_COVID_ILL 1 - Unscheduled Visit on Dec/21/2020

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Form Status: Data Complete

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Subject Initials: ---

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

Dec-29-2020 20:24:47 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sponsor-Defined Identifier: 611 Test:: Lymphocytes_P X611 Result:: 2,2 Not Done:: Lab Normal Range: <i>Low</i> 1,2 <i>High</i> 5,8 <i>Unit</i> /uL	Initial Entry
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Header Text: C4591001

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Subject No: 12091014

Generated By: (b) (4)

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

Form Status: Data Complete

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

5.j Sponsor ID:

Date	Location	User	Value	Reason
Dec-29-2020 20:24:47 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 611	Initial Entry

5.j Test:

Date	Location	User	Value	Reason
Dec-29-2020 20:24:47 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Lymphocytes_PX611	Initial Entry

5.j Result:

Date	Location	User	Value	Reason
Dec-29-2020 20:24:47 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 2,2	Initial Entry

5.j LNMT

Date	Location	User	Value	Reason
Dec-29-2020 20:24:47 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: <i>Low</i> 1,2 <i>High</i> 5,8 <i>Unit</i> /uL	Initial Entry

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Header Text: C4591001**Visit:** POT_COVID_ILL 1 - Unscheduled Visit on Dec/21/2020 **Form:** VITAL SIGNS - COVID - eCRF Audit Trail History**Form Version:** 10-Oct-2020 15:59**Form Status:** Data Complete**Site No:** 1209**Site Name:** (1209) Turkish MoH Yedikule Chest Diseases and Chest Surgery Training and Application Center**Subject No:** 12091014**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 13:11[Back to Form](#)**1. Date:**

Date	Location	User	Value	Reason
Dec-29-2020 20:30:21 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

2.a

Date	Location	User	Value	Reason
Dec-29-2020 20:30:21 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Record Identifier:: Not Done Systolic:: Not Done Diastolic:: Not Done Respiratory Rate in respirati ons/minute: Not Done Heart Rate in beats/minute: Not Done	Initial Entry

2.a Record Identifier:

Date	Location	User	Value	Reason
Dec-29-2020 20:30:21 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

2.a Systolic:

Date	Location	User	Value	Reason
Dec-29-2020 20:30:21 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

2.a Diastolic:

Date	Location	User	Value	Reason
Dec-29-2020 20:30:21 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Dec/21/2020 **Form:** VITAL SIGNS - COVID - eCRF Audit Trail History

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Subject No: 12091014

Subject Initials: ---

Generated By: (b) (4)

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2.a Respiratory Rate in respirations/minute:

Date	Location	User	Value	Reason
Dec-29-2020 20:30:21 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

2.a Heart Rate in beats/minute:

Date	Location	User	Value	Reason
Dec-29-2020 20:30:21 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

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Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Dec/21/2020 Form: VITAL SIGNS - PULSE OX ROOM AIR - eCRF Audit Trail History

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Form Status: Data Complete

Site No: 1209

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Subject Initials: ---

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1. Date:

Date	Location	User	Value	Reason
Dec-29-2020 20:30:41 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

2.a

Date	Location	User	Value	Reason
Dec-29-2020 20:30:41 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Record Identifier:: Not Done Oxygen Saturation: Not Done	Initial Entry

2.a Record Identifier:

Date	Location	User	Value	Reason
Dec-29-2020 20:30:41 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

2.a SPO2 Pulse Oximetry %

Date	Location	User	Value	Reason
Dec-29-2020 20:30:41 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

090177e196ae30cb\Final\Final On: 01-Apr-2021 04:17 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Dec/21/2020 **Form:** OXYGENATION PARAMETERS - eCRF Audit Trail History

Form Version: 06-Jul-2020 21:52

Form Status: Data Complete

Site No: 1209

Site Name: (1209) Turkish MoH Yedikule Chest Diseases and Chest Surgery Training and Application Center

Subject No: 12091014

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
Dec-29-2020 20:31:02 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

2. Arterial Blood Gases PaO2 (mmHg):

Date	Location	User	Value	Reason
Dec-29-2020 20:31:02 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

3. FiO2 (Fraction of Inhaled Oxygen):

Date	Location	User	Value	Reason
Dec-29-2020 20:31:02 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

090177e196ae30cb\Final\Final On: 01-Apr-2021 04:17 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Dec/21/2020 **Form:** CONCOMITANT MEDICATIONS - VASOPRESSORS - Audit Trail

Form Version: 06-Jul-2020 21:55

Form Status:

Site No: 1209

Site Name: (1209) Turkish MoH Yedikule Chest Diseases and Chest Surgery Training and Application Center

Subject No: 12091014

Subject Initials: ---

Generated By: (b) (4)

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

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Date	Location	User	Value	Reason
Dec-29-2020 20:32:23 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Created	

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Dec/21/2020 **Form:** CONCOMITANT MEDICATIONS - VASOPRESSORS - Audit Trail

Form Version: 06-Jul-2020 21:55

Form Status:

Site No: 1209

Site Name: (1209) Turkish MoH Yedikule Chest Diseases and Chest Surgery Training and Application Center

Subject No: 12091014

Subject Initials: ---

Generated By: (b) (4)

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

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Date	Location	User	Value	Reason
Dec-29-2020 20:33:05 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Created	

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Dec/21/2020 **Form:** CONCOMITANT MEDICATIONS - VASOPRESSORS - Audit Trail

Form Version: 06-Jul-2020 21:55

Form Status:

Site No: 1209

Site Name: (1209) Turkish MoH Yedikule Chest Diseases and Chest Surgery Training and Application Center

Subject No: 12091014

Subject Initials: ---

Generated By: (b) (4)

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

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Date	Location	User	Value	Reason
Dec-29-2020 20:34:37 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Created	

Header Text: C4591001**Visit:** POT_COVID_ILL 1 - Unscheduled Visit on Dec/21/2020**Form Version:** 06-Jul-2020 21:55**Site No:** 1209**Subject No:** 12091014**Generated By:** (b) (4)**Form:** CONCOMITANT MEDICATIONS - VASOPRESSORS - eCRF Audit Trail History**Form Status:** Data Complete**Site Name:** (1209) Turkish MoH Yedikule Chest Diseases and Chest Surgery Training and Application Center**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 13:11[Back to Form](#)**1. What is the medication identifier?**

Date	Location	User	Value	Reason
Jan-01-2021 18:42:20 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Not Applicable	Initial Entry
Jan-01-2021 18:41:19 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry:	Transcription Error
Dec-29-2020 20:32:23 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 1	Initial Entry

2. Category:

Date	Location	User	Value	Reason
Jan-01-2021 18:42:20 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Not Applicable	Initial Entry
Jan-01-2021 18:41:19 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry:	Transcription Error
Dec-29-2020 20:32:23 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: GENERAL CONCOMITANT MEDICATIONS	Initial Entry

3. Concomitant Medications Pre-specified:

Date	Location	User	Value	Reason
Jan-01-2021 18:42:20 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Not Applicable	Initial Entry
Jan-01-2021 18:41:19 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry:	Transcription Error
Dec-29-2020 20:32:23 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: NO	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-06-2021 18:46:27 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query

Header Text: C4591001**Visit:** POT_COVID_ILL 1 - Unscheduled Visit on Dec/21/2020**Form Version:** 06-Jul-2020 21:55**Site No:** 1209**Subject No:** 12091014**Generated By:** (b) (4)**Form:** CONCOMITANT MEDICATIONS - VASOPRESSORS - eCRF Audit Trail History**Form Status:** Data Complete**Site Name:** (1209) Turkish MoH Yedikule Chest Diseases and Chest Surgery Training and Application Center**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 13:11

Jan-01-2021 18:42:20 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry
Jan-01-2021 18:41:19 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Transcription Error
Jan-01-2021 18:41:19 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Transcription Error
Dec-31-2020 19:12:53 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	Clin: Only vasopressors should be recorded on this CRF. If not a vasopressor, please remove and mark with FORM LEVEL comment of Not Applicable.
Dec-29-2020 20:32:23 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Remdesivir	Initial Entry

5. Start Date:

Date	Location	User	Value	Reason
Jan-01-2021 18:42:20 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry
Jan-01-2021 18:41:40 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Transcription Error
Dec-29-2020 20:32:23 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Dec/18/2020	Initial Entry

6. Ongoing?

Date	Location	User	Value	Reason
Jan-01-2021 18:42:20 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry
Jan-01-2021 18:41:52 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Transcription Error

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Dec/21/2020

Form Version: 06-Jul-2020 21:55

Site No: 1209

Subject No: 12091014

Generated By: (b) (4)

Form: CONCOMITANT MEDICATIONS - VASOPRESSORS - eCRF Audit Trail History

Form Status: Data Complete

Site Name: (1209) Turkish MoH Yedikule Chest Diseases and Chest Surgery Training and Application Center

Subject Initials: ---

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

Dec-29-2020 20:32:23 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO End Date: Dec/25/2020	Initial Entry
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090177e196ae30cb\Final\Final On: 01-Apr-2021 04:17 (GMT)

Header Text: C4591001**Visit:** POT_COVID_ILL 1 - Unscheduled Visit on Dec/21/2020**Form Version:** 06-Jul-2020 21:55**Site No:** 1209**Subject No:** 12091014**Generated By:** (b) (4)**Form:** CONCOMITANT MEDICATIONS - VASOPRESSORS - eCRF Audit Trail History**Form Status:** Data Complete**Site Name:** (1209) Turkish MoH Yedikule Chest Diseases and Chest Surgery Training and Application Center**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 13:11[Back to Form](#)**1. What is the medication identifier?**

Date	Location	User	Value	Reason
Jan-07-2021 11:36:00 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Not Applicable	Initial Entry
Jan-07-2021 09:54:01 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry:	Transcription Error
Dec-29-2020 20:33:05 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 2	Initial Entry

2. Category:

Date	Location	User	Value	Reason
Jan-07-2021 11:36:00 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Not Applicable	Initial Entry
Jan-07-2021 09:54:01 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry:	Transcription Error
Dec-29-2020 20:33:05 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: GENERAL CONCOMITANT MEDICATIONS	Initial Entry

3. Concomitant Medications Pre-specified:

Date	Location	User	Value	Reason
Jan-07-2021 11:36:00 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Not Applicable	Initial Entry
Jan-07-2021 09:54:01 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry:	Transcription Error
Dec-29-2020 20:33:05 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: NO	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-07-2021 22:22:22 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (6) [Redacted] [Redacted]	Query 1: Closed	Response satisfies query

Header Text: C4591001**Visit:** POT_COVID_ILL 1 - Unscheduled Visit on Dec/21/2020**Form Version:** 06-Jul-2020 21:55**Site No:** 1209**Subject No:** 12091014**Generated By:** (b) (4)**Form:** CONCOMITANT MEDICATIONS - VASOPRESSORS - eCRF Audit Trail History**Form Status:** Data Complete**Site Name:** (1209) Turkish MoH Yedikule Chest Diseases and Chest Surgery Training and Application Center**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 13:11

		(b) (4)		
Jan-07-2021 11:36:00 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry
Jan-07-2021 09:54:01 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Transcription Error
Jan-07-2021 09:54:01 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Transcription Error
Jan-06-2021 18:46:44 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b)(6)	Query 1: Opened	Clin: Only vasopressors should be recorded on this CRF. If not a vasopressor, please remove and mark with FORM LEVEL comment of Not Applicable.
Dec-29-2020 20:33:05 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Enoxaparin sodium (Clexane)	Initial Entry

5. Start Date:

Date	Location	User	Value	Reason
Jan-07-2021 11:36:00 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry
Jan-07-2021 11:35:22 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Transcription Error
Dec-29-2020 20:33:05 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Dec/18/2020	Initial Entry

6. Ongoing?

Date	Location	User	Value	Reason
Jan-07-2021 11:36:00 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry
Jan-07-2021 11:35:45 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Transcription Error
Dec-29-2020 20:33:05 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO End Date:	Initial Entry

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Dec/21/2020

Form Version: 06-Jul-2020 21:55

Site No: 1209

Subject No: 12091014

Generated By: (b) (4)

Form: CONCOMITANT MEDICATIONS - VASOPRESSORS - eCRF Audit Trail History

Form Status: Data Complete

Site Name: (1209) Turkish MoH Yedikule Chest Diseases and Chest Surgery Training and Application Center

Subject Initials: ---

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

			Dec/25/2020	
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090177e196ae30cb\Final\Final On: 01-Apr-2021 04:17 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Dec/21/2020

Form: CONCOMITANT MEDICATIONS - VASOPRESSORS - eCRF Audit Trail History

Form Version: 06-Jul-2020 21:55

Form Status: Data Complete

Site No: 1209

Site Name: (1209) Turkish MoH Yedikule Chest Diseases and Chest Surgery Training and Application Center

Subject No: 12091014

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-07-2021 11:39:55 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Not Applicable	Initial Entry
Jan-07-2021 09:52:07 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry:	Transcription Error
Dec-29-2020 20:34:37 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 3	Initial Entry

2. Category:

Date	Location	User	Value	Reason
Jan-07-2021 11:39:55 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Not Applicable	Initial Entry
Jan-07-2021 09:52:07 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry:	Transcription Error
Dec-29-2020 20:34:37 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: GENERAL CONCOMITANT MEDICATIONS	Initial Entry

3. Concomitant Medications Pre-specified:

Date	Location	User	Value	Reason
Jan-07-2021 11:39:55 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Not Applicable	Initial Entry
Jan-07-2021 09:52:07 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry:	Transcription Error
Dec-29-2020 20:34:37 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: NO	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-07-2021 22:22:37 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query

090177e196ae30cb\Final\Final On: 01-Apr-2021 04:17 (GMT)

Header Text: C4591001**Visit:** POT_COVID_ILL 1 - Unscheduled Visit on Dec/21/2020**Form Version:** 06-Jul-2020 21:55**Site No:** 1209**Subject No:** 12091014**Generated By:** (b) (4)**Form:** CONCOMITANT MEDICATIONS - VASOPRESSORS - eCRF Audit Trail History**Form Status:** Data Complete**Site Name:** (1209) Turkish MoH Yedikule Chest Diseases and Chest Surgery Training and Application Center**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 13:11

		(b) (4)		
Jan-07-2021 11:39:55 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry
Jan-07-2021 09:52:07 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Transcription Error
Jan-07-2021 09:52:07 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Transcription Error
Jan-06-2021 18:46:59 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	Clin: Only vasopressors should be recorded on this CRF. If not a vasopressor, please remove and mark with FORM LEVEL comment of Not Applicable.
Dec-29-2020 20:34:37 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Pantoprazol (Pantpas)	Initial Entry

5. Start Date:

Date	Location	User	Value	Reason
Jan-07-2021 11:39:55 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry
Jan-07-2021 11:39:05 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Transcription Error
Dec-29-2020 20:34:37 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Dec/18/2020	Initial Entry

6. Ongoing?

Date	Location	User	Value	Reason
Jan-07-2021 11:39:55 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry
Jan-07-2021 11:37:45 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Transcription Error
Dec-29-2020 20:34:37 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO End Date:	Initial Entry

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Dec/21/2020

Form Version: 06-Jul-2020 21:55

Site No: 1209

Subject No: 12091014

Generated By: (b) (4)

Form: CONCOMITANT MEDICATIONS - VASOPRESSORS - eCRF Audit Trail History

Form Status: Data Complete

Site Name: (1209) Turkish MoH Yedikule Chest Diseases and Chest Surgery Training and Application Center

Subject Initials: ---

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

			Dec/25/2020	
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090177e196ae30cb\Final\Final On: 01-Apr-2021 04:17 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Dec/21/2020 **Form:** IMAGING - Audit Trail

Form Version: 06-Jul-2020 21:53

Form Status:

Site No: 1209

Site Name: (1209) Turkish MoH Yedikule Chest Diseases and Chest Surgery Training and Application Center

Subject No: 12091014

Subject Initials: ---

Generated By: (b) (4)

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

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Date	Location	User	Value	Reason
Jan-08-2021 14:31:53 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Created	

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Dec/21/2020 Form: IMAGING - eCRF Audit Trail History

Form Version: 06-Jul-2020 21:53

Form Status: Data Complete

Site No: 1209

Site Name: (1209) Turkish MoH Yedikule Chest Diseases and Chest Surgery Training and Application Center

Subject No: 12091014

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-11-2021 08:28:34 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Jan-08-2021 14:52:28 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	After the subject's PCR result came out as a positive, they hospitalized for COVID-19 illness.
Jan-08-2021 14:31:53 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	Date of Assessment is before Date of First Symptom Started on the Signs and Symptoms form in the same visit. Please review and update as appropriate.
Jan-08-2021 14:31:53 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Dec/18/2020	Initial Entry
Jan-08-2021 14:21:37 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Initial Entry
Dec-29-2020 20:34:54 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

2. Location of Assessment:

Date	Location	User	Value	Reason
Jan-08-2021 14:31:53 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: CHEST	Initial Entry
Jan-08-2021 14:21:37 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Initial Entry
Dec-29-2020 20:34:54 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

090177e196ae30cb\Final\Final On: 01-Apr-2021 04:17 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Dec/21/2020 Form: IMAGING - eCRF Audit Trail History

Form Version: 06-Jul-2020 21:53

Form Status: Data Complete

Site No: 1209

Site Name: (1209) Turkish MoH Yedikule Chest Diseases and Chest Surgery Training and Application Center

Subject No: 12091014

Subject Initials: ---

Generated By: (b) (4)

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

3. Type of Imaging Exam:

Date	Location	User	Value	Reason
Jan-08-2021 14:31:53 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: CT SCAN	Initial Entry
Jan-08-2021 14:21:37 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Initial Entry
Dec-29-2020 20:34:54 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

4. Assessment:

Date	Location	User	Value	Reason
Jan-13-2021 19:25:38 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Jan-13-2021 09:55:36 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Transcription Error
Jan-13-2021 09:55:36 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: ABNORMAL <i>If abnormal, specify findings:</i> there is icy glass appearance of the upper and down lobe of left lung	Transcription Error
Jan-12-2021 16:31:36 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	Clin: Please record assessment.
Jan-08-2021 14:31:53 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: UNKNOWN	Initial Entry
Jan-08-2021 14:21:37 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Initial Entry
Dec-29-2020 20:34:54 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

090177e196ae30cb\Final\Final On: 01-Apr-2021 04:17 (GMT)

Header Text: C4591001

Visit: POT_COVID_CONVA 1 - Unscheduled Visit **Form:** DATE OF VISIT - ILLNESS CONVALESCENT - eCRF Audit Trail
on Feb/02/2021 History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Frozen, Verified

Site No: 1209

Site Name: (1209) Turkish MoH Yedikule Chest Diseases and Chest Surgery
Training and Application Center

Subject No: 12091014

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-02-2021 09:13:19 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Feb/2/2021	Initial Entry

3. COVID-19 Illness Visit:

Date	Location	User	Value	Reason
Feb-02-2021 09:13:19 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: COVID_A1	Initial Entry

090177e196ae30cb\Final\Final On: 01-Apr-2021 04:17 (GMT)

Header Text: C4591001**Visit:** POT_COVID_CONVA 1 - Unscheduled Visit
on Feb/02/2021**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - eCRF
Audit Trail History**Form Version:** 22-Apr-2020 21:03**Form Status:** Data Complete, Frozen, Verified**Site No:** 1209**Site Name:** (1209) Turkish MoH Yedikule Chest Diseases and Chest Surgery
Training and Application Center**Subject No:** 12091014**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-02-2021 09:14:48 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Feb-02-2021 09:14:48 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SERUM	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Feb-02-2021 09:17:24 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Feb-02-2021 09:14:48 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Feb-02-2021 09:14:48 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Date of Collection: Feb/2/2021	Initial Entry

5.a

Date	Location	User	Value	Reason
Feb-02-2021 09:17:24 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BPZBS5	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Feb-02-2021 09:17:24 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BPZBS5	Initial Entry

5.b

Header Text: C4591001

Visit: POT_COVID_CONVA 1 - Unscheduled Visit on Feb/02/2021

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1209

Site Name: (1209) Turkish MoH Yedikule Chest Diseases and Chest Surgery Training and Application Center

Subject No: 12091014

Subject Initials: ---

Generated By: (b) (4)

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

Date	Location	User	Value	Reason
Feb-02-2021 09:17:40 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Sample ID: BPZBS6	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Feb-02-2021 09:17:40 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> BPZBS6	Initial Entry

5.c

Date	Location	User	Value	Reason
Feb-02-2021 09:17:57 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Sample ID: BRZDRV	Initial Entry

5.c Sample ID

Date	Location	User	Value	Reason
Feb-02-2021 09:17:57 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> BRZDRV	Initial Entry

5.d

Date	Location	User	Value	Reason
Feb-02-2021 09:18:11 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Sample ID: BRZDRW	Initial Entry

5.d Sample ID

Date	Location	User	Value	Reason
Feb-02-2021 09:18:11 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> BRZDRW	Initial Entry

090177e196ae30cb\Final\Final On: 01-Apr-2021 04:17 (GMT)

Header Text: C4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1209

Subject No: 12091014

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - Audit Trail

Form Status:

Site Name: (1209) Turkish MoH Yedikule Chest Diseases and Chest Surgery Training and Application Center

Subject Initials: ---

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

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Date	Location	User	Value	Reason
Jan-18-2021 15:10:02 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Created	

Header Text: C4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1209

Subject No: 12091014

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Frozen

Site Name: (1209) Turkish MoH Yedikule Chest Diseases and Chest Surgery Training and Application Center

Subject Initials: ---

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

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1. Category:

Date	Location	User	Value	Reason
Jan-18-2021 15:10:02 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: ADVERSE EVENT	Initial Entry

2. AE ID:

Date	Location	User	Value	Reason
Jan-18-2021 15:10:02 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 1	Initial Entry

3. Adverse Event:

(If possible specify diagnosis, not individual symptoms)

Date	Location	User	Value	Reason
Jan-18-2021 15:10:02 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: COVID-19 Illness	Initial Entry

4. Start Date Time:

Date	Location	User	Value	Reason
Jan-18-2021 15:10:48 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Dec/18/2020 UNK:UNK	Transcription Error
Jan-18-2021 15:10:02 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Jan/18/2021 UNK:UNK	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Jan-18-2021 15:10:48 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Jan-18-2021 15:10:28 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	For COVID-19 Illness End Date & Time 23/Dec/2020 UNK:UNK is before the Start Date & Time 18/Jan/2021 UNK:UNK.
Jan-18-2021 15:10:28	ACV0PFEINFP6000	(b) (6)	Data Entry:	Transcription Error

090177e196ae30cb\Final\Final On: 01-Apr-2021 04:17 (GMT)

Header Text: C4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1209

Subject No: 12091014

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Frozen

Site Name: (1209) Turkish MoH Yedikule Chest Diseases and Chest Surgery Training and Application Center

Subject Initials: ---

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

(UTC+03:00) Istanbul		(b) (4), (b) (6)	NO End Date Time: Dec/23/2020 UNK:UNK	
Jan-18-2021 15:10:02 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	For COVID-19 Illness End Date & Time 20/Dec/2020 UNK:UNK is before the Start Date & Time 18/Jan/2021 UNK:UNK.
Jan-18-2021 15:10:02 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO End Date Time: Dec/20/2020 UNK:UNK	Initial Entry

6. Toxicity Grade:

Date	Location	User	Value	Reason
Feb-03-2021 00:10:10 (UTC+03:00) Istanbul	ACV0PFEINFP6000	Quan Jason Gong (b) (4)	Query 1: Closed	Response satisfies query
Feb-02-2021 16:46:14 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	The subject hospitalized for isolation, so this SAE does not interfere with subject's usual function.
Feb-01-2021 23:11:18 (UTC+03:00) Istanbul	ACV0PFEINFP6000	Quan Jason Gong (b) (4)	Query 1: Opened	GPDClin: Please clarify the severity grade for this SAE according to protocol 10.3.3.
Jan-18-2021 15:10:02 (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).

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Header Text: C4591001

Visit: Logs - Unscheduled

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Site No: 1209

Subject No: 12091014

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Frozen

Site Name: (1209) Turkish MoH Yedikule Chest Diseases and Chest Surgery Training and Application Center

Subject Initials: ---

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

Date	Location	User	Value	Reason
Jan-20-2021 14:40:46 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Closed	Response satisfies query
Jan-19-2021 15:17:02 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Answered	Transcription Error
Jan-19-2021 15:17:02 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Is this serious event associated with congenital anomaly or birth defect? NO Did this serious event result in death? NO Did this serious event require or prolong hospitalization? YES Did this serious event result in persistent or significant disability/incapacity? NO Is this serious event life threatening? NO Other medically important serious event NO	Transcription Error
Jan-19-2021 12:59:30 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Opened	SAE RECON:AER#2020506841 Covid-19 (onset date:21Dec2020)was reported as serious in Safety database but updated to nonserious in AE CRF. Please confirm

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Header Text: C4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1209

Subject No: 12091014

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Frozen

Site Name: (1209) Turkish MoH Yedikule Chest Diseases and Chest Surgery Training and Application Center

Subject Initials: ---

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				and update CRF. If safety update is required, submit a follow-up SAE Form.
Jan-19-2021 12:58:08 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Deleted	Query can be addressed internally
Jan-19-2021 04:45:08 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	For AE COVID-19 Illness: Response to "Is the adverse event serious?" is 'No' but "Serious Adverse Event Number" is present.
Jan-18-2021 15:10:02 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

8. Is this adverse event the result of a study Medication Error?
If Yes, record the type of medication error on the Medication Error Log.

Date	Location	User	Value	Reason
Jan-18-2021 15:10:02 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

9. Is this event related to study treatment:

Date	Location	User	Value	Reason
Jan-18-2021 15:10:02 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NOT RELATED If Not Related to study treatment(s), this event is due to: OTHER If Other, specify: Covid-19 pandemic	Initial Entry

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Jan-18-2021 15:10:02 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NOT APPLICABLE	Initial Entry

11. Was a Concomitant Medication given?

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Header Text: C4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1209

Subject No: 12091014

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Frozen

Site Name: (1209) Turkish MoH Yedikule Chest Diseases and Chest Surgery Training and Application Center

Subject Initials: ---

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

Date	Location	User	Value	Reason
Feb-04-2021 15:59:30 (UTC+03:00) Istanbul	ACV0PFEINFP6000	Quan Jason Gong (b) (4)	Query 1: Closed	Response satisfies query
Feb-04-2021 10:45:58 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Transcription Error
Feb-04-2021 10:45:58 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Transcription Error
Feb-03-2021 18:17:39 (UTC+03:00) Istanbul	ACV0PFEINFP6000	Quan Jason Gong (b) (4)	Query 1: Reissued:Opened	GPDClin: Thank you for the information! This question is not only asking the medication intended to cure Covid-19. Any medication given to manage the AE would be included. Based on your response, suggest to change answer to "Yes".
Feb-03-2021 15:14:21 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	There are no concomitant medications known given to the subject. They treated the subject with Remdesivir, Enoxaparin sodium and, Pantoprazole.
Feb-01-2021 23:12:56 (UTC+03:00) Istanbul	ACV0PFEINFP6000	Quan Jason Gong (b) (4)	Query 1: Opened	GPDClin: Please clarify if any treatment was given to the subject.
Jan-18-2021 15:10:02 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Jan-18-2021 15:10:02 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

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Header Text: C4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1209

Subject No: 12091014

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Frozen

Site Name: (1209) Turkish MoH Yedikule Chest Diseases and Chest Surgery Training and Application Center

Subject Initials: ---

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

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

Date	Location	User	Value	Reason
Jan-18-2021 15:10:02 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: RECOVERED/RESOLVED	Initial Entry

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

Date	Location	User	Value	Reason
Jan-18-2021 15:10:02 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

15. Serious Adverse Event Number: For Pfizer Use Only

Date	Location	User	Value	Reason
Jan-19-2021 04:45:08 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 2020506841	Initial Entry

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Header Text: C4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1209

Subject No: 12091014

Generated By: (b) (4)

Form: CONCOMITANT MEDICATIONS - NON STUDY VACCINATIONS - Audit Trail

Form Status:

Site Name: (1209) Turkish MoH Yedikule Chest Diseases and Chest Surgery Training and Application Center

Subject Initials: ---

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

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Date	Location	User	Value	Reason
Dec-23-2020 13:47:02 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Created	

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: 1209

Site Name: (1209) Turkish MoH Yedikule Chest Diseases and Chest Surgery Training and Application Center

Subject No: 12091014

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-23-2020 13:47:02 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> 1	Initial Entry

2. Category:

Date	Location	User	Value	Reason
Dec-23-2020 13:47:02 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> VACCINATIONS	Initial Entry

3. Concomitant Medications Pre-specified:

Date	Location	User	Value	Reason
Dec-23-2020 13:47:02 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> NO	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-23-2020 13:47:02 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> SKY Cellflu Quadrivalent	Initial Entry

5. Date:

Date	Location	User	Value	Reason
Dec-23-2020 13:47:02 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Dec/16/2020	Initial Entry

090177e196ae30cb\Final\Final On: 01-Apr-2021 04:17 (GMT)

Header Text: C4591001

Visit: End of Treatment - Unscheduled

Form Version: 10-Dec-2020 02:29

Site No: 1209

Subject No: 12091014

Generated By: (b) (4)

Form: DISPOSITION - TREATMENT - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1209) Turkish MoH Yedikule Chest Diseases and Chest Surgery Training and Application Center

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-31-2020 09:53:17 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Dec/31/2020	Initial Entry

2. Phase of Disposition:

Date	Location	User	Value	Reason
Dec-31-2020 09:53:17 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: VACCINATION	Initial Entry

3. Status:

Date	Location	User	Value	Reason
Dec-31-2020 09:53:17 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: COMPLETED	Initial Entry

090177e196ae30cb\Final\Final On: 01-Apr-2021 04:17 (GMT)

Header Text: C4591001

Visit: Potential ReVax Initial Contact - Unscheduled **Form:** DATE OF VISIT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen, Verified

Site No: 1209

Site Name: (1209) Turkish MoH Yedikule Chest Diseases and Chest Surgery Training and Application Center

Subject No: 12091014

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-20-2021 14:11:05 (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:** FURTHER VACCINATION CONFIRMATION - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:25

Form Status: Data Complete, Frozen, Verified

Site No: 1209

Site Name: (1209) Turkish MoH Yedikule Chest Diseases and Chest Surgery Training and Application Center

Subject No: 12091014

Subject Initials: ---

Generated By: (b) (4)

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

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

Date	Location	User	Value	Reason
Jan-20-2021 14:11:25 (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

Header Text: C4591001

Visit: Disposition - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1209

Subject No: 12091014

Generated By: (b) (4)

Form: TREATMENT UNBLINDED - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1209) Turkish MoH Yedikule Chest Diseases and Chest Surgery Training and Application Center

Subject Initials: ---

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

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1. Date Treatment Unblinded :

Date	Location	User	Value	Reason
Jan-20-2021 14:08:50 (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
Jan-20-2021 14:08:50 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: ASSESS ELIGIBILITY FOR ADDITI ONAL VACCINATION	Initial Entry

Header Text: C4591001

Visit: Disposition - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1209

Subject No: 12091014

Generated By: (b) (4)

Form: WITHDRAWAL OF CONSENT - eCRF Audit Trail History

Form Status: Data Complete, Verified

Site Name: (1209) Turkish MoH Yedikule Chest Diseases and Chest Surgery Training and Application Center

Subject Initials: ---

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

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1. Withdrawal of Consent Date :

Date	Location	User	Value	Reason
Jan-20-2021 14:09:02 (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: 1209

Subject No: 12091014

Generated By: (b) (4)

Form: DEATH DETAILS CODED - eCRF Audit Trail History

Form Status: Data Complete, Verified

Site Name: (1209) Turkish MoH Yedikule Chest Diseases and Chest Surgery Training and Application Center

Subject Initials: ---

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

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1. Date of Collection / Notification of Death:

Date	Location	User	Value	Reason
Jan-20-2021 14:09:28 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

Header Text: C4591001

Visit: V101_VAX3

Form Version: 22-Apr-2020 21:02

Site No: 1209

Subject No: 12091014

Generated By: (b) (4)

Form: DATE OF VISIT - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1209) Turkish MoH Yedikule Chest Diseases and Chest Surgery Training and Application Center

Subject Initials: ---

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

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1. Date of Visit

Date	Location	User	Value	Reason
Feb-26-2021 09:54:22 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Feb/26/2021	Initial Entry

Header Text: C4591001

Visit: V101_VAX3

Form Version: 10-Dec-2020 02:31

Site No: 1209

Subject No: 12091014

Generated By: (b) (4)

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

Form Status: Data Complete, Frozen, Verified

Site Name: (1209) Turkish MoH Yedikule Chest Diseases and Chest Surgery Training and Application Center

Subject Initials: ---

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

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I. Consent Was:

Date	Location	User	Value	Reason
Feb-26-2021 09:54:34 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: OBTAINED Date Written Consent Obtained Feb/26/2021	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: 1209

Site Name: (1209) Turkish MoH Yedikule Chest Diseases and Chest Surgery Training and Application Center

Subject No: 12091014

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-26-2021 09:54:59 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Feb/26/2021	Initial Entry

2. Phase of Disposition:

Date	Location	User	Value	Reason
Feb-26-2021 09:54:59 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: REPEAT SCREENING 1	Initial Entry

3. Status:

Date	Location	User	Value	Reason
Feb-26-2021 09:54:59 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: COMPLETED	Initial Entry

090177e196ae30cb\Final\Final On: 01-Apr-2021 04:17 (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:** 1209**Site Name:** (1209) Turkish MoH Yedikule Chest Diseases and Chest Surgery
Training and Application Center**Subject No:** 12091014**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-26-2021 09:55:39 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Feb-26-2021 09:55:39 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SERUM	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Feb-26-2021 10:03:22 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Feb-26-2021 09:55:39 (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-26-2021 09:55:39 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Date of Collection: Feb/26/2021	Initial Entry

5.a

Date	Location	User	Value	Reason
Feb-26-2021 10:03:22 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BPZBSW	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Feb-26-2021 10:03:22 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BPZBSW	Initial Entry

5.b

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: 1209

Site Name: (1209) Turkish MoH Yedikule Chest Diseases and Chest Surgery
Training and Application Center

Subject No: 12091014

Subject Initials: ---

Generated By: (b) (4)

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

Date	Location	User	Value	Reason
Feb-26-2021 10:03:39 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Sample ID: BPZBSX	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Feb-26-2021 10:03:39 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> BPZBSX	Initial Entry

5.c

Date	Location	User	Value	Reason
Feb-26-2021 10:04:00 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Sample ID: BRZDRZ	Initial Entry

5.c Sample ID

Date	Location	User	Value	Reason
Feb-26-2021 10:04:00 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> BRZDRZ	Initial Entry

5.d

Date	Location	User	Value	Reason
Feb-26-2021 10:04:16 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Sample ID: BRZDS0	Initial Entry

5.d Sample ID

Date	Location	User	Value	Reason
Feb-26-2021 10:04:16 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> BRZDS0	Initial Entry

090177e196ae30cb\Final\Final On: 01-Apr-2021 04:17 (GMT)

Header Text: C4591001**Visit:** V101_VAX3**Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB - eCRF Audit Trail History**Form Version:** 22-Apr-2020 21:03**Form Status:** Data Complete, Frozen, Verified**Site No:** 1209**Site Name:** (1209) Turkish MoH Yedikule Chest Diseases and Chest Surgery Training and Application Center**Subject No:** 12091014**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-26-2021 10:04:45 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Feb-26-2021 10:04:45 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: NASAL_SWAB	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Feb-26-2021 10:05:04 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Feb-26-2021 10:04:45 (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-26-2021 10:04:45 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Date of Collection: Feb/26/2021	Initial Entry

5.a

Date	Location	User	Value	Reason
Feb-26-2021 10:05:04 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BPZBSV	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Feb-26-2021 10:05:04 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BPZBSV	Initial Entry

Header Text: C4591001

Visit: V101_VAX3

Form Version: 10-Dec-2020 02:26

Site No: 1209

Subject No: 12091014

Generated By: (b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1209) Turkish MoH Yedikule Chest Diseases and Chest Surgery Training and Application Center

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-26-2021 10:05:41 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NO	Initial Entry

2. Treatment Name

Date	Location	User	Value	Reason
Feb-26-2021 10:05:41 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> BNT162b2	Initial Entry

3. Formulation:

Date	Location	User	Value	Reason
Feb-26-2021 10:05:41 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> INJECTION	Initial Entry

4. Dose Date Time:

Date	Location	User	Value	Reason
Feb-26-2021 10:05:41 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Feb/26/2021 10:00	Initial Entry

5. Anatomical Location:

Date	Location	User	Value	Reason
Feb-26-2021 10:05:41 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> DELTOID MUSCLE	Initial Entry

6. Body Side:

Date	Location	User	Value	Reason
Feb-26-2021 10:05:41 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> LEFT	Initial Entry

7. Route:

Date	Location	User	Value	Reason
Feb-26-2021 10:05:41 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> INTRAMUSCULAR	Initial Entry

8. Actual Dose:

Date	Location	User	Value	Reason
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090177e196ae30cb\Final\Final On: 01-Apr-2021 04:17 (GMT)

Header Text: C4591001

Visit: V101_VAX3

Form Version: 10-Dec-2020 02:26

Site No: 1209

Subject No: 12091014

Generated By: (b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1209) Turkish MoH Yedikule Chest Diseases and Chest Surgery Training and Application Center

Subject Initials: ---

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

Date	Location	User	Value	Reason
Feb-26-2021 10:05:41 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> 30.0	Initial Entry

9. Unit:

Date	Location	User	Value	Reason
Feb-26-2021 10:05:41 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> ug	Initial Entry

10. Timeframe Subject Was Observed

Date	Location	User	Value	Reason
Feb-26-2021 10:05:41 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> 30 MINUTES	Initial Entry

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

Date	Location	User	Value	Reason
Feb-26-2021 10:36:42 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> YES	Initial Entry

090177e196ae30cb\Final\Final On: 01-Apr-2021 04:17 (GMT)

Header Text: C4591001

Visit: Subject Status - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1209

Subject No: 12091014

Generated By: (b) (4)

Form: SUBJECT STATUS - eCRF Audit Trail History

Form Status: Data Complete, Verified

Site Name: (1209) Turkish MoH Yedikule Chest Diseases and Chest Surgery Training and Application Center

Subject Initials: ---

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

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1. Subject Status

Date	Location	User	Value	Reason
Dec-31-2020 09:53:17 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: FOLLOW-UP	Initial Entry
Nov-03-2020 14:35:47 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: ENROLLED/RANDOMIZED	Initial Entry
Nov-03-2020 14:25:52 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SCREENED	Initial Entry

2. Subject Status Date

Date	Location	User	Value	Reason
Jan-19-2021 04:45:55 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Closed	Response satisfies query
Jan-18-2021 15:12:36 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Answered	Changed data per query
Jan-17-2021 13:09:25 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Opened	SAE RECON:AER#2020506841 Covid-19 (onset date:21Dec2020)was reported as serious in Safety database but missing in AE CRF. Please confirm and update CRF. If safety update is required, submit a follow-up SAE Form.
Jan-05-2021 10:59:26 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Illness visit completed
Dec-31-2020 09:53:17 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Dec/31/2020	Initial Entry
Dec-30-2020 17:45:02 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reissued:Candidate	RQ1: Thank you for the response. Please complete details once available for reported Illness eDiary response on 20DEC2020.
Dec-29-2020 21:31:56 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	The subject discharged from the hospital on 25

090177e196ae30cb\Final\Final On: 01-Apr-2021 04:17 (GMT)

Header Text: C4591001**Visit:** Subject Status - Unscheduled**Form Version:** 22-Apr-2020 21:03**Site No:** 1209**Subject No:** 12091014**Generated By:** (b) (4)**Form:** SUBJECT STATUS - eCRF Audit Trail History**Form Status:** Data Complete, Verified**Site Name:** (1209) Turkish MoH Yedikule Chest Diseases and Chest Surgery Training and Application Center**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 13:11

				Dec 2020. Also the subject is considering withdrawal from the study at the moment. When everything is clear and the subject is available for covid illness visit at site, cov ill visit will be performed asap.
Dec-29-2020 13:15:18 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reissued:Opened	RQ1: Thank you for the response, please confirm if the COVID visit is scheduled for symptoms reported on 20Dec2020 and update the details accordingly , else clarify.
Dec-28-2020 14:03:44 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reissued:Candidate	RQ1: Thank you for the response. Please complete details once available for reported Illness eDiary response on 20DEC2020.
Dec-24-2020 09:58:09 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	The site personnel called and questioned the subject at 21 Dec 2020 about their condition. Since the subject is not stable enough to make pot covid illness visit yet and their isolation is still ongoing, this visit will be planned as soon as possible.
Dec-23-2020 18:28:13 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	Illness ed diary: As per Illness ed diary records, subject reported "Yes" for the question "Have you experienced any of the following?" for the COVID-19 symptoms or diagnosis on 20DEC2020. But corresponding COVID Illness visit not reported. Please clarify.
Nov-03-2020 14:35:47 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Nov/3/2020	Initial Entry
Nov-03-2020 14:25:52 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Nov/3/2020	Initial Entry

Header Text: C4591001

Visit: Investigator Signature - Unscheduled

Form Version: 22-Apr-2020 21:04

Site No: 1209

Subject No: 12091014

Generated By: (b) (4)

Form: CASEBOOK SIGNATURE FORM - eCRF Audit Trail History

Form Status: Data Complete, Signed, Verified

Site Name: (1209) Turkish MoH Yedikule Chest Diseases and Chest Surgery Training and Application Center

Subject Initials: ---

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

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1. Casebook Signature

Date	Location	User	Value	Reason
Jan-21-2021 12:06:57 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Click Here to Enable	Initial Entry