

**Header Text:** C4591001

**Visit:** COHORT\_SELECTION

**Form Version:** 10-Oct-2020 16:01

**Site No:** 1207

**Subject No:** 12071055

**Generated By:** (b) (4)

**Form:** COHORT\_SELECTION

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site Name:** (1207) Ankara University Medical Faculty

**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

<b>Header Text:</b> C4591001	<b>Form:</b> MAIN INFORMED CONSENT
<b>Visit:</b> COHORT_SELECTION	<b>Form Status:</b> Data Complete, Locked, Frozen, Verified
<b>Form Version:</b> 22-Apr-2020 21:02	<b>Site Name:</b> (1207) Ankara University Medical Faculty
<b>Site No:</b> 1207	<b>Subject Initials:</b> ---
<b>Subject No:</b> 12071055	<b>Generated Time (GMT):</b> 29-Mar-2021 13:11
<b>Generated By:</b> (b) (4)	

[eCRF Audit Trail History](#)

**Informed Consent**

1.	Consent Was:	OBTAINED Date Written Consent Obtained Nov/5/2020
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090177e196ae4002\Final\Final On: 01-Apr-2021 05:28 (GMT)

**Header Text:** C4591001  
**Visit:** COHORT\_SELECTION **Form:** DEMOGRAPHY  
**Form Version:** 15-Sep-2020 21:54 **Form Status:** Data Complete, Locked, Frozen, Verified  
**Site No:** 1207 **Site Name:** (1207) Ankara University Medical Faculty  
**Subject No:** 12071055 **Subject Initials:** ---  
**Generated By:** (b) (4) **Generated Time (GMT):** 29-Mar-2021 13:11

[eCRF Audit Trail History](#)

Demography		
1.	Subject ID	[12071055]
2.	Birth Date:	(b) (6)/1955
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:	

090177e196ae4002\Final\Final On: 01-Apr-2021 05:28 (GMT)

**Header Text** C4591001

**Visit:** V1\_DAY1\_VAX1\_L

**Form Version:** 22-Apr-2020 21:02

**Site No:** 1207

**Subject No:** 12071055

**Generated By:** (b) (4)

**Form:** DATE OF VISIT

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site Name:** (1207) Ankara University Medical Faculty

**Subject Initials:** ---

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

[eCRF Audit Trail History](#)

**Date of Visit**

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

**Header Text:** C4591001

**Visit:** V1\_DAY1\_VAX1\_L

**Form Version:** 10-Oct-2020 16:00

**Site No:** 1207

**Subject No:** 12071055

**Generated By:** (b) (4)

**Form:** INCLUSION/EXCLUSION CRITERIA

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site Name:** (1207) Ankara University Medical Faculty

**Subject Initials:** ---

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

**Form Comments**

**Inclusion Criteria Not Met**

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

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

**Header Text:** C4591001  
**Visit:** V1\_DAY1\_VAX1\_L  
**Form Version:** 15-Sep-2020 21:52  
**Site No:** 1207  
**Subject No:** 12071055  
**Generated By:** (b) (4)

**Form:** DISPOSITION - SCREENING  
**Form Status:** Data Complete, Locked, Frozen, Verified  
**Site Name:** (1207) Ankara University Medical Faculty  
**Subject Initials:** ---  
**Generated Time (GMT):** 29-Mar-2021 13:11

[eCRF Audit Trail History](#)

Disposition - Screening		
1.	Date of Completion/Discontinuation /Death	Nov/5/2020
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:** 1207

**Subject No:** 12071055

**Generated By:** (b) (4)

**Form:** GENERAL MEDICAL HISTORY

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site Name:** (1207) Ankara University Medical Faculty

**Subject Initials:** ---

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

[eCRF Audit Trail History](#)

**Medical History Details**

1.a	Line/MH Number:	[1]
	Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:	[type 2 diabetes]
	Start Date:	UNK/UNK/2010
	Ongoing:	YES
1.b	Line/MH Number:	[2]
	Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:	[heart stent replacement surgery]
	Start Date:	UNK/UNK/2005
	Ongoing:	NO End Date: UNK/UNK/2005
1.c	Line/MH Number:	[3]
	Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:	[secong degree liver cirrhosis]
	Start Date:	UNK/UNK/2015
	Ongoing:	YES

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**Header Text:** C4591001

**Visit:** V1\_DAY1\_VAX1\_L

**Form Version:** 15-Sep-2020 21:57

**Site No:** 1207

**Subject No:** 12071055

**Generated By:** (b) (4)

**Form:** HIV STATUS

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site Name:** (1207) Ankara University Medical Faculty

**Subject Initials:** ---

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

[eCRF Audit Trail History](#)

**HIV Status**

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



**Header Text:** C4591001

**Visit:** V1\_DAY1\_VAX1\_L

**Form Version:** 10-Oct-2020 16:04

**Site No:** 1207

**Subject No:** 12071055

**Generated By:** (b) (4)

**Form:** VITAL SIGNS - BASELINE

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site Name:** (1207) Ankara University Medical Faculty

**Subject Initials:** ---

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

[eCRF Audit Trail History](#)

**Vital Signs**

1.	Date:	Nov/5/2020
2.	Weight:	[84.9]
3.	Unit:	kg
4.	Height:	[173.0]
5.	Unit:	cm
6.	Body Mass Index:	[28.4]

**Vital Signs Details**

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

090177e196ae4002\Final\Final On: 01-Apr-2021 05:28 (GMT)

<b>Header Text:</b> C4591001	<b>Form:</b> RANDOMIZATION
<b>Visit:</b> V1_DAY1_VAX1_L	<b>Form Status:</b> Data Complete, Locked, Frozen, Verified
<b>Form Version:</b> 22-Apr-2020 21:03	<b>Site Name:</b> (1207) Ankara University Medical Faculty
<b>Site No:</b> 1207	<b>Subject Initials:</b> ---
<b>Subject No:</b> 12071055	<b>Generated Time (GMT):</b> 29-Mar-2021 13:11
<b>Generated By:</b> (b) (4)	

[eCRF Audit Trail History](#)

Disposition		
1.	Randomization Date :	Nov/5/2020
2.	Randomization Number:	[274049]
3.	Randomization Group:	[ ]

**Header Text:** C4591001

**Visit:** V1\_DAY1\_VAX1\_L

**Form Version:** 22-Apr-2020 21:03

**Site No:** 1207

**Subject No:** 12071055

**Generated By:** (b) (4)

**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

**Form Status:** Data Complete, Frozen, Verified

**Site Name:** (1207) Ankara University Medical Faculty

**Subject Initials:** ---

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

[eCRF Audit Trail History](#)

**Electronic Sample Tracking**

1.	Data Origin	SITE
2.	Sample Type	SERUM
3.	Sample Collected?	YES Date of Collection: Nov/5/2020
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	[BRDGSR]
5.b	Sample ID	[BRDGSS]
5.c	Sample ID	[BSHZN9]
5.d	Sample ID	[BSHZNB]

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**Header Text:** C4591001

**Visit:** V1\_DAY1\_VAX1\_L

**Form Version:** 22-Apr-2020 21:03

**Site No:** 1207

**Subject No:** 12071055

**Generated By:** (b) (4)

**Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site Name:** (1207) Ankara University Medical Faculty

**Subject Initials:** ---

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

[eCRF Audit Trail History](#)

**Electronic Sample Tracking**

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB
3.	Sample Collected?	YES Date of Collection: Nov/5/2020
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	[BRDGR7]
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**Header Text:** C4591001

**Visit:** V1\_DAY1\_VAX1\_L

**Form Version:** 22-Apr-2020 21:04

**Site No:** 1207

**Subject No:** 12071055

**Generated By:** (b) (4)

**Form:** VACCINATION

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site Name:** (1207) Ankara University Medical Faculty

**Subject Initials:** ---

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

[eCRF Audit Trail History](#)

**Vaccination**

1.	Was there a temporary delay of vaccination?	NO
2.	Treatment Name	[BLINDED THERAPY]
3.	Formulation:	INJECTION
4.	Dose Date Time:	Nov/5/2020 10:22
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

090177e196ae4002\Final\Final On: 01-Apr-2021 05:28 (GMT)

<b>Header Text:</b> C4591001	<b>Form:</b> REACTOGENICITY DIARY
<b>Visit:</b> V1_DAY1_VAX1_L	<b>Form Status:</b> Data Complete, Locked, Frozen, Verified
<b>Form Version:</b> 06-Jul-2020 21:53	<b>Site Name:</b> (1207) Ankara University Medical Faculty
<b>Site No:</b> 1207	<b>Subject Initials:</b> ---
<b>Subject No:</b> 12071055	<b>Generated Time (GMT):</b> 29-Mar-2021 13:11
<b>Generated By:</b> (b) (4)	

[eCRF Audit Trail History](#)

Reactogenicity Diary		
1.	Select appropriate response - Reactogenicity diary collection	YES - REACTOGENICITY E-DIARY COLLECTED FOR THIS SUBJECT

090177e196ae4002\Final\Final On: 01-Apr-2021 05:28 (GMT)

**Header Text** C4591001

**Visit:** V2\_VAX2\_L

**Form Version:** 22-Apr-2020 21:02

**Site No:** 1207

**Subject No:** 12071055

**Generated By:** (b) (4)

**Form:** DATE OF VISIT

**Form Status:** Data Complete, Frozen, Verified

**Site Name:** (1207) Ankara University Medical Faculty

**Subject Initials:** ---

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

[eCRF Audit Trail History](#)

Date of Visit		
1.	Date of Visit	Nov/26/2020
2.	Erroneous Visit	

Header Text: C4591001

Visit: V2\_VAX2\_L

Form Version: 10-Oct-2020 16:03

Site No: 1207

Subject No: 12071055

Generated By: (b) (4)

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES

Form Status: Data Complete, Frozen, Verified

Site Name: (1207) Ankara University Medical Faculty

Subject Initials: ---

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

[eCRF Audit Trail History](#)

**Vaccination Symptoms Diary - Symptom Resolved Dates**

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

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**Header Text:** C4591001

**Visit:** V2\_VAX2\_L

**Form Version:** 10-Oct-2020 16:03

**Site No:** 1207

**Subject No:** 12071055

**Generated By:** (b) (4)

**Form:** VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES

**Form Status:** Data Complete, Frozen, Verified

**Site Name:** (1207) Ankara University Medical Faculty

**Subject Initials:** ---

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

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

090177e196ae4002\Final\Final On: 01-Apr-2021 05:28 (GMT)

**Header Text:** C4591001

**Visit:** V2\_VAX2\_L

**Form Version:** 10-Oct-2020 16:01

**Site No:** 1207

**Subject No:** 12071055

**Generated By:** (b) (4)

**Form:** VITAL SIGNS - TEMP

**Form Status:** Data Complete, Frozen, Verified

**Site Name:** (1207) Ankara University Medical Faculty

**Subject Initials:** ---

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

[eCRF Audit Trail History](#)

**Vital Signs**

1.	Date:	Nov/26/2020
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**Vital Signs Details**

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

**Header Text:** C4591001

**Visit:** V2\_VAX2\_L

**Form Version:** 22-Apr-2020 21:03

**Site No:** 1207

**Subject No:** 12071055

**Generated By:** (b) (4)

**Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB

**Form Status:** Data Complete, Frozen, Verified

**Site Name:** (1207) Ankara University Medical Faculty

**Subject Initials:** ---

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

[eCRF Audit Trail History](#)

**Electronic Sample Tracking**

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB
3.	Sample Collected?	YES Date of Collection: Nov/26/2020
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	[BRDGVN]
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090177e196ae4002\Final\Final On: 01-Apr-2021 05:28 (GMT)

**Header Text:** C4591001  
**Visit:** V2\_VAX2\_L **Form:** VACCINATION  
**Form Version:** 22-Apr-2020 21:04 **Form Status:** Data Complete, Frozen, Verified  
**Site No:** 1207 **Site Name:** (1207) Ankara University Medical Faculty  
**Subject No:** 12071055 **Subject Initials:** ---  
**Generated By:** (b) (4) **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/26/2020 10:54
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

090177e196ae4002\Final\Final On: 01-Apr-2021 05:28 (GMT)

<b>Header Text</b> C4591001	
<b>Visit:</b> V3_MONTH1_POSTVAX2_L	<b>Form:</b> DATE OF VISIT
<b>Form Version:</b> 22-Apr-2020 21:02	<b>Form Status:</b> Data Complete, Frozen, Verified
<b>Site No:</b> 1207	<b>Site Name:</b> (1207) Ankara University Medical Faculty
<b>Subject No:</b> 12071055	<b>Subject Initials:</b> ---
<b>Generated By:</b> (b) (4)	<b>Generated Time (GMT):</b> 29-Mar-2021 13:11

[eCRF Audit Trail History](#)

Date of Visit		
1.	Date of Visit	Jan/14/2021
2.	Erroneous Visit	

Header Text: C4591001

Visit: V3\_MONTH1\_POSTVAX2\_L

Form Version: 10-Oct-2020 16:03

Site No: 1207

Subject No: 12071055

Generated By: (b) (4)

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES

Form Status: Data Complete, Frozen, Verified

Site Name: (1207) Ankara University Medical Faculty

Subject Initials: ---

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

[eCRF Audit Trail History](#)

**Vaccination Symptoms Diary - Symptom Resolved Dates**

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

090177e196ae4002\Final\Final On: 01-Apr-2021 05:28 (GMT)

**Header Text:** C4591001

**Visit:** V3\_MONTH1\_POSTVAX2\_L

**Form Version:** 10-Oct-2020 16:03

**Site No:** 1207

**Subject No:** 12071055

**Generated By:** (b) (4)

**Form:** VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES

**Form Status:** Data Complete, Frozen, Verified

**Site Name:** (1207) Ankara University Medical Faculty

**Subject Initials:** ---

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

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

090177e196ae4002\Final\Final On: 01-Apr-2021 05:28 (GMT)

**Header Text:** C4591001

**Visit:** V3\_MONTH1\_POSTVAX2\_L

**Form Version:** 22-Apr-2020 21:03

**Site No:** 1207

**Subject No:** 12071055

**Generated By:** (b) (4)

**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

**Form Status:** Data Complete, Frozen, Verified

**Site Name:** (1207) Ankara University Medical Faculty

**Subject Initials:** ---

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

[eCRF Audit Trail History](#)

**Electronic Sample Tracking**

1.	Data Origin	SITE
2.	Sample Type	SERUM
3.	Sample Collected?	YES Date of Collection: Jan/14/2021
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	[BR5P01]
5.b	Sample ID	[BR5P02]
5.c	Sample ID	[BSHZWN]
5.d	Sample ID	[BSHZWP]

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**Header Text** C4591001

**Visit:** V4\_MONTH6\_L

**Form Version:** 22-Apr-2020 21:02

**Site No:** 1207

**Subject No:** 12071055

**Generated By:** (b) (4)

**Form:** DATE OF VISIT

**Form Status:** Not Started

**Site Name:** (1207) Ankara University Medical Faculty

**Subject Initials:** ---

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

**Date of Visit**

1.	Date of Visit	//
2.	Erroneous Visit	

**Header Text:** C4591001

**Visit:** V4\_MONTH6\_L

**Form Version:** 22-Apr-2020 21:03

**Site No:** 1207

**Subject No:** 12071055

**Generated By:** (b) (4)

**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

**Form Status:** Not Started

**Site Name:** (1207) Ankara University Medical Faculty

**Subject Initials:** ---

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

**Electronic Sample Tracking**

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

**Aliquot**

Please enter barcode for each aliquot.

5.	Sample ID	[ ]
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**Header Text** C4591001

**Visit:** V5\_MONTH12\_L

**Form Version:** 22-Apr-2020 21:02

**Site No:** 1207

**Subject No:** 12071055

**Generated By:** (b) (4)

**Form:** DATE OF VISIT

**Form Status:** Not Started

**Site Name:** (1207) Ankara University Medical Faculty

**Subject Initials:** ---

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

**Date of Visit**

1.	Date of Visit	//
2.	Erroneous Visit	

**Header Text:** C4591001

**Visit:** V5\_MONTH12\_L

**Form Version:** 22-Apr-2020 21:03

**Site No:** 1207

**Subject No:** 12071055

**Generated By:** (b) (4)

**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

**Form Status:** Not Started

**Site Name:** (1207) Ankara University Medical Faculty

**Subject Initials:** ---

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

**Electronic Sample Tracking**

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

**Aliquot**

Please enter barcode for each aliquot.

5.	Sample ID	[ ]
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**Header Text** C4591001

**Visit:** V6\_MONTH24\_L

**Form Version:** 22-Apr-2020 21:02

**Site No:** 1207

**Subject No:** 12071055

**Generated By:** (b) (4)

**Form:** DATE OF VISIT

**Form Status:** Not Started

**Site Name:** (1207) Ankara University Medical Faculty

**Subject Initials:** ---

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

**Date of Visit**

1.	Date of Visit	//
2.	Erroneous Visit	

**Header Text:** C4591001

**Visit:** V6\_MONTH24\_L

**Form Version:** 22-Apr-2020 21:03

**Site No:** 1207

**Subject No:** 12071055

**Generated By:** (b) (4)

**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

**Form Status:** Not Started

**Site Name:** (1207) Ankara University Medical Faculty

**Subject Initials:** ---

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

**Electronic Sample Tracking**

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

**Aliquot**

Please enter barcode for each aliquot.

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

**Header Text** C4591001

**Visit:** POT\_COVID\_ILL - New Unscheduled Visit

**Form:** DATE OF VISIT - ILLNESS ONSET

**Form Version:** 22-Apr-2020 21:03

**Form Status:** Not Started

**Site No:** 1207

**Site Name:** (1207) Ankara University Medical Faculty

**Subject No:** 12071055

**Subject Initials:** ---

**Generated By:** (b) (4)

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

**Date of Visit**

1.	Date of Visit	//
2.	Erroneous Visit	

**COVID-19 Illness Visit**

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

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL - New Unscheduled Visit

**Form:** SIGNS AND SYMPTOMS OF POTENTIAL COVID-19

**Form Version:** 20-Feb-2021 02:17

**Form Status:** Not Started

**Site No:** 1207

**Site Name:** (1207) Ankara University Medical Faculty

**Subject No:** 12071055

**Subject Initials:** ---

**Generated By:** (b) (4)

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

**Signs and Symptoms**

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

**Symptoms**

4.	Symptoms:	
	Was symptom present?	

**Symptoms - Other**

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



**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL - New Unscheduled Visit

**Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB SELF

**Form Version:** 22-Apr-2020 21:03

**Form Status:** Not Started

**Site No:** 1207

**Site Name:** (1207) Ankara University Medical Faculty

**Subject No:** 12071055

**Subject Initials:** ---

**Generated By:** (b) (4)

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

**Electronic Sample Tracking**

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

**Aliquot**

Please enter barcode for each aliquot.

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

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL - New Unscheduled Visit

**Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB

**Form Version:** 22-Apr-2020 21:03

**Form Status:** Not Started

**Site No:** 1207

**Site Name:** (1207) Ankara University Medical Faculty

**Subject No:** 12071055

**Subject Initials:** ---

**Generated By:** (b) (4)

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

**Electronic Sample Tracking**

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

**Aliquot**

Please enter barcode for each aliquot.

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

**Header Text:** C4591001  
**Visit:** POT\_COVID\_ILL - New Unscheduled Visit      **Form:** HEALTH CARE UTILIZATION  
**Form Version:** 20-Feb-2021 02:19      **Form Status:** Not Started  
**Site No:** 1207      **Site Name:** (1207) Ankara University Medical Faculty  
**Subject No:** 12071055      **Subject Initials:** ---  
**Generated By:** (b) (4)      **Generated Time (GMT):** 29-Mar-2021 13:11

**Health Care Utilization**

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

**Health Care Utilization Other**

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

**Health Care Utilization**

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

090177e196ae4002\Final\Final On: 01-Apr-2021 05:28 (GMT)

**Header Text:** C4591001  
**Visit:** POT\_COVID\_ILL - New Unscheduled Visit      **Form:** ILLNESS DETAILS  
**Form Version:** 06-Jul-2020 21:52      **Form Status:** Not Started  
**Site No:** 1207      **Site Name:** (1207) Ankara University Medical Faculty  
**Subject No:** 12071055      **Subject Initials:** ---  
**Generated By:** (b) (4)      **Generated Time (GMT):** 29-Mar-2021 13:11

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

**Header Text** C4591001

**Visit:** POT\_COVID\_CONVA - New Unscheduled Visit **Form:** DATE OF VISIT - ILLNESS CONVALESCENT

**Form Version:** 22-Apr-2020 21:04

**Form Status:** Not Started

**Site No:** 1207

**Site Name:** (1207) Ankara University Medical Faculty

**Subject No:** 12071055

**Subject Initials:** ---

**Generated By:** (b) (4)

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

**Date of Visit**

1.	Date of Visit	//
2.	Erroneous Visit	

**COVID-19 Illness Visit**

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

**Header Text:** C4591001

**Visit:** POT\_COVID\_CONVA - New Unscheduled Visit **Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

**Form Version:** 22-Apr-2020 21:03

**Form Status:** Not Started

**Site No:** 1207

**Site Name:** (1207) Ankara University Medical Faculty

**Subject No:** 12071055

**Subject Initials:** ---

**Generated By:** (b) (4)

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

**Electronic Sample Tracking**

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

**Aliquot**

Please enter barcode for each aliquot.

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

**Header Text** C4591001

**Visit:** POT\_COVID\_REPEAT\_SWAB - New  
Unscheduled Visit

**Form:** DATE OF VISIT - REPEAT SWAB

**Form Version:** 10-Oct-2020 15:57

**Form Status:** Not Started

**Site No:** 1207

**Site Name:** (1207) Ankara University Medical Faculty

**Subject No:** 12071055

**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:	
----	-----------------------	--

090177e196ae4002\Final\Final On: 01-Apr-2021 05:28 (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:** 1207

**Site Name:** (1207) Ankara University Medical Faculty

**Subject No:** 12071055

**Subject Initials:** ---

**Generated By:** (b) (4)

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

**Electronic Sample Tracking**

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

**Aliquot**

Please enter barcode for each aliquot.

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



**Header Text** C4591001

**Visit:** Logs

**Form:** ADVERSE EVENT REPORT

**Form Version:** 22-Apr-2020 21:02

**Site No:** 1207

**Site Name:** (1207) Ankara University Medical Faculty

**Subject No:** 12071055

**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	Bacterial Pneumonia	Feb/5/2021 UNK:UNK	NO End Date Time: Feb/9/2021 UNK:UNK	<a href="#">Repeating Pages</a>

090177e196ae4002\Final\Final On: 01-Apr-2021 05:28 (GMT)

Header Text: C4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1207

Subject No: 12071055

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Frozen, Verified

Site Name: (1207) Ankara University Medical Faculty

Subject Initials: ---

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

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[Form Audit Trail](#)

**Adverse Event Report**

1.	Category:	ADVERSE EVENT
2.	AE ID:	[1]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[Bacterial Pneumonia]
4.	Start Date Time:	Feb/5/2021 UNK:UNK
5.	Is the adverse event still ongoing?	NO End Date Time: Feb/9/2021 UNK:UNK
6.	Toxicity Grade:	4
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? YES  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? YES  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: [bacterial]
10.	Latest Action Taken with Study Treatment:	NOT APPLICABLE
11.	Was a Concomitant Medication given?	NO
12.	Was a Non-Drug Treatment given?	NO

090177e196ae4002\Final\Final On: 01-Apr-2021 05:28 (GMT)

**Header Text:** C4591001

**Visit:** Logs - Unscheduled

**Form Version:** 22-Apr-2020 21:02

**Site No:** 1207

**Subject No:** 12071055

**Generated By:** (b) (4)

**Form:** ADVERSE EVENT REPORT

**Form Status:** Data Complete, Frozen, Verified

**Site Name:** (1207) Ankara University Medical Faculty

**Subject Initials:** ---

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

13.	What was the outcome of this adverse event?:	FATAL
14.	Did the adverse event cause the subject to be discontinued from the study?	YES
15.	Serious Adverse Event Number: For Pfizer Use Only	[2021139362]

090177e196ae4002\Final\Final On: 01-Apr-2021 05:28 (GMT)

**Header Text:** C4591001

**Visit:** Logs

**Form:** MEDICATION ERROR

**Form Version:** 17-Jul-2020 21:54

**Site No:** 1207

**Site Name:** (1207) Ankara University Medical Faculty

**Subject No:** 12071055

**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.						<a href="#">Repeating Pages</a>

**Header Text:** C4591001

**Visit:** Logs - Unscheduled

**Form Version:** 17-Jul-2020 21:54

**Site No:** 1207

**Subject No:** 12071055

**Generated By:** (b) (4)

**Form:** MEDICATION ERROR

**Form Status:** Not Started

**Site Name:** (1207) Ankara University Medical Faculty

**Subject Initials:** ---

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

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**Medication Error**

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

090177e196ae4002\Final\Final On: 01-Apr-2021 05:28 (GMT)

**Header Text:** C4591001  
**Visit:** Logs **Form:** CONCOMITANT MEDICATIONS - NON STUDY VACCINATIONS  
**Form Version:** 22-Apr-2020 21:03  
**Site No:** 1207 **Site Name:** (1207) Ankara University Medical Faculty  
**Subject No:** 12071055 **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.						<a href="#">Repeating Pages</a>

090177e196ae4002\Final\Final On: 01-Apr-2021 05:28 (GMT)

**Header Text:** C4591001

**Visit:** Logs - Unscheduled

**Form Version:** 22-Apr-2020 21:03

**Site No:** 1207

**Subject No:** 12071055

**Generated By:** (b) (4)

**Form:** CONCOMITANT MEDICATIONS - NON STUDY VACCINATIONS

**Form Status:** Not Started

**Site Name:** (1207) Ankara University Medical Faculty

**Subject Initials:** ---

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

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**Concomitant Medications**

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

090177e196ae4002\Final\Final On: 01-Apr-2021 05:28 (GMT)

**Header Text:** C4591001  
**Visit:** Logs **Form:** CONCOMITANT MEDICATIONS - PROHIBITED  
**Form Version:** 22-Apr-2020 21:03  
**Site No:** 1207 **Site Name:** (1207) Ankara University Medical Faculty  
**Subject No:** 12071055 **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.						<a href="#">Repeating Pages</a>

090177e196ae4002\Final\Final On: 01-Apr-2021 05:28 (GMT)



**Header Text:** C4591001

**Visit:** Logs - Unscheduled

**Form Version:** 22-Apr-2020 21:03

**Site No:** 1207

**Subject No:** 12071055

**Generated By:** (b) (4)

**Form:** CONCOMITANT MEDICATIONS - PROHIBITED

**Form Status:** Not Started

**Site Name:** (1207) Ankara University Medical Faculty

**Subject Initials:** ---

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

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**Concomitant Medications**

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

090177e196ae4002\Final\Final On: 01-Apr-2021 05:28 (GMT)

**Header Text:** C4591001

**Visit:** Logs

**Form:** RADIATION TREATMENT

**Form Version:** 22-Apr-2020 21:02

**Site No:** 1207

**Site Name:** (1207) Ankara University Medical Faculty

**Subject No:** 12071055

**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.						<a href="#">Repeating Pages</a>

**Header Text:** C4591001

**Visit:** Logs - Unscheduled

**Form Version:** 22-Apr-2020 21:02

**Site No:** 1207

**Subject No:** 12071055

**Generated By:** (b) (4)

**Form:** RADIATION TREATMENT

**Form Status:** Not Started

**Site Name:** (1207) Ankara University Medical Faculty

**Subject Initials:** ---

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

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**Radiation Treatment**

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

<b>Header Text:</b> C4591001			
<b>Visit:</b> Logs		<b>Form:</b> TRANSFUSIONS	
<b>Form Version:</b> 22-Apr-2020 21:03			
<b>Site No:</b> 1207		<b>Site Name:</b> (1207) Ankara University Medical Faculty	
<b>Subject No:</b> 12071055		<b>Subject Initials:</b> ---	
<b>Generated By:</b> (b) (4)		<b>Generated Time (GMT):</b> 29-Mar-2021 13:11	
#	Transfusion Type	Date of Transfusion	Form Instance
1.			<a href="#">Repeating Pages</a>

**Header Text:** C4591001

**Visit:** Logs - Unscheduled

**Form Version:** 22-Apr-2020 21:03

**Site No:** 1207

**Subject No:** 12071055

**Generated By:** (b) (4)

**Form:** TRANSFUSIONS

**Form Status:** Not Started

**Site Name:** (1207) Ankara University Medical Faculty

**Subject Initials:** ---

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

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

090177e196ae4002\Final\Final On: 01-Apr-2021 05:28 (GMT)

**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:** 1207

**Site Name:** (1207) Ankara University Medical Faculty

**Subject No:** 12071055

**Subject Initials:** ---

**Generated By:** (b) (4)

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

**Date of Visit**

1.	Date of Visit	//
2.	Erroneous Visit	

<b>Header Text:</b> C4591001		<b>Form:</b> UNPLANNED VISIT
<b>Visit:</b> Unplanned - New Unscheduled Visit		<b>Form Status:</b> Not Started
<b>Form Version:</b> 22-Apr-2020 21:04		<b>Site Name:</b> (1207) Ankara University Medical Faculty
<b>Site No:</b> 1207		<b>Subject Initials:</b> ---
<b>Subject No:</b> 12071055		<b>Generated Time (GMT):</b> 29-Mar-2021 13:11
<b>Generated By:</b> (b) (4)		
<b>Unplanned Assessments</b>		
1.	Assessments	

**Header Text** C4591001

**Visit:** Unplanned Vaccination - Unscheduled

**Form:** DATE OF VISIT

**Form Version:** 22-Apr-2020 21:02

**Form Status:** Not Started

**Site No:** 1207

**Site Name:** (1207) Ankara University Medical Faculty

**Subject No:** 12071055

**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:** 1207

**Site Name:** (1207) Ankara University Medical Faculty

**Subject No:** 12071055

**Subject Initials:** ---

**Generated By:** (b) (4)

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

**Vital Signs**

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

**Vital Signs Details**

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

**Header Text:** C4591001

**Visit:** Unplanned Vaccination - Unscheduled

**Form:** VACCINATION

**Form Version:** 10-Dec-2020 02:26

**Form Status:** Not Started

**Site No:** 1207

**Site Name:** (1207) Ankara University Medical Faculty

**Subject No:** 12071055

**Subject Initials:** ---

**Generated By:** (b) (4)

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

**Vaccination**

1.	Was there a temporary delay of vaccination?	
2.	Treatment Name	[ ]
3.	Formulation:	
4.	Dose Date Time:	//
5.	Anatomical Location:	
6.	Body Side:	
7.	Route:	
8.	Actual Dose:	[ ]
9.	Unit:	
10.	Timeframe Subject Was Observed	
11.	Was the subject observed for at least the protocol specified observation period after investigational product administration?	

090177e196ae4002\Final\Final On: 01-Apr-2021 05:28 (GMT)

**Header Text:** C4591001  
**Visit:** Unplanned Vaccination - Unscheduled  
**Form Version:** 10-Oct-2020 15:57  
**Site No:** 1207  
**Subject No:** 12071055  
**Generated By:** (b) (4)

**Form:** CONTACT OUTCOME - MONTH 1  
**Form Status:** Not Started  
**Site Name:** (1207) Ankara University Medical Faculty  
**Subject Initials:** ---  
**Generated Time (GMT):** 29-Mar-2021 13:11

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

090177e196ae4002\Final\Final On: 01-Apr-2021 05:28 (GMT)

**Header Text:** C4591001  
**Visit:** Unplanned Vaccination - Unscheduled  
**Form Version:** 10-Oct-2020 16:01  
**Site No:** 1207  
**Subject No:** 12071055  
**Generated By:** (b) (4)

**Form:** CONTACT OUTCOME - MONTH 6  
**Form Status:** Not Started  
**Site Name:** (1207) Ankara University Medical Faculty  
**Subject Initials:** ---  
**Generated Time (GMT):** 29-Mar-2021 13:11

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

**Header Text** C4591001

**Visit:** V201\_SURVEIL\_CONSENT - Unscheduled

**Form:** DATE OF VISIT

**Form Version:** 22-Apr-2020 21:02

**Form Status:** Not Started

**Site No:** 1207

**Site Name:** (1207) Ankara University Medical Faculty

**Subject No:** 12071055

**Subject Initials:** ---

**Generated By:** (b) (4)

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

**Date of Visit**

1.	Date of Visit	//
2.	Erroneous Visit	

<b>Header Text:</b> C4591001		<b>Form:</b> INFORMED CONSENT - ASYMPTOMATIC SURVEILLANCE
<b>Visit:</b> V201_SURVEIL_CONSENT - Unscheduled		<b>Form Status:</b> Not Started
<b>Form Version:</b> 14-Jan-2021 02:29		<b>Site Name:</b> (1207) Ankara University Medical Faculty
<b>Site No:</b> 1207		<b>Subject Initials:</b> ---
<b>Subject No:</b> 12071055		<b>Generated Time (GMT):</b> 29-Mar-2021 13:11
<b>Generated By:</b> (b) (4)		
<b>Informed Consent - Asymptomatic Surveillance</b>		
1.	Consent Was:	

**Header Text:** C4591001

**Visit:** V201\_SURVEIL\_CONSENT - Unscheduled

**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

**Form Version:** 22-Apr-2020 21:03

**Form Status:** Not Started

**Site No:** 1207

**Site Name:** (1207) Ankara University Medical Faculty

**Subject No:** 12071055

**Subject Initials:** ---

**Generated By:** (b) (4)

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

**Electronic Sample Tracking**

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

**Aliquot**

Please enter barcode for each aliquot.

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

**Header Text:** C4591001

**Visit:** V201\_SURVEIL\_CONSENT - Unscheduled

**Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB

**Form Version:** 22-Apr-2020 21:03

**Form Status:** Not Started

**Site No:** 1207

**Site Name:** (1207) Ankara University Medical Faculty

**Subject No:** 12071055

**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:** End of Treatment - Unscheduled

**Form:** DISPOSITION - TREATMENT

**Form Version:** 10-Dec-2020 02:29

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1207

**Site Name:** (1207) Ankara University Medical Faculty

**Subject No:** 12071055

**Subject Initials:** ---

**Generated By:** (b) (4)

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

[eCRF Audit Trail History](#)

**Disposition - Treatment**

1.	Date of Completion/Discontinuation /Death :	Jan/14/2021
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:** 1207

**Site Name:** (1207) Ankara University Medical Faculty

**Subject No:** 12071055

**Subject Initials:** ---

**Generated By:** (b) (4)

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

[eCRF Audit Trail History](#)

Date of Visit		
1.	Date of Visit	Jan/18/2021
2.	Erroneous Visit	

**Header Text:** C4591001

**Visit:** Potential ReVax Initial Contact - Unscheduled

**Form:** FURTHER VACCINATION CONFIRMATION

**Form Version:** 10-Dec-2020 02:25

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1207

**Site Name:** (1207) Ankara University Medical Faculty

**Subject No:** 12071055

**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 other protocol allowance(s) and confirmed to have received only placebo at Vaccination 1/2
----	---	--

090177e196ae4002\Final\Final On: 01-Apr-2021 05:28 (GMT)

**Header Text** C4591001

**Visit:** Follow-Up - Unscheduled

**Form Version:** 15-Sep-2020 21:53

**Site No:** 1207

**Subject No:** 12071055

**Generated By:** (b) (4)

**Form:** DISPOSITION - FOLLOW-UP

**Form Status:** Data Complete, Frozen, Verified

**Site Name:** (1207) Ankara University Medical Faculty

**Subject Initials:** ---

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

[eCRF Audit Trail History](#)

**Disposition - Follow-Up**

1.	Date of Completion/Discontinuation /Death :	Feb/9/2021
2.	Phase of Disposition:	FOLLOW-UP
3.	Status:	DEATH
4.	Specify Status:	[ ]

**Header Text** C4591001

**Visit:** Disposition - Unscheduled

**Form Version:** 22-Apr-2020 21:03

**Site No:** 1207

**Subject No:** 12071055

**Generated By:** (b) (4)

**Form:** TREATMENT UNBLINDED

**Form Status:** Data Complete, Frozen, Verified

**Site Name:** (1207) Ankara University Medical Faculty

**Subject Initials:** ---

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

[eCRF Audit Trail History](#)

**Treatment Unblinded**

1.	Date Treatment Unblinded :	Jan/18/2021
2.	Primary Reason for Unblinding:	ASSESS ELIGIBILITY FOR ADDITIONAL VACCINATION

**Header Text:** C4591001  
**Visit:** Disposition - Unscheduled  
**Form Version:** 22-Apr-2020 21:03  
**Site No:** 1207  
**Subject No:** 12071055  
**Generated By:** (b) (4)

**Form:** WITHDRAWAL OF CONSENT  
**Form Status:** Data Complete, Frozen, Verified  
**Site Name:** (1207) Ankara University Medical Faculty  
**Subject Initials:** ---  
**Generated Time (GMT):** 29-Mar-2021 13:11

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

Withdrawal Of Consent			
1.	Withdrawal of Consent Date :	Not Applicable //	<a href="#">Comments</a>

**Header Text:** C4591001

**Visit:** Disposition - Unscheduled

**Form Version:** 22-Apr-2020 21:03

**Site No:** 1207

**Subject No:** 12071055

**Generated By:** (b) (4)

**Form:** DEATH DETAILS CODED

**Form Status:** Data Complete, Frozen, Verified

**Site Name:** (1207) Ankara University Medical Faculty

**Subject Initials:** ---

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

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

**Death Details**

1.	Date of Collection / Notification of Death:	Feb/11/2021	<a href="#">Comments</a>
----	---	-------------	--------------------------

**Cause of Death**

2.a	Cause of Death Status:	PRIMARY CAUSE OF DEATH
	Cause of Death:	[Bacterial pneumonia]

**Header Text** C4591001

**Visit:** V101\_VAX3

**Form Version:** 22-Apr-2020 21:02

**Site No:** 1207

**Subject No:** 12071055

**Generated By:** (b) (4)

**Form:** DATE OF VISIT

**Form Status:** Data Complete, Verified

**Site Name:** (1207) Ankara University Medical Faculty

**Subject Initials:** ---

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

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

**Date of Visit**

1.	Date of Visit	Not Done _____ //	<a href="#">Comments</a>
2.	Erroneous Visit	Not Done _____	<a href="#">Comments</a>



**Header Text:** C4591001

**Visit:** V101\_VAX3

**Form Version:** 10-Dec-2020 02:31

**Site No:** 1207

**Subject No:** 12071055

**Generated By:** (b) (4)

**Form:** INFORMED CONSENT - FURTHER VACCINATION

**Form Status:** Data Complete, Frozen, Verified

**Site Name:** (1207) Ankara University Medical Faculty

**Subject Initials:** ---

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

[Form Comments](#)

[eCRF Audit Trail History](#)

**Informed Consent - Further Vaccination**

1.	Consent Was:	Not Done	<a href="#">Comments</a>
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**Header Text:** C4591001

**Visit:** V101\_VAX3

**Form Version:** 10-Dec-2020 02:30

**Site No:** 1207

**Subject No:** 12071055

**Generated By:** (b) (4)

**Form:** INCLUSION/EXCLUSION CRITERIA - FURTHER VACCINATION

**Form Status:** Data Complete, Frozen, Verified

**Site Name:** (1207) Ankara University Medical Faculty

**Subject Initials:** ---

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

**Form Comments**

**Inclusion Criteria Not Met**

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

**Exclusion Criteria Met**

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

**Header Text:** C4591001

**Visit:** V101\_VAX3

**Form Version:** 10-Dec-2020 02:31

**Site No:** 1207

**Subject No:** 12071055

**Generated By:** (b) (4)

**Form:** DISPOSITION - SCREENING FOR FURTHER VACCINATION

**Form Status:** Data Complete, Verified

**Site Name:** (1207) Ankara University Medical Faculty

**Subject Initials:** ---

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

[eCRF Audit Trail History](#)

**Disposition - Screening for Further Vaccination**

1.	Date of Completion/Discontinuation /Death :	Feb/9/2021
2.	Phase of Disposition:	REPEAT SCREENING 1
3.	Status:	DEATH
4.	Specify Status:	[visit did not occur because of subject death. this page needs to be complete.]

**Header Text** C4591001

**Visit:** Subject Status - Unscheduled

**Form Version:** 22-Apr-2020 21:03

**Site No:** 1207

**Subject No:** 12071055

**Generated By:** (b) (4)

**Form:** SUBJECT STATUS

**Form Status:** Data Complete, Verified

**Site Name:** (1207) Ankara University Medical Faculty

**Subject Initials:** ---

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

[eCRF Audit Trail History](#)

Subject Status		
1.	Subject Status	DISCONTINUED
2.	Subject Status Date	Feb/9/2021

**Header Text** C4591001

**Visit:** Investigator Signature - Unscheduled

**Form Version:** 22-Apr-2020 21:04

**Site No:** 1207

**Subject No:** 12071055

**Generated By:** (b) (4)

**Form:** CASEBOOK SIGNATURE FORM

**Form Status:** Data Complete, Signed, Verified

**Site Name:** (1207) Ankara University Medical Faculty

**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:** 1207

**Subject No:** 12071055

**Generated By:** (b) (4)

**Form:** CASEBOOK SIGNATURE FORM

**Form Status:** Data Complete, Signed, Verified

**Site Name:** (1207) Ankara University Medical Faculty

**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
Ismail Balik	Approved	Mar-10-2021 10:28:06 (UTC+03:00) Istanbul	BOOK	Signed

**Affidavit:**

By my dated signature below, I, IsmailBalik, 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:** 1207

**Subject No:** 12071055

**Generated By:** (b) (4)

**Form:** INCLUSION/EXCLUSION CRITERIA - Comments

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site Name:** (1207) Ankara University Medical Faculty

**Subject Initials:** ---

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

[Back to Form](#)

Item	Date	User	Comment
Form	Nov-05-2020 14:39:24 (UTC+03:00) Istanbul	(b) (4), (b) (6)	Not Applicable

090177e196ae4002\Final\Final On: 01-Apr-2021 05:28 (GMT)

**Header Text:** C4591001

**Visit:** Disposition - Unscheduled

**Form Version:** 22-Apr-2020 21:03

**Site No:** 1207

**Subject No:** 12071055

**Generated By:** (b) (4)

**Form:** WITHDRAWAL OF CONSENT - Comments

**Form Status:** Data Complete, Frozen, Verified

**Site Name:** (1207) Ankara University Medical Faculty

**Subject Initials:** ---

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

[Back to Form](#)

Item	Date	User	Comment
Form	Jan-18-2021 16:28:35 (UTC+03:00) Istanbul	(b) (4), (b) (6)	Not Applicable



**Header Text:** C4591001

**Visit:** Disposition

**Form Version:** 22-Apr-2020 21:03

**Site No:** 1207

**Subject No:** 12071055

**Generated By:** (b) (4)

**Form:** WITHDRAWAL OF CONSENT - Comments

**Form Status:** Data Complete, Frozen, Verified

**Site Name:** (1207) Ankara University Medical Faculty

**Subject Initials:** ---

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

[Back to Form](#)

Item	Date	User	Comment
1	Jan-18-2021 16:28:35 (UTC+03:00) Istanbul	(b) (4), (b) (6)	Not Applicable

090177e196ae4002\Final\Final On: 01-Apr-2021 05:28 (GMT)

**Header Text:** C4591001

**Visit:** Disposition - Unscheduled

**Form Version:** 22-Apr-2020 21:03

**Site No:** 1207

**Subject No:** 12071055

**Generated By:** (b) (4)

**Form:** DEATH DETAILS CODED - Comments

**Form Status:** Data Complete, Frozen, Verified

**Site Name:** (1207) Ankara University Medical Faculty

**Subject Initials:** ---

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

[Back to Form](#)

Item	Date	User	Comment
Form	Feb-15-2021 10:23:34 (UTC+03:00) Istanbul	(b) (4), (b) (6)	
Form	Jan-18-2021 16:28:53 (UTC+03:00) Istanbul	(b) (4), (b) (6)	Not Applicable

**Header Text:** C4591001

**Visit:** Disposition

**Form Version:** 22-Apr-2020 21:03

**Site No:** 1207

**Subject No:** 12071055

**Generated By:** (b) (4)

**Form:** DEATH DETAILS CODED - Comments

**Form Status:** Data Complete, Frozen, Verified

**Site Name:** (1207) Ankara University Medical Faculty

**Subject Initials:** ---

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

[Back to Form](#)

Item	Date	User	Comment
1	Feb-15-2021 10:23:34 (UTC+03:00) Istanbul	(b) (4), (b) (6)	
1	Jan-18-2021 16:28:53 (UTC+03:00) Istanbul	(b) (4), (b) (6)	Not Applicable

090177e196ae4002\Final\Final On: 01-Apr-2021 05:28 (GMT)

**Header Text:** C4591001

**Visit:** V101\_VAX3

**Form Version:** 22-Apr-2020 21:02

**Site No:** 1207

**Subject No:** 12071055

**Generated By:** (b) (4)

**Form:** DATE OF VISIT - Comments

**Form Status:** Data Complete, Verified

**Site Name:** (1207) Ankara University Medical Faculty

**Subject Initials:** ---

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

[Back to Form](#)

Item	Date	User	Comment
Form	Mar-09-2021 14:04:16 (UTC+03:00) Istanbul	(b) (4), (b) (6)	Not Done
Form	Mar-09-2021 14:02:22 (UTC+03:00) Istanbul	(b) (4), (b) (6)	
Form	Feb-11-2021 12:26:54 (UTC+03:00) Istanbul	(b) (4), (b) (6)	Not Done

**Header Text:** C4591001

**Visit:** V101\_VAX3

**Form Version:** 22-Apr-2020 21:02

**Site No:** 1207

**Subject No:** 12071055

**Generated By:** (b) (4)

**Form:** DATE OF VISIT - Comments

**Form Status:** Data Complete, Verified

**Site Name:** (1207) Ankara University Medical Faculty

**Subject Initials:** ---

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

[Back to Form](#)

Item	Date	User	Comment
1	Mar-09-2021 14:04:16 (UTC+03:00) Istanbul	(b) (4), (b) (6)	Not Done
1	Mar-09-2021 14:02:22 (UTC+03:00) Istanbul	(b) (4), (b) (6)	
1	Feb-11-2021 12:26:54 (UTC+03:00) Istanbul	(b) (4), (b) (6)	Not Done

**Header Text:** C4591001

**Visit:** V101\_VAX3

**Form Version:** 22-Apr-2020 21:02

**Site No:** 1207

**Subject No:** 12071055

**Generated By:** (b) (4)

**Form:** DATE OF VISIT - Comments

**Form Status:** Data Complete, Verified

**Site Name:** (1207) Ankara University Medical Faculty

**Subject Initials:** ---

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

[Back to Form](#)

Item	Date	User	Comment
2	Mar-09-2021 14:04:16 (UTC+03:00) Istanbul	(b) (4), (b) (6)	Not Done
2	Mar-09-2021 14:02:22 (UTC+03:00) Istanbul	(b) (4), (b) (6)	
2	Feb-11-2021 12:26:54 (UTC+03:00) Istanbul	(b) (4), (b) (6)	Not Done

**Header Text:** C4591001

**Visit:** V101\_VAX3

**Form Version:** 10-Dec-2020 02:31

**Site No:** 1207

**Subject No:** 12071055

**Generated By:** (b) (4)

**Form:** INFORMED CONSENT - FURTHER VACCINATION - Comments

**Form Status:** Data Complete, Frozen, Verified

**Site Name:** (1207) Ankara University Medical Faculty

**Subject Initials:** ---

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

[Back to Form](#)

Item	Date	User	Comment
Form	Feb-11-2021 12:27:16 (UTC+03:00) Istanbul	(b) (4), (b) (6)	Not Done

090177e196ae4002\Final\Final On: 01-Apr-2021 05:28 (GMT)

**Header Text:** C4591001

**Visit:** V101\_VAX3

**Form Version:** 10-Dec-2020 02:31

**Site No:** 1207

**Subject No:** 12071055

**Generated By:** (b) (4)

**Form:** INFORMED CONSENT - FURTHER VACCINATION - Comments

**Form Status:** Data Complete, Frozen, Verified

**Site Name:** (1207) Ankara University Medical Faculty

**Subject Initials:** ---

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

[Back to Form](#)

Item	Date	User	Comment
1	Feb-11-2021 12:27:16 (UTC+03:00) Istanbul	(b) (4), (b) (6)	Not Done



**Header Text:** C4591001

**Visit:** V101\_VAX3

**Form:** INCLUSION/EXCLUSION CRITERIA - FURTHER VACCINATION - Comments

**Form Version:** 10-Dec-2020 02:30

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1207

**Site Name:** (1207) Ankara University Medical Faculty

**Subject No:** 12071055

**Subject Initials:** ---

**Generated By:** (b) (4)

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

[Back to Form](#)

Item	Date	User	Comment
Form	Feb-11-2021 12:27:37 (UTC+03:00) Istanbul	(b) (4), (b) (6)	Not Applicable

090177e196ae4002\Final\Final On: 01-Apr-2021 05:28 (GMT)

Header Text: C4591001

Visit: Investigator Signature - Unscheduled

Form: CASEBOOK SIGNATURE FORM - Signature History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Signed, Verified

Site No: 1207

Site Name: (1207) Ankara University Medical Faculty

Subject No: 12071055

Subject Initials: ---

Generated By: (b) (4)

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

[Back to Form](#)

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

- CRF\_Sign

Name	Signature Meaning	Date	Type	Action
Ismail Balik	Approved	Mar-10-2021 10:28:06 (UTC+03:00) Istanbul	BOOK	Signed

**Affidavit:**

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

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

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

(b) (6)	N/A	Mar-09-2021 14:02:22 (UTC+03:00) Istanbul		Edit - All signatures invalidated
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**Affidavit:**

N/A

Ismail Balik	Approved	Feb-22-2021 14:23:24 (UTC+03:00) Istanbul	BOOK	Signed
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**Affidavit:**

By my dated signature below, I, IsmailBalik, 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-22-2021 13:40:58 (UTC+03:00) Istanbul		Edit - All signatures invalidated
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**Affidavit:**

N/A

Ismail Balik	Approved	Feb-19-2021 10:49:19 (UTC+03:00) Istanbul	BOOK	Signed
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**Affidavit:**

By my dated signature below, I, IsmailBalik, 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.

090177e196ae4002\Final\Final On: 01-Apr-2021 05:28 (GMT)

Header Text: C4591001

Visit: Investigator Signature - Unscheduled

Form: CASEBOOK SIGNATURE FORM - Signature History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Signed, Verified

Site No: 1207

Site Name: (1207) Ankara University Medical Faculty

Subject No: 12071055

Subject Initials: ---

Generated By: (b) (4)

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

(b) (6)	N/A	Feb-19-2021 10:22:01 (UTC+03:00) Istanbul		Edit - All signatures invalidated
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**Affidavit:**

N/A

Ismail Balik	Approved	Feb-18-2021 12:39:47 (UTC+03:00) Istanbul	BOOK	Signed
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**Affidavit:**

By my dated signature below, I, IsmailBalik, 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-18-2021 11:22:33 (UTC+03:00) Istanbul		Edit - All signatures invalidated
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**Affidavit:**

N/A

Ismail Balik	Approved	Feb-17-2021 12:38:22 (UTC+03:00) Istanbul	BOOK	Signed
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**Affidavit:**

By my dated signature below, I, IsmailBalik, 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-17-2021 12:34:10 (UTC+03:00) Istanbul		Edit - All signatures invalidated
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**Affidavit:**

N/A

Ismail Balik	Approved	Feb-17-2021 10:33:21 (UTC+03:00) Istanbul	BOOK	Signed
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090177e196ae4002\Final\Final On: 01-Apr-2021 05:28 (GMT)

**Header Text:** C4591001

**Visit:** Investigator Signature - Unscheduled

**Form:** CASEBOOK SIGNATURE FORM - Signature History

**Form Version:** 22-Apr-2020 21:04

**Form Status:** Data Complete, Signed, Verified

**Site No:** 1207

**Site Name:** (1207) Ankara University Medical Faculty

**Subject No:** 12071055

**Subject Initials:** ---

**Generated By:** (b) (4)

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

**Affidavit:**

By my dated signature below, I, IsmailBalik, 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-17-2021 10:23:05 (UTC+03:00) Istanbul		Edit - All signatures invalidated
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**Affidavit:**

N/A

Ismail Balik	Approved	Feb-15-2021 14:34:45 (UTC+03:00) Istanbul	BOOK	Signed
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**Affidavit:**

By my dated signature below, I, IsmailBalik, 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-15-2021 14:17:51 (UTC+03:00) Istanbul		Edit - All signatures invalidated
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**Affidavit:**

N/A

Ismail Balik	Approved	Feb-15-2021 11:50:13 (UTC+03:00) Istanbul	BOOK	Signed
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**Affidavit:**

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

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

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

(b) (6)	N/A	Feb-12-2021 19:38:23 (UTC+03:00) Istanbul		Edit - All signatures invalidated
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**Affidavit:**

N/A

090177e196ae4002\Final\Final On: 01-Apr-2021 05:28 (GMT)

**Header Text:** C4591001

**Visit:** Investigator Signature - Unscheduled

**Form:** CASEBOOK SIGNATURE FORM - Signature History

**Form Version:** 22-Apr-2020 21:04

**Form Status:** Data Complete, Signed, Verified

**Site No:** 1207

**Site Name:** (1207) Ankara University Medical Faculty

**Subject No:** 12071055

**Subject Initials:** ---

**Generated By:** (b) (4)

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

Ismail Balik	Approved	Feb-12-2021 12:45:28 (UTC+03:00) Istanbul	BOOK	Signed
<b>Affidavit:</b> By my dated signature below, I, IsmailBalik, 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-11-2021 11:52:52 (UTC+03:00) Istanbul		Edit - All signatures invalidated
<b>Affidavit:</b> N/A				
Ismail Balik	Approved	Feb-10-2021 15:19:06 (UTC+03:00) Istanbul	BOOK	Signed
<b>Affidavit:</b> By my dated signature below, I, IsmailBalik, 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-10-2021 14:19:37 (UTC+03:00) Istanbul		Edit - All signatures invalidated
<b>Affidavit:</b> N/A				
Ismail Balik	Approved	Feb-09-2021 15:37:02 (UTC+03:00) Istanbul	BOOK	Signed
<b>Affidavit:</b> By my dated signature below, I, IsmailBalik, 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-09-2021 13:49:24 (UTC+03:00) Istanbul		Edit - All signatures invalidated

090177e196ae4002\Final\Final On: 01-Apr-2021 05:28 (GMT)

**Header Text:** C4591001

**Visit:** Investigator Signature - Unscheduled

**Form:** CASEBOOK SIGNATURE FORM - Signature History

**Form Version:** 22-Apr-2020 21:04

**Form Status:** Data Complete, Signed, Verified

**Site No:** 1207

**Site Name:** (1207) Ankara University Medical Faculty

**Subject No:** 12071055

**Subject Initials:** ---

**Generated By:** (b) (4)

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

**Affidavit:**

N/A

Ismail Balik	Approved	Jan-19-2021 15:29:24 (UTC+03:00) Istanbul	BOOK	Signed
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**Affidavit:**

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

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

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

(b) (6)	N/A	Jan-18-2021 16:26:53 (UTC+03:00) Istanbul		Edit - All signatures invalidated
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**Affidavit:**

N/A

Ismail Balik	Approved	Jan-15-2021 09:56:17 (UTC+03:00) Istanbul	BOOK	Signed
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**Affidavit:**

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

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

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

(b) (6)	N/A	Jan-15-2021 09:51:20 (UTC+03:00) Istanbul		Edit - All signatures invalidated
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**Affidavit:**

N/A

Ismail Balik	Approved	Jan-12-2021 15:29:27 (UTC+03:00) Istanbul	BOOK	Signed
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**Affidavit:**

By my dated signature below, I, IsmailBalik, 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.

090177e196ae4002\Final\Final On: 01-Apr-2021 05:28 (GMT)

**Header Text:** C4591001

**Visit:** Investigator Signature - Unscheduled

**Form:** CASEBOOK SIGNATURE FORM - Signature History

**Form Version:** 22-Apr-2020 21:04

**Form Status:** Data Complete, Signed, Verified

**Site No:** 1207

**Site Name:** (1207) Ankara University Medical Faculty

**Subject No:** 12071055

**Subject Initials:** ---

**Generated By:** (b) (4)

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

(b) (6)	N/A	Jan-12-2021 11:38:14 (UTC+03:00) Istanbul		Edit - All signatures invalidated
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**Affidavit:**

N/A

Ismail Balik	Approved	Dec-01-2020 10:07:08 (UTC+03:00) Istanbul	BOOK	Signed
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**Affidavit:**

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

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

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

(b) (6)	N/A	Nov-26-2020 11:57:39 (UTC+03:00) Istanbul		Edit - All signatures invalidated
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**Affidavit:**

N/A

Ismail Balik	Approved	Nov-17-2020 20:32:15 (UTC+03:00) Istanbul	BOOK	Signed
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**Affidavit:**

By my dated signature below, I, IsmailBalik, 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.

090177e196ae4002\Final\Final On: 01-Apr-2021 05:28 (GMT)

**Header Text:** C4591001

**Visit:** COHORT\_SELECTION

**Form Version:** 10-Oct-2020 16:01

**Site No:** 1207

**Subject No:** 12071055

**Generated By:** (b) (4)

**Form:** COHORT\_SELECTION - eCRF Audit Trail History

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site Name:** (1207) Ankara University Medical Faculty

**Subject Initials:** ---

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

[Back to Form](#)

*1. Select appropriate response - Protocol version*

Date	Location	User	Value	Reason
Nov-05-2020 12:57:42 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 08 SEP 2020	Initial Entry

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

Date	Location	User	Value	Reason
Nov-05-2020 12:57:42 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> STAGE 3 COHORTS	Initial Entry



**Header Text:** C4591001

**Visit:** COHORT\_SELECTION

**Form Version:** 22-Apr-2020 21:02

**Site No:** 1207

**Subject No:** 12071055

**Generated By:** (b) (4)

**Form:** MAIN INFORMED CONSENT - eCRF Audit Trail History

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site Name:** (1207) Ankara University Medical Faculty

**Subject Initials:** ---

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

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*I. Consent Was:*

Date	Location	User	Value	Reason
Nov-05-2020 14:37:39 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> OBTAINED Date Written Consent Obtained  Nov/5/2020	Initial Entry

Header Text: C4591001

Visit: COHORT\_SELECTION

Form: DEMOGRAPHY - eCRF Audit Trail History

Form Version: 15-Sep-2020 21:54

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1207

Site Name: (1207) Ankara University Medical Faculty

Subject No: 12071055

Subject Initials: ---

Generated By: (b) (4)

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

[Back to Form](#)

**1. Subject ID**

Date	Location	User	Value	Reason
Nov-05-2020 12:57:29 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 12071055	Item copied from previous form

**2. Birth Date:**

Date	Location	User	Value	Reason
Nov-05-2020 12:57:23 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> (b) (6)/1955	Enrollment Entry

**3. Sex:**

Date	Location	User	Value	Reason
Nov-05-2020 14:38:36 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> MALE	Initial Entry

**4. Ethnicity:**

Date	Location	User	Value	Reason
Nov-05-2020 14:38:36 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NOT HISPANIC OR LATINO(A) OR OF SPANISH ORIGIN	Initial Entry

**5. Race: (Check X all that apply):**

Date	Location	User	Value	Reason
Nov-05-2020 14:38:36 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> WHITE	Initial Entry

090177e196ae4002\Final\Final On: 01-Apr-2021 05:28 (GMT)

**Header Text** C4591001

**Visit:** V1\_DAY1\_VAX1\_L

**Form Version:** 22-Apr-2020 21:02

**Site No:** 1207

**Subject No:** 12071055

**Generated By:** (b) (4)

**Form:** DATE OF VISIT - eCRF Audit Trail History

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site Name:** (1207) Ankara University Medical Faculty

**Subject Initials:** ---

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

[Back to Form](#)

*I. Date of Visit*

Date	Location	User	Value	Reason
Nov-05-2020 14:39:08 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Nov/5/2020	Initial Entry

Header Text: C4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 15-Sep-2020 21:52

Site No: 1207

Subject No: 12071055

Generated By: (b) (4)

Form: DISPOSITION - SCREENING - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1207) Ankara University Medical Faculty

Subject Initials: ---

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

[Back to Form](#)

**1. Date of Completion/Discontinuation/Death**

Date	Location	User	Value	Reason
Nov-05-2020 14:39:45 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Nov/5/2020	Initial Entry

**2. Phase of Disposition:**

Date	Location	User	Value	Reason
Nov-05-2020 14:39:45 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SCREENING	Initial Entry

**3. Status:**

Date	Location	User	Value	Reason
Nov-05-2020 14:39:45 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> COMPLETED	Initial Entry

090177e196ae4002\Final\Final On: 01-Apr-2021 05:28 (GMT)

Header Text: C4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 22-Apr-2020 21:03

Site No: 1207

Subject No: 12071055

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1207) Ankara University Medical Faculty

Subject Initials: ---

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

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*I.a*

Date	Location	User	Value	Reason
Nov-05-2020 14:40:40 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Line/MH Number:</b> 1 <b>Medical History Term</b> type 2 diabetes : <b>Start Date:</b> UNK/UNK/2010 <b>Ongoing:</b> YES	Initial Entry

*I.a Line/MH Number:*

Date	Location	User	Value	Reason
Nov-05-2020 14:40:40 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 1	Initial Entry

*I.a Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:*

Date	Location	User	Value	Reason
Nov-05-2020 14:40:40 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> type 2 diabetes	Initial Entry

*I.a Start Date:*

Date	Location	User	Value	Reason
Nov-05-2020 14:40:40 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> UNK/UNK/2010	Initial Entry

*I.a Ongoing:*

Date	Location	User	Value	Reason
Nov-05-2020 14:40:40 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

*I.b*

Date	Location	User	Value	Reason
Nov-05-2020 14:41:32 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Line/MH Number:</b> 2 <b>Medical History Term:</b> heart stent replacement surgery <b>Start Date:</b> UNK/UNK/2005	Initial Entry

090177e196ae4002\Final\Final On: 01-Apr-2021 05:28 (GMT)

Header Text: C4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 22-Apr-2020 21:03

Site No: 1207

Subject No: 12071055

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1207) Ankara University Medical Faculty

Subject Initials: ---

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

			<b>Ongoing:</b> NO End Date: UNK/UNK/2005	
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**I.b Line/MH Number:**

Date	Location	User	Value	Reason
Nov-05-2020 14:41:32 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 2	Initial Entry

**I.b Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:**

Date	Location	User	Value	Reason
Nov-05-2020 14:41:32 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> heart stent replacement surgery	Initial Entry

**I.b Start Date:**

Date	Location	User	Value	Reason
Nov-05-2020 14:41:32 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> UNK/UNK/2005	Initial Entry

**I.b Ongoing:**

Date	Location	User	Value	Reason
Nov-05-2020 14:41:32 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO End Date: UNK/UNK/2005	Initial Entry

**I.c**

Date	Location	User	Value	Reason
Nov-05-2020 22:23:51 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Line/MH Number: 3 <b>Medical History</b> secong degree liver <b>Term:</b> circhosis <b>Start Date:</b> UNK/UNK/2015 <b>Ongoing:</b> YES	Transcription Error
Nov-05-2020 14:43:54 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> Line/MH Number: 3 <b>Medical History</b> secong degree cir <b>Term:</b> hosis <b>Start Date:</b> UNK/UNK/2015	Initial Entry

090177e196ae4002\Final\Final On: 01-Apr-2021 05:28 (GMT)

**Header Text:** C4591001

**Visit:** V1\_DAY1\_VAX1\_L

**Form Version:** 22-Apr-2020 21:03

**Site No:** 1207

**Subject No:** 12071055

**Generated By:** (b) (4)

**Form:** GENERAL MEDICAL HISTORY - eCRF Audit Trail History

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site Name:** (1207) Ankara University Medical Faculty

**Subject Initials:** ---

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

			<b>Ongoing:</b>	YES	
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Header Text: C4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 22-Apr-2020 21:03

Site No: 1207

Subject No: 12071055

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1207) Ankara University Medical Faculty

Subject Initials: ---

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

**I.c Line/MH Number:**

Date	Location	User	Value	Reason
Nov-05-2020 14:43:54 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 3	Initial Entry

**I.c Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:**

Date	Location	User	Value	Reason
Nov-06-2020 05:34:47 (UTC+03:00) Istanbul	ACV0PFEINFP6000.InFormAdapter.Discrepancy	PFETMS Oracle (b) (4)	Query 1: Closed	Discrepancy has been closed.
Nov-05-2020 22:23:51 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Transcription Error
Nov-05-2020 22:23:51 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> second degree liver c irrhosis	Transcription Error
Nov-05-2020 16:43:40 (UTC+03:00) Istanbul	ACV0PFEINFP6000.InFormAdapter.Discrepancy	PFETMS Oracle (b) (4)	Query 1: Opened	Clarify SECONG DEGREE CIRRHOSIS as follows...The term appears incomplete. Are you reporting LIVER CIRRHOSIS? BILIARY CIRRHOSIS? CARDIAC CIRRHOSIS? Other? Please update the verbatim term to clarify. Thank you.
Nov-05-2020 14:43:54 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> second degree cirhosi s	Initial Entry

**I.c Start Date:**

Date	Location	User	Value	Reason
Nov-05-2020 14:43:54 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> UNK/UNK/2015	Initial Entry

090177e196ae4002\Final\Final On: 01-Apr-2021 05:28 (GMT)



**Header Text:** C4591001

**Visit:** V1\_DAY1\_VAX1\_L

**Form Version:** 22-Apr-2020 21:03

**Site No:** 1207

**Subject No:** 12071055

**Generated By:** (b) (4)

**Form:** GENERAL MEDICAL HISTORY - eCRF Audit Trail History

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site Name:** (1207) Ankara University Medical Faculty

**Subject Initials:** ---

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

*I.c Ongoing:*

Date	Location	User	Value	Reason
Nov-05-2020 14:43:54 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> YES	Initial Entry

**Header Text:** C4591001

**Visit:** V1\_DAY1\_VAX1\_L

**Form Version:** 15-Sep-2020 21:57

**Site No:** 1207

**Subject No:** 12071055

**Generated By:** (b) (4)

**Form:** HIV STATUS - eCRF Audit Trail History

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site Name:** (1207) Ankara University Medical Faculty

**Subject Initials:** ---

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

[Back to Form](#)

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

Date	Location	User	Value	Reason
Nov-05-2020 14:44:05 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 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: 1207

Subject No: 12071055

Generated By: (b) (4)

Form: VITAL SIGNS - BASELINE - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1207) Ankara University Medical Faculty

Subject Initials: ---

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

[Back to Form](#)

**1. Date:**

Date	Location	User	Value	Reason
Nov-05-2020 14:44:47 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Nov/5/2020	Initial Entry

**2. Weight:**

Date	Location	User	Value	Reason
Nov-05-2020 14:44:47 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 84.9	Initial Entry

**3. Unit:**

Date	Location	User	Value	Reason
Nov-05-2020 14:44:47 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> kg	Initial Entry

**4. Height:**

Date	Location	User	Value	Reason
Nov-05-2020 14:44:47 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 173.0	Initial Entry

**5. Unit:**

Date	Location	User	Value	Reason
Nov-05-2020 14:44:47 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> cm	Initial Entry

**6. Body Mass Index:**

Date	Location	User	Value	Reason
Nov-05-2020 14:44:47 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 28.4	Initial Entry

**7.a**

Date	Location	User	Value	Reason
Nov-05-2020 14:44:47 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Record Identifier:: 1 Temperature: 36.6 Temperature Unit: C Temperature Location FOREHEA :: D	Initial Entry

090177e196ae4002\Final\Final On: 01-Apr-2021 05:28 (GMT)

**Header Text:** C4591001

**Visit:** V1\_DAY1\_VAX1\_L

**Form Version:** 10-Oct-2020 16:04

**Site No:** 1207

**Subject No:** 12071055

**Generated By:** (b) (4)

**Form:** VITAL SIGNS - BASELINE - eCRF Audit Trail History

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site Name:** (1207) Ankara University Medical Faculty

**Subject Initials:** ---

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

**7.a Record Identifier:**

Date	Location	User	Value	Reason
Nov-05-2020 14:44:47 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> 1	Initial Entry

**7.a Temperature:**

Date	Location	User	Value	Reason
Nov-05-2020 14:44:47 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> 36.6	Initial Entry

**7.a Unit:**

Date	Location	User	Value	Reason
Nov-05-2020 14:44:47 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> C	Initial Entry

**7.a Temperature Location:**

Date	Location	User	Value	Reason
Nov-05-2020 14:44:47 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> FOREHEAD	Initial Entry

090177e196ae4002\Final\Final On: 01-Apr-2021 05:28 (GMT)

**Header Text:** C4591001

**Visit:** V1\_DAY1\_VAX1\_L

**Form Version:** 22-Apr-2020 21:03

**Site No:** 1207

**Subject No:** 12071055

**Generated By:** (b) (4)

**Form:** RANDOMIZATION - eCRF Audit Trail History

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site Name:** (1207) Ankara University Medical Faculty

**Subject Initials:** ---

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

[Back to Form](#)

**1. Randomization Date :**

Date	Location	User	Value	Reason
Nov-05-2020 14:47:23 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Nov/5/2020	Initial Entry

**2. Randomization Number:**

Date	Location	User	Value	Reason
Nov-05-2020 14:47:23 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 274049	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:** 1207**Site Name:** (1207) Ankara University Medical Faculty**Subject No:** 12071055**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-05-2020 14:47:43 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SITE	Initial Entry

**2. Sample Type**

Date	Location	User	Value	Reason
Nov-05-2020 14:47:43 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SERUM	Initial Entry

**3. Sample Collected?**

Date	Location	User	Value	Reason
Nov-05-2020 15:45:43 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Nov-05-2020 14:47:43 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Nov-05-2020 14:47:43 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES Date of Collection:  Nov/5/2020	Initial Entry

**5.a**

Date	Location	User	Value	Reason
Nov-05-2020 15:45:43 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sample ID: BRDGSR	Initial Entry

**5.a Sample ID**

Date	Location	User	Value	Reason
Nov-05-2020 15:45:43 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BRDGSR	Initial Entry

**5.b**

Date	Location	User	Value	Reason
Nov-05-2020 15:46:02	ACV0PFEINFP6000	(b) (6)	<b>Data Entry:</b>	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: 1207

Site Name: (1207) Ankara University Medical Faculty

Subject No: 12071055

Subject Initials: ---

Generated By: (b) (4)

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

(UTC+03:00) Istanbul		(b) (4)	Sample ID: BRDGSS	
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**5.b Sample ID**

Date	Location	User	Value	Reason
Nov-05-2020 15:46:02 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> BRDGSS	Initial Entry

**5.c**

Date	Location	User	Value	Reason
Jan-12-2021 11:38:14 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Sample ID: BSHZN9	Initial Entry

**5.c Sample ID**

Date	Location	User	Value	Reason
Jan-12-2021 11:38:14 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> BSHZN9	Initial Entry

**5.d**

Date	Location	User	Value	Reason
Jan-12-2021 11:38:27 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Sample ID: BSHZNB	Initial Entry

**5.d Sample ID**

Date	Location	User	Value	Reason
Jan-12-2021 11:38:27 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> BSHZNB	Initial Entry

090177e196ae4002\Final\Final On: 01-Apr-2021 05:28 (GMT)

Header Text: C4591001

Visit: V1\_DAY1\_VAX1\_L

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1207

Site Name: (1207) Ankara University Medical Faculty

Subject No: 12071055

Subject Initials: ---

Generated By: (b) (4)

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

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**1. Data Origin**

Date	Location	User	Value	Reason
Nov-05-2020 14:48:02 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SITE	Initial Entry

**2. Sample Type**

Date	Location	User	Value	Reason
Nov-05-2020 14:48:02 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> NASAL_SWAB	Initial Entry

**3. Sample Collected?**

Date	Location	User	Value	Reason
Nov-05-2020 15:46:18 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Nov-05-2020 14:48:02 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Nov-05-2020 14:48:02 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES Date of Collection:  Nov/5/2020	Initial Entry

**5.a**

Date	Location	User	Value	Reason
Nov-05-2020 15:46:18 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sample ID: BRDGR7	Initial Entry

**5.a Sample ID**

Date	Location	User	Value	Reason
Nov-05-2020 15:46:18 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BRDGR7	Initial Entry

090177e196ae4002\Final\Final On: 01-Apr-2021 05:28 (GMT)



Header Text: C4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 22-Apr-2020 21:04

Site No: 1207

Subject No: 12071055

Generated By: (b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1207) Ankara University Medical Faculty

Subject Initials: ---

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

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**1. Was there a temporary delay of vaccination?**

Date	Location	User	Value	Reason
Nov-05-2020 14:48:29 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**2. Treatment Name**

Date	Location	User	Value	Reason
Nov-05-2020 14:48:29 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> BLINDED THERAPY	Initial Entry

**3. Formulation:**

Date	Location	User	Value	Reason
Nov-05-2020 14:48:29 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> INJECTION	Initial Entry

**4. Dose Date Time:**

Date	Location	User	Value	Reason
Nov-05-2020 14:48:29 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Nov/5/2020 10:22	Initial Entry

**5. Anatomical Location:**

Date	Location	User	Value	Reason
Nov-05-2020 14:48:29 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> DELTOID MUSCLE	Initial Entry

**6. Body Side:**

Date	Location	User	Value	Reason
Nov-05-2020 14:48:29 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> LEFT	Initial Entry

**7. Route:**

Date	Location	User	Value	Reason
Nov-05-2020 14:48:29 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> INTRAMUSCULAR	Initial Entry

**10. Timeframe Subject Was Observed**

Date	Location	User	Value	Reason
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090177e196ae4002\Final\Final On: 01-Apr-2021 05:28 (GMT)

**Header Text:** C4591001

**Visit:** V1\_DAY1\_VAX1\_L

**Form Version:** 22-Apr-2020 21:04

**Site No:** 1207

**Subject No:** 12071055

**Generated By:** (b) (4)

**Form:** VACCINATION - eCRF Audit Trail History

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site Name:** (1207) Ankara University Medical Faculty

**Subject Initials:** ---

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

Nov-05-2020 14:48:29 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> THE PROTOCOL SPECIFIED OBSERVATION PERIOD	Initial Entry
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*II. Was the subject observed for at least the protocol specified observation period after investigational product administration?*

Date	Location	User	Value	Reason
Nov-05-2020 14:48:29 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

**Header Text:** C4591001

**Visit:** V1\_DAY1\_VAX1\_L

**Form Version:** 06-Jul-2020 21:53

**Site No:** 1207

**Subject No:** 12071055

**Generated By:** (b) (4)

**Form:** REACTOGENICITY DIARY - eCRF Audit Trail History

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site Name:** (1207) Ankara University Medical Faculty

**Subject Initials:** ---

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

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*1. Select appropriate response - Reactogenicity diary collection*

Date	Location	User	Value	Reason
Nov-05-2020 14:48:38 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 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:** 1207

**Subject No:** 12071055

**Generated By:** (b) (4)

**Form:** DATE OF VISIT - eCRF Audit Trail History

**Form Status:** Data Complete, Frozen, Verified

**Site Name:** (1207) Ankara University Medical Faculty

**Subject Initials:** ---

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

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*I. Date of Visit*

Date	Location	User	Value	Reason
Nov-26-2020 11:57:39 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Nov/26/2020	Initial Entry

Header Text: C4591001

Visit: V2\_VAX2\_L

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

Form Version: 10-Oct-2020 16:03

Form Status: Data Complete, Frozen, Verified

Site No: 1207

Site Name: (1207) Ankara University Medical Faculty

Subject No: 12071055

Subject Initials: ---

Generated By: (b) (4)

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

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

Date	Location	User	Value	Reason
Nov-26-2020 12:00:50 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

*2.a*

Date	Location	User	Value	Reason
Nov-26-2020 12:00:50 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptom::</b> FE VE R  <b>Were fever or systemic symptoms present on the last day the Subject Diary was completed?:</b> NO	Initial Entry

*2.a Symptom:*

Date	Location	User	Value	Reason
Nov-26-2020 12:00:50 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 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-26-2020 12:00:50 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

*2.b*

Date	Location	User	Value	Reason
Nov-26-2020 12:00:50 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptom::</b> FAT IGU E  <b>Were fever or systemic symptoms present on the last day the Subject Diary was completed?:</b> :	Initial Entry

090177e196ae4002\Final\Final On: 01-Apr-2021 05:28 (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: 1207

Site Name: (1207) Ankara University Medical Faculty

Subject No: 12071055

Subject Initials: ---

Generated By: (b) (4)

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

2.b Symptom:

Date	Location	User	Value	Reason
Nov-26-2020 12:00:50 (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-26-2020 12:00:50 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NO	Initial Entry

2.c

Date	Location	User	Value	Reason
Nov-26-2020 12:00:50 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> <u>Symptom::</u> HEA DAC HE  Were fever or systemic sympt oms present on the last day th e Subject Diary was complete d?:	Initial Entry

2.c Symptom:

Date	Location	User	Value	Reason
Nov-26-2020 12:00:50 (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-26-2020 12:00:50 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NO	Initial Entry

2.d

Date	Location	User	Value	Reason
Nov-26-2020 12:00:50 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> <u>Symptom::</u> CH ILL S  Were fever or systemic sympto ms present on the last day the Subject Diary was completed?:	Initial Entry

090177e196ae4002\Final\Final On: 01-Apr-2021 05:28 (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: 1207

Site Name: (1207) Ankara University Medical Faculty

Subject No: 12071055

Subject Initials: ---

Generated By: (b) (4)

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

2.d Symptom:

Date	Location	User	Value	Reason
Nov-26-2020 12:00:50 (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-26-2020 12:00:50 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NO	Initial Entry

2.e

Date	Location	User	Value	Reason
Nov-26-2020 12:00:50 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> <u>Symptom::</u> VO MITI NG  Were fever or systemic symptoms present on the last day the Subject Diary was completed?:	Initial Entry

2.e Symptom:

Date	Location	User	Value	Reason
Nov-26-2020 12:00:50 (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-26-2020 12:00:50 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NO	Initial Entry

2.f

Date	Location	User	Value	Reason
Nov-26-2020 12:00:50 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> <u>Symptom::</u> DIA RRH EA  Were fever or systemic symptoms present on the last day the Subject Diary was completed?:	Initial Entry

090177e196ae4002\Final\Final On: 01-Apr-2021 05:28 (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: 1207

Site Name: (1207) Ankara University Medical Faculty

Subject No: 12071055

Subject Initials: ---

Generated By: (b) (4)

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

2.f Symptom:

Date	Location	User	Value	Reason
Nov-26-2020 12:00:50 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 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-26-2020 12:00:50 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

2.g

Date	Location	User	Value	Reason
Nov-26-2020 12:00:50 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptom::</b> NEW OR WORSE ED MUSC LE PAIN  <b>Were fever or systemic NO symptoms present on th e last day the Subject D iary was completed?:</b>	Initial Entry

2.g Symptom:

Date	Location	User	Value	Reason
Nov-26-2020 12:00:50 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NEW OR WORSE NED MUSCLE PA IN	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-26-2020 12:00:50 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

2.h

Date	Location	User	Value	Reason
Nov-26-2020 12:00:50 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptom::</b> NEW OR WORSE NED JOINT PAIN	Initial Entry

090177e196ae4002\Final\Final On: 01-Apr-2021 05:28 (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: 1207

Site Name: (1207) Ankara University Medical Faculty

Subject No: 12071055

Subject Initials: ---

Generated By: (b) (4)

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

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

Date	Location	User	Value	Reason
Nov-26-2020 12:00:50 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NEW OR WORSENERD JOINT PAIN	Initial Entry

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

Date	Location	User	Value	Reason
Nov-26-2020 12:00:50 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NO	Initial Entry

3. Injection Site Location:

Date	Location	User	Value	Reason
Nov-26-2020 12:00:50 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> DELTOID MUSCLE	Initial Entry

4. Injection Site Body Side:

Date	Location	User	Value	Reason
Nov-26-2020 12:00:50 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> LEFT	Initial Entry

5.a

Date	Location	User	Value	Reason
Nov-26-2020 12:00:50 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Injection Site Reaction:: RE DN ESS  Were injection site reactions present on the last day the Subject Diary was completed?: NO	Initial Entry

5.a Injection Site Reaction:

Date	Location	User	Value	Reason
Nov-26-2020 12:00:50 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> REDNESS	Initial Entry

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

090177e196ae4002\Final\Final On: 01-Apr-2021 05:28 (GMT)

Header Text: C4591001

Visit: V2\_VAX2\_L

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

Form Status: Data Complete, Frozen, Verified

Site No: 1207

Site Name: (1207) Ankara University Medical Faculty

Subject No: 12071055

Subject Initials: ---

Generated By: (b) (4)

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

Date	Location	User	Value	Reason
Nov-26-2020 12:00:50 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

5.b

Date	Location	User	Value	Reason
Nov-26-2020 12:00:50 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Injection Site Reaction::</b> SWE LLIN G <b>Were injection site reactions</b> NO <b>present on the last day the Su</b> <b>bject Diary was completed?:</b>	Initial Entry

5.b Injection Site Reaction:

Date	Location	User	Value	Reason
Nov-26-2020 12:00:50 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 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-26-2020 12:00:50 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

5.c

Date	Location	User	Value	Reason
Nov-26-2020 12:00:50 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Injection Site Reaction::</b> PAIN AT INJECTI ON SIT E <b>Were injection site reactio</b> NO <b>ns present on the last day</b> <b>the Subject Diary was co</b> <b>mpleted?:</b>	Initial Entry

090177e196ae4002\Final\Final On: 01-Apr-2021 05:28 (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:** 1207

**Site Name:** (1207) Ankara University Medical Faculty

**Subject No:** 12071055

**Subject Initials:** ---

**Generated By:** (b) (4)

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

**5.c Injection Site Reaction:**

Date	Location	User	Value	Reason
Nov-26-2020 12:00:50 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 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-26-2020 12:00:50 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

Header Text: C4591001

Visit: V2\_VAX2\_L

Form Version: 10-Oct-2020 16:01

Site No: 1207

Subject No: 12071055

Generated By: (b) (4)

Form: VITAL SIGNS - TEMP - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1207) Ankara University Medical Faculty

Subject Initials: ---

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

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**1. Date:**

Date	Location	User	Value	Reason
Nov-26-2020 12:01:21 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Nov/26/2020	Initial Entry

**2.a**

Date	Location	User	Value	Reason
Nov-26-2020 12:01:21 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Record Identifier::</b> 1 <b>Temperature:</b> 36.5 <b>Temperature Unit:</b> C <b>Temperature Location</b> FOREHEA <b>::</b> D	Initial Entry

**2.a Record Identifier:**

Date	Location	User	Value	Reason
Nov-26-2020 12:01:21 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 1	Initial Entry

**2.a Temperature:**

Date	Location	User	Value	Reason
Nov-26-2020 12:01:21 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 36.5	Initial Entry

**2.a Unit:**

Date	Location	User	Value	Reason
Nov-26-2020 12:01:21 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> C	Initial Entry

**2.a Temperature Location:**

Date	Location	User	Value	Reason
Nov-26-2020 12:01:21 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> FOREHEAD	Initial Entry

090177e196ae4002\Final\Final On: 01-Apr-2021 05:28 (GMT)

Header Text: C4591001

Visit: V2\_VAX2\_L

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1207

Site Name: (1207) Ankara University Medical Faculty

Subject No: 12071055

Subject Initials: ---

Generated By: (b) (4)

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

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**1. Data Origin**

Date	Location	User	Value	Reason
Nov-26-2020 12:01:58 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SITE	Initial Entry

**2. Sample Type**

Date	Location	User	Value	Reason
Nov-26-2020 12:01:58 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> NASAL_SWAB	Initial Entry

**3. Sample Collected?**

Date	Location	User	Value	Reason
Nov-26-2020 12:02:24 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Nov-26-2020 12:01:58 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Nov-26-2020 12:01:58 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES Date of Collection:  Nov/26/2020	Initial Entry

**5.a**

Date	Location	User	Value	Reason
Nov-26-2020 12:02:24 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sample ID: BRDGVN	Initial Entry

**5.a Sample ID**

Date	Location	User	Value	Reason
Nov-26-2020 12:02:24 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BRDGVN	Initial Entry

090177e196ae4002\Final\Final On: 01-Apr-2021 05:28 (GMT)

Header Text: C4591001

Visit: V2\_VAX2\_L

Form Version: 22-Apr-2020 21:04

Site No: 1207

Subject No: 12071055

Generated By: (b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1207) Ankara University Medical Faculty

Subject Initials: ---

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

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**1. Was there a temporary delay of vaccination?**

Date	Location	User	Value	Reason
Nov-26-2020 12:51:43 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**2. Treatment Name**

Date	Location	User	Value	Reason
Nov-26-2020 12:51:43 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> BLINDED THERAPY	Initial Entry

**3. Formulation:**

Date	Location	User	Value	Reason
Nov-26-2020 12:51:43 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> INJECTION	Initial Entry

**4. Dose Date Time:**

Date	Location	User	Value	Reason
Nov-26-2020 12:51:43 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Nov/26/2020 10:54	Initial Entry

**5. Anatomical Location:**

Date	Location	User	Value	Reason
Nov-26-2020 12:51:43 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> DELTOID MUSCLE	Initial Entry

**6. Body Side:**

Date	Location	User	Value	Reason
Nov-26-2020 12:51:43 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> LEFT	Initial Entry

**7. Route:**

Date	Location	User	Value	Reason
Nov-26-2020 12:51:43 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> INTRAMUSCULAR	Initial Entry

**10. Timeframe Subject Was Observed**

Date	Location	User	Value	Reason
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090177e196ae4002\Final\Final On: 01-Apr-2021 05:28 (GMT)

**Header Text:** C4591001

**Visit:** V2\_VAX2\_L

**Form Version:** 22-Apr-2020 21:04

**Site No:** 1207

**Subject No:** 12071055

**Generated By:** (b) (4)

**Form:** VACCINATION - eCRF Audit Trail History

**Form Status:** Data Complete, Frozen, Verified

**Site Name:** (1207) Ankara University Medical Faculty

**Subject Initials:** ---

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

Nov-26-2020 12:51:43 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> THE PROTOCOL SPECIFIED OBSERVATION PERIOD	Initial Entry
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*11. Was the subject observed for at least the protocol specified observation period after investigational product administration?*

Date	Location	User	Value	Reason
Nov-26-2020 12:51:43 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

Header Text C4591001

Visit: V3\_MONTH1\_POSTVAX2\_L

Form Version: 22-Apr-2020 21:02

Site No: 1207

Subject No: 12071055

Generated By: (b) (4)

Form: DATE OF VISIT - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1207) Ankara University Medical Faculty

Subject Initials: ---

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

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**I. Date of Visit**

Date	Location	User	Value	Reason
Jan-20-2021 08:30:30 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Closed	Response satisfies query
Jan-19-2021 12:48:04 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Answered	Changed data per query
Jan-19-2021 12:40:41 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Opened	DM: The treatment period is defined as 1st vaccination visit through the 1-month post vaccination visit after the 2nd vaccination. Please complete treatment disposition CRF and update date of EOT to match date of visit at visit 3.
Jan-19-2021 10:30:43 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Per site confirmation_Updated PD tracker
Jan-18-2021 09:17:48 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Original value is correct
Jan-18-2021 08:57:39 (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 14 days from V2_VAX2_L DOV or V2 Vaccination date. Please verify and update. Else, confirm in query response appropriately. (b) (4)
Jan-15-2021 09:51:20 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Jan/14/2021	Initial Entry

090177e196ae4002\Final\Final On: 01-Apr-2021 05:28 (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: 1207

Site Name: (1207) Ankara University Medical Faculty

Subject No: 12071055

Subject Initials: ---

Generated By: (b) (4)

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

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

Date	Location	User	Value	Reason
Jan-15-2021 09:52:38 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

*2.a*

Date	Location	User	Value	Reason
Jan-15-2021 09:52:38 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptom::</b> FE VE R  <b>Were fever or systemic symptoms present on the last day the Subject Diary was completed?:</b> NO	Initial Entry

*2.a Symptom:*

Date	Location	User	Value	Reason
Jan-15-2021 09:52:38 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> FEVER	Initial Entry

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

Date	Location	User	Value	Reason
Jan-15-2021 09:52:38 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

*2.b*

Date	Location	User	Value	Reason
Jan-15-2021 09:52:38 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptom::</b> FAT IGU E  <b>Were fever or systemic symptoms present on the last day the Subject Diary was completed?:</b> NO	Initial Entry

090177e196ae4002\Final\Final On: 01-Apr-2021 05:28 (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: 1207

Site Name: (1207) Ankara University Medical Faculty

Subject No: 12071055

Subject Initials: ---

Generated By: (b) (4)

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

2.b Symptom:

Date	Location	User	Value	Reason
Jan-15-2021 09:52:38 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> FATIGUE	Initial Entry

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

Date	Location	User	Value	Reason
Jan-15-2021 09:52:38 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

2.c

Date	Location	User	Value	Reason
Jan-15-2021 09:52:38 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptom::</b> HEA DAC HE  <b>Were fever or systemic symptoms present on the last day the Subject Diary was completed?:</b> NO	Initial Entry

2.c Symptom:

Date	Location	User	Value	Reason
Jan-15-2021 09:52:38 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> HEADACHE	Initial Entry

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

Date	Location	User	Value	Reason
Jan-15-2021 09:52:38 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

2.d

Date	Location	User	Value	Reason
Jan-15-2021 09:52:38 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptom::</b> CH ILL S  <b>Were fever or systemic symptoms present on the last day the Subject Diary was completed?:</b> NO	Initial Entry

090177e196ae4002\Final\Final On: 01-Apr-2021 05:28 (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: 1207

Site Name: (1207) Ankara University Medical Faculty

Subject No: 12071055

Subject Initials: ---

Generated By: (b) (4)

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

2.d Symptom:

Date	Location	User	Value	Reason
Jan-15-2021 09:52:38 (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
Jan-15-2021 09:52:38 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NO	Initial Entry

2.e

Date	Location	User	Value	Reason
Jan-15-2021 09:52:38 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> <u>Symptom::</u> VO MITI NG  Were fever or systemic symptoms present on the last day the Subject Diary was completed?:	Initial Entry

2.e Symptom:

Date	Location	User	Value	Reason
Jan-15-2021 09:52:38 (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
Jan-15-2021 09:52:38 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NO	Initial Entry

2.f

Date	Location	User	Value	Reason
Jan-15-2021 09:52:38 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> <u>Symptom::</u> DIA RRH EA  Were fever or systemic symptoms present on the last day the Subject Diary was completed?:	Initial Entry

090177e196ae4002\Final\Final On: 01-Apr-2021 05:28 (GMT)

Header Text: C4591001

Visit: V3\_MONTH1\_POSTVAX2\_L

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

Form Status: Data Complete, Frozen, Verified

Site No: 1207

Site Name: (1207) Ankara University Medical Faculty

Subject No: 12071055

Subject Initials: ---

Generated By: (b) (4)

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

2.f Symptom:

Date	Location	User	Value	Reason
Jan-15-2021 09:52:38 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> DIARRHEA	Initial Entry

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

Date	Location	User	Value	Reason
Jan-15-2021 09:52:38 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

2.g

Date	Location	User	Value	Reason
Jan-15-2021 09:52:38 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptom::</b> NEW OR WORSE ED MUSC LE PAIN  <b>Were fever or systemic NO symptoms present on th e last day the Subject D iary was completed?:</b>	Initial Entry

2.g Symptom:

Date	Location	User	Value	Reason
Jan-15-2021 09:52:38 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NEW OR WORSE NED MUSCLE PA IN	Initial Entry

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

Date	Location	User	Value	Reason
Jan-15-2021 09:52:38 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

2.h

Date	Location	User	Value	Reason
Jan-15-2021 09:52:38 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptom::</b> NEW OR WORSE NED JOINT PAIN	Initial Entry

090177e196ae4002\Final\Final On: 01-Apr-2021 05:28 (GMT)

Header Text: C4591001

Visit: V3\_MONTH1\_POSTVAX2\_L

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

Form Status: Data Complete, Frozen, Verified

Site No: 1207

Site Name: (1207) Ankara University Medical Faculty

Subject No: 12071055

Subject Initials: ---

Generated By: (b) (4)

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

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

Date	Location	User	Value	Reason
Jan-15-2021 09:52:38 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NEW OR WORSENERD JOINT PAIN	Initial Entry

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

Date	Location	User	Value	Reason
Jan-15-2021 09:52:38 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NO	Initial Entry

3. Injection Site Location:

Date	Location	User	Value	Reason
Jan-15-2021 09:52:38 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> DELTOID MUSCLE	Initial Entry

4. Injection Site Body Side:

Date	Location	User	Value	Reason
Jan-15-2021 09:52:38 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> LEFT	Initial Entry

5.a

Date	Location	User	Value	Reason
Jan-15-2021 09:52:38 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Injection Site Reaction:: RE DN ESS  Were injection site reactions present on the last day the Subject Diary was completed?: NO	Initial Entry

5.a Injection Site Reaction:

Date	Location	User	Value	Reason
Jan-15-2021 09:52:38 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> REDNESS	Initial Entry

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

090177e196ae4002\Final\Final On: 01-Apr-2021 05:28 (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: 1207

Site Name: (1207) Ankara University Medical Faculty

Subject No: 12071055

Subject Initials: ---

Generated By: (b) (4)

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

Date	Location	User	Value	Reason
Jan-15-2021 09:52:38 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

5.b

Date	Location	User	Value	Reason
Jan-15-2021 09:52:38 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Injection Site Reaction::</b> SWE LLIN G <b>Were injection site reactions</b> NO <b>present on the last day the Su</b> <b>bject Diary was completed?:</b>	Initial Entry

5.b Injection Site Reaction:

Date	Location	User	Value	Reason
Jan-15-2021 09:52:38 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> SWELLING	Initial Entry

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

Date	Location	User	Value	Reason
Jan-15-2021 09:52:38 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

5.c

Date	Location	User	Value	Reason
Jan-15-2021 09:52:38 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Injection Site Reaction::</b> PAIN AT INJECTI ON SIT E <b>Were injection site reactio</b> NO <b>ns present on the last day</b> <b>the Subject Diary was co</b> <b>mpleted?:</b>	Initial Entry

090177e196ae4002\Final\Final On: 01-Apr-2021 05:28 (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:** 1207

**Site Name:** (1207) Ankara University Medical Faculty

**Subject No:** 12071055

**Subject Initials:** ---

**Generated By:** (b) (4)

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

**5.c Injection Site Reaction:**

Date	Location	User	Value	Reason
Jan-15-2021 09:52:38 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> PAIN AT INJECTION SITE	Initial Entry

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

Date	Location	User	Value	Reason
Jan-15-2021 09:52:38 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 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:** 1207**Site Name:** (1207) Ankara University Medical Faculty**Subject No:** 12071055**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
Jan-15-2021 09:52:54 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SITE	Initial Entry

**2. Sample Type**

Date	Location	User	Value	Reason
Jan-15-2021 09:52:54 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SERUM	Initial Entry

**3. Sample Collected?**

Date	Location	User	Value	Reason
Jan-15-2021 09:53:21 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Jan-15-2021 09:52:54 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Jan-15-2021 09:52:54 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES Date of Collection:  Jan/14/2021	Initial Entry

**5.a**

Date	Location	User	Value	Reason
Jan-15-2021 09:53:21 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sample ID: BR5P01	Initial Entry

**5.a Sample ID**

Date	Location	User	Value	Reason
Jan-15-2021 09:53:21 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BR5P01	Initial Entry

**5.b**

Date	Location	User	Value	Reason
Jan-15-2021 09:53:38	ACV0PFEINFP6000	(b) (6)	<b>Data Entry:</b>	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: 1207

Site Name: (1207) Ankara University Medical Faculty

Subject No: 12071055

Subject Initials: ---

Generated By: (b) (4)

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

(UTC+03:00) Istanbul		(b) (4)	Sample ID: BR5P02	
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5.b Sample ID

Date	Location	User	Value	Reason
Jan-15-2021 09:53:38 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> BR5P02	Initial Entry

5.c

Date	Location	User	Value	Reason
Jan-15-2021 09:53:58 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Sample ID: BSHZWN	Initial Entry

5.c Sample ID

Date	Location	User	Value	Reason
Jan-15-2021 09:53:58 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> BSHZWN	Initial Entry

5.d

Date	Location	User	Value	Reason
Jan-15-2021 09:54:12 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Sample ID: BSHZWP	Initial Entry

5.d Sample ID

Date	Location	User	Value	Reason
Jan-15-2021 09:54:12 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> BSHZWP	Initial Entry

090177e196ae4002\Final\Final On: 01-Apr-2021 05:28 (GMT)

**Header Text** C4591001

**Visit:** Logs - Unscheduled

**Form Version:** 22-Apr-2020 21:02

**Site No:** 1207

**Subject No:** 12071055

**Generated By:** (b) (4)

**Form:** ADVERSE EVENT REPORT - Audit Trail

**Form Status:**

**Site Name:** (1207) Ankara University Medical Faculty

**Subject Initials:** ---

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

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Date	Location	User	Value	Reason
Feb-09-2021 13:49:24 (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: 1207

Subject No: 12071055

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1207) Ankara University Medical Faculty

Subject Initials: ---

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**1. Category:**

Date	Location	User	Value	Reason
Feb-09-2021 13:49:24 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> ADVERSE EVENT	Initial Entry

**2. AE ID:**

Date	Location	User	Value	Reason
Feb-09-2021 13:49:24 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 1	Initial Entry

**3. Adverse Event:**

*(If possible specify diagnosis, not individual symptoms)*

Date	Location	User	Value	Reason
Mar-03-2021 15:36:39 (UTC+03:00) Istanbul	ACV0PFEINFP6000	Giselle Castillo (b) (4)	Query 2: Closed	Thanks for confirming. Clinical will continue to FU at a later date.
Feb-25-2021 10:26:46 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Answered	participant family could not receive the medical records to the site yet
Feb-25-2021 00:01:47 (UTC+03:00) Istanbul	ACV0PFEINFP6000	Giselle Castillo (b) (4)	Query 2: Reissued:O pened	Thanks for your response, would you provide updates so I can close the query?
Feb-18-2021 10:50:32 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Answered	medical records are not available right now. Clarification will be done when information obtained.
Feb-17-2021 22:12:26 (UTC+03:00) Istanbul	ACV0PFEINFP6000	Giselle Castillo (b) (4)	Query 2: Opened	Medical Monitor_ Pls provide further information on hospital stay. Could you provide updates on Med records? Thanks
Feb-09-2021 17:14:39 (UTC+03:00) Istanbul	ACV0PFEINFP6000.InFormAdapter.Discrepancy	PFETMS Oracle (b) (4)	Query 1: Closed	Discrepancy has been closed.

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Subject No: 12071055

Generated By: (b) (4)

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Feb-09-2021 15:19:57 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Transcription Error
Feb-09-2021 15:19:57 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Bacterial Pneumonia	Transcription Error
Feb-09-2021 15:15:03 (UTC+03:00) Istanbul	ACV0PFEINFP6000.InFormAdapter.Discrepancy	PFETMS Oracle (b) (4)	Query 1: Opened	Clarify BACTERIAL PNEUMONI as follows...The term appears truncated. Are you reporting BACTERIAL PNEUMONIA? If so, update the verbatim term as such. Otherwise clarify and edit the term. Thank you.
Feb-09-2021 13:49:24 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Bacterial Pneumoni	Initial Entry

4. Start Date Time:

Date	Location	User	Value	Reason
Feb-09-2021 13:49:24 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Feb/5/2021 UNK:UNK	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Feb-17-2021 12:51:19 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Closed	Response satisfies query
Feb-17-2021 12:34:38 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Answered	Transcription Error
Feb-17-2021 12:34:38 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO End Date Time: Feb/9/2021 UNK:UNK	Transcription Error
Feb-17-2021 12:09:11 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Opened	please update the date, subject death date 09Feb21

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Header Text: C4591001

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Site No: 1207

Subject No: 12071055

Generated By: (b) (4)

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Feb-11-2021 12:32:55 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Feb-11-2021 12:32:55 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO End Date Time: Feb/10/2021 UNK:UNK	New Information
Feb-11-2021 12:29:00 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	'Disposition Follow-up form is completed and this Adverse Event is still ongoing. Please review and update as appropriate.
Feb-09-2021 13:49:24 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

6. Toxicity Grade:

Date	Location	User	Value	Reason
Feb-09-2021 13:49:24 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 4	Initial Entry

7. Is the adverse event serious?

If Yes, NOTIFY PFIZER IMMEDIATELY.

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

Date	Location	User	Value	Reason
Feb-18-2021 07:46:03 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Closed	Response satisfies query
Feb-17-2021 12:50:04 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 5: Closed	Response satisfies query
Feb-17-2021 12:49:48 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 4: Closed	Response satisfies query
Feb-17-2021 12:34:10 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto query (autoquery)	Query 5: Answered	Transcription Error
Feb-17-2021 12:34:10 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto query (autoquery)	Query 4: Answered	Transcription Error
Feb-17-2021 12:34:10 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES Is this serious event associated with congenital anomaly or birth defect?	Transcription Error

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Header Text: C4591001

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Subject No: 12071055

Generated By: (b) (4)

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			<p>NO</p> <p>Did this serious event result in death?</p> <p>YES</p> <p>Did this serious event require or prolong hospitalization?</p> <p>YES</p> <p>Did this serious event result in persistent or significant disability/incapacity?</p> <p>NO</p> <p>Is this serious event life threatening?</p> <p>YES</p> <p>Other medically important serious event</p> <p>NO</p>	
Feb-17-2021 12:11:56 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 5: Opened	please correct the answer for question "Other medically important serious event" in line with SAE FU report, thank you
Feb-17-2021 12:10:59 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 4: Opened	please correct the answer for question "persistent or significant disability/incapacity" in line with SAE FU report.
Feb-17-2021 10:23:05 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto query (autoquery)	Query 3: Answered	Transcription Error
Feb-17-2021 10:23:05 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<p><b>Data Entry:</b></p> <p>YES</p> <p>Is this serious event associated with congenital anomaly or birth defect?</p> <p>NO</p> <p>Did this serious event result in death?</p> <p>YES</p>	Transcription Error

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			<p>Did this serious event require or prolong hospitalization?</p> <p>YES</p> <p>Did this serious event result in persistent or significant disability/incapacity?</p> <p>YES</p> <p>Is this serious event life threatening?</p> <p>YES</p> <p>Other medically important serious event</p> <p>YES</p>	
Feb-17-2021 08:47:53 (UTC+03:00) Istanbul	ACV0PFEINFP6000	Balaji Prabu R (b) (4)	Query 3: Opened	Outcome of this AE is FATAL, but the question "Did this serious event result in death?" is answered as NO. Please verify and update as appropriate. Else clarify.
Feb-12-2021 19:40:57 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Closed	SDB updated
Feb-11-2021 12:25:43 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Answered	SAE form was submitted to TUR.AEReporting@pfizer.com on 09feb2021.
Feb-11-2021 11:57:34 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Opened	SAE RECON: Bacterial Pneumonia(Onset date:05Feb20221) is not reported to Safety database but marked serious on AE CRF. Confirm seriousness and report to Pfizer immediately. If this event is not serious, downgrade the event on AE CRF
Feb-11-2021 11:56:56 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Deleted	Query can be addressed internally
Feb-09-2021 15:19:57 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	For AE Bacterial Pneumonia: Response to "Is the adverse event serious?" is 'Yes' but "Serious Adverse Event Number" is blank.

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**Header Text:** C4591001**Visit:** Logs - Unscheduled**Form Version:** 22-Apr-2020 21:02**Site No:** 1207**Subject No:** 12071055**Generated By:** (b) (4)**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History**Form Status:** Data Complete, Frozen, Verified**Site Name:** (1207) Ankara University Medical Faculty**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 13:11

Feb-09-2021 13:49:24 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	For AE Bacterial Pneumoni: Response to "Is the adverse event serious?" is 'Yes' but "Serious Adverse Event Number" is blank.
Feb-09-2021 13:49:24 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES Is this serious event associated with congenital anomaly or bir th 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 disabil ity/incapacity?  YES  Is this serious event life threate ning?  YES  Other medically important seri ous event  YES	Initial Entry

**8. Is this adverse event the result of a study Medication Error?***If Yes, record the type of medication error on the Medication Error Log.*

Date	Location	User	Value	Reason
Feb-09-2021 13:49:24 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**9. Is this event related to study treatment:**

Date	Location	User	Value	Reason
Feb-15-2021 21:07:25 (UTC+03:00) Istanbul	ACV0PFEINFP6000	Quan Jason Gong (b) (4)	Query 1: Closed	Response satisfies query



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Generated By: (b) (4)

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Feb-11-2021 11:48:02 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	according to verbal information covid test is negative. Result is not shared with site.
Feb-11-2021 01:53:07 (UTC+03:00) Istanbul	ACV0PFEINFP6000	Quan Jason Gong (b) (4)	Query 1: Opened	GPDClin: Please clarify if covid-19 test was done at hospital. If yes, what's the result?
Feb-09-2021 13:49:24 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NOT RELATED If Not Related to study treatment(s), this event is due to:  OTHER  <i>If Other, specify:</i>  bacterial	Initial Entry

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Feb-09-2021 13:49:24 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NOT APPLICABLE	Initial Entry

11. Was a Concomitant Medication given?

Date	Location	User	Value	Reason
Feb-10-2021 15:07:11 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Feb-10-2021 14:19:37 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Transcription Error
Feb-10-2021 14:19:37 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Transcription Error
Feb-10-2021 12:33:10 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	there is no medication information to treat SAE in source, please change your answer as "no", if you learn that subject take medication you can update this part as yes afterwards

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Header Text: C4591001

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Site No: 1207

Subject No: 12071055

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

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11. Was a Concomitant Medication given?

Date	Location	User	Value	Reason
Feb-09-2021 13:49:24 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Feb-09-2021 13:49:24 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

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

Date	Location	User	Value	Reason
Feb-17-2021 09:29:29 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 4: Closed	outcome updated to Fatal in SDB
Feb-16-2021 08:20:03 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Closed	Response satisfies query
Feb-15-2021 12:20:10 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 4: Reissued: Candidate	Pending SDB update
Feb-15-2021 10:25:16 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Answered	Changed data per query
Feb-15-2021 10:24:44 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Deleted	Answer Auto Query
Feb-15-2021 10:22:23 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 4: Answered	FU form submitted on 11feb2021
Feb-12-2021 19:39:42 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 4: Opened	SAE RECON:AER#2021139362,outcome was reported as RECOVERING/RESOLVING to Safety DB however, recorded as

090177e196ae4002\Final\Final On: 01-Apr-2021 05:28 (GMT)

Header Text: C4591001

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				FATAL on AE CRF. Please confirm correct outcome. If safety update is required, please submit a follow-up form.
Feb-12-2021 18:11:06 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Reissued: Opened	Please complete the Death Details page. The path is Visit/Form: Disposition > DEATH DETAILS CODED.
Feb-12-2021 11:36:42 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Answered	FUP page is completed as death, is there any page should site complete?
Feb-12-2021 07:15:18 (UTC+03:00) Istanbul	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (b) (4)	Query 3: Opened	DMW7232817;The outcome of this AE is selected as FATAL, but there are no Disposition eCRFs with a 'Status' of DEATH. Please review and update as appropriate.
Feb-12-2021 00:05:05 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Reissued: Candidate	Please review to see if 'Date of Collection/Notification of Death on the Death Details is updated by 12Feb.
Feb-11-2021 12:35:07 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Answered	SAE form will me submitted within today
Feb-11-2021 12:33:21 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Opened	Response to "What was the outcome of this adverse event?" is 'Fatal' but Date of Collection / Notification of Death on the Death Details form is not completed. Please review and update as appropriate.
Feb-11-2021 12:33:21 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Feb-11-2021 12:33:21 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry</b> : FATAL	New Information
Feb-11-2021 12:32:55 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	For AE Bacterial Pneumonia: Response to "What was the outcome of this adverse event?" is 'Recovering/Resolving' but AE End Date/Time is present.

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Generated By: (b) (4)

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Subject Initials: ---

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Feb-09-2021 13:49:24 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry</b> : RECO VERI NG/R ESOL VING	Initial Entry
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14. Did the adverse event cause the subject to be discontinued from the study?

Date	Location	User	Value	Reason
Feb-22-2021 15:17:44 (UTC+03:00) Istanbul	ACV0PFEINFP6000	Hayley Wyper (b) (4)	Query 1: Closed	Response satisfies query
Feb-22-2021 13:40:58 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Transcription Error
Feb-22-2021 13:40:58 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Transcription Error
Feb-19-2021 20:55:48 (UTC+03:00) Istanbul	ACV0PFEINFP6000	Hayley Wyper (b) (4)	Query 1: Opened	CLINQUERY: Please review this selection for this fatal event occurring whilst subject was still on study
Feb-09-2021 13:49:24 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

15. Serious Adverse Event Number: For Pfizer Use Only

Date	Location	User	Value	Reason
Feb-12-2021 19:38:23 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 2021139362	Initial Entry

090177e196ae4002\Final\Final On: 01-Apr-2021 05:28 (GMT)

Header Text C4591001

Visit: End of Treatment - Unscheduled

Form: DISPOSITION - TREATMENT - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:29

Form Status: Data Complete, Frozen, Verified

Site No: 1207

Site Name: (1207) Ankara University Medical Faculty

Subject No: 12071055

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-11-2021 11:54:18 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Jan/14/2021	Transcription Error
Feb-11-2021 11:52:52 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Feb/10/2021	New Information
Jan-19-2021 12:48:47 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Jan/14/2021	Transcription Error
Jan-19-2021 12:48:30 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Jan/19/2021	Initial Entry

**2. Phase of Disposition:**

Date	Location	User	Value	Reason
Jan-19-2021 12:48:30 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> VACCINATION	Initial Entry

**3. Status:**

Date	Location	User	Value	Reason
Feb-11-2021 11:54:33 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Feb-11-2021 11:54:33 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> COMPLETED	Transcription Error
Feb-11-2021 11:53:22 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	'Response to 'Status' is 'Death' on Disposition-Follow up, but 'Death' CRF is not yet initiated. Please review and update as appropriate.
Feb-11-2021 11:53:22 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> DEATH	New Information
Jan-19-2021 12:48:30 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> COMPLETED	Initial Entry

090177e196ae4002\Final\Final On: 01-Apr-2021 05:28 (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:** 1207

**Site Name:** (1207) Ankara University Medical Faculty

**Subject No:** 12071055

**Subject Initials:** ---

**Generated By:** (b) (4)

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

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*I. Date of Visit*

Date	Location	User	Value	Reason
Jan-18-2021 16:26:53 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Jan/18/2021	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:** 1207

**Site Name:** (1207) Ankara University Medical Faculty

**Subject No:** 12071055

**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-18-2021 16:28:23 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Jan-18-2021 16:28:02 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	The response indicates participant was unblinded, however the TREATMENT UNBLINDED date is missing in the DISP visit. Please complete this date.
Jan-18-2021 16:28:02 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Participant is willing to return for Vaccination 3 Participant is:  eligible per other protocol allowance(s) and confirmed to have received only placebo at Vaccination 1/2	Initial Entry

090177e196ae4002\Final\Final On: 01-Apr-2021 05:28 (GMT)

Header Text C4591001

Visit: Follow-Up - Unscheduled

Form: DISPOSITION - FOLLOW-UP - eCRF Audit Trail History

Form Version: 15-Sep-2020 21:53

Form Status: Data Complete, Frozen, Verified

Site No: 1207

Site Name: (1207) Ankara University Medical Faculty

Subject No: 12071055

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-17-2021 10:25:28 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Feb/9/2021	Transcription Error
Feb-11-2021 12:29:00 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Feb/10/2021	Initial Entry

**2. Phase of Disposition:**

Date	Location	User	Value	Reason
Feb-11-2021 12:29:00 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> FOLLOW-UP	Initial Entry

**3. Status:**

Date	Location	User	Value	Reason
Feb-16-2021 00:59:42 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Feb-15-2021 10:24:44 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Answer Auto Query
Feb-12-2021 18:12:33 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reissued:Opened	The path is Visit/Form: Disposition > DEATH DETAILS CODED
Feb-12-2021 11:34:38 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	There isn't death detail page in CRF. Could you please add the page to subject?
Feb-12-2021 02:13:52 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reissued:Opened	DM RQ: Per the CRFCR, if a participant ends the study due to death, The Death Details Coded (DEATH DTL) CRF is required to be completed. Currently, the CRF is not completed. Please review and update accordingly.
Feb-11-2021 12:31:35 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	SAE FU report will be submitted within today
Feb-11-2021 12:31:20 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Closed	Close Auto Query

090177e196ae4002\Final\Final On: 01-Apr-2021 05:28 (GMT)



**Header Text:** C4591001

**Visit:** Follow-Up - Unscheduled

**Form:** DISPOSITION - FOLLOW-UP - eCRF Audit Trail History

**Form Version:** 15-Sep-2020 21:53

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1207

**Site Name:** (1207) Ankara University Medical Faculty

**Subject No:** 12071055

**Subject Initials:** ---

**Generated By:** (b) (4)

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

Feb-11-2021 12:30:49 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Opened	Response to "Status" is DEATH but "Specify Status" is Provided.
Feb-11-2021 12:29:00 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	'Response to 'Status' is 'Death' on Disposition-Follow up, but 'Death' CRF is not yet initiated. Please review and update as appropriate.
Feb-11-2021 12:29:00 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> DEATH	Initial Entry

**4. Specify Status:**

Date	Location	User	Value	Reason
Feb-11-2021 12:31:20 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>	Transcription Error
Feb-11-2021 12:30:49 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> SAE FU report will be submitted with in today	Initial Entry

090177e196ae4002\Final\Final On: 01-Apr-2021 05:28 (GMT)

**Header Text** C4591001

**Visit:** Disposition - Unscheduled

**Form Version:** 22-Apr-2020 21:03

**Site No:** 1207

**Subject No:** 12071055

**Generated By:** (b) (4)

**Form:** TREATMENT UNBLINDED - eCRF Audit Trail History

**Form Status:** Data Complete, Frozen, Verified

**Site Name:** (1207) Ankara University Medical Faculty

**Subject Initials:** ---

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

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**1. Date Treatment Unblinded :**

Date	Location	User	Value	Reason
Jan-18-2021 16:28:23 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Jan/18/2021	Initial Entry

**2. Primary Reason for Unblinding:**

Date	Location	User	Value	Reason
Jan-18-2021 16:28:23 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> ASSESS ELIGIBILITY FOR ADDITI ONAL VACCINATION	Initial Entry

**Header Text:** C4591001

**Visit:** Disposition - Unscheduled

**Form Version:** 22-Apr-2020 21:03

**Site No:** 1207

**Subject No:** 12071055

**Generated By:** (b) (4)

**Form:** WITHDRAWAL OF CONSENT - eCRF Audit Trail History

**Form Status:** Data Complete, Frozen, Verified

**Site Name:** (1207) Ankara University Medical Faculty

**Subject Initials:** ---

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

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*1. Withdrawal of Consent Date :*

Date	Location	User	Value	Reason
Jan-18-2021 16:28:35 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

Header Text: C4591001

Visit: Disposition - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1207

Subject No: 12071055

Generated By: (b) (4)

Form: DEATH DETAILS CODED - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1207) Ankara University Medical Faculty

Subject Initials: ---

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

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***I. Date of Collection / Notification of Death:***

Date	Location	User	Value	Reason
Feb-20-2021 02:20:16 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Closed	Per query responses, subject died on 09Feb2021 (consistent with SAE report), and site was notified of death 11feb2021. Date of death on FUP (09Feb2021) and Death details (notification of death is 11Feb2021) appear to be correct based on this information.
Feb-20-2021 02:12:51 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Closed	Response satisfies query
Feb-19-2021 10:26:33 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Answered	we have notified about subject death on 11feb2021 and send to DSU team FU report. Subject died on 09feb2021. If FUP page must be update as 11feb2021 could you unfreeze the page so i can uptade it?
Feb-19-2021 10:22:01 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto query (autoquery)	Query 3: Opened	Date of Collection / Notification of Death is greater than the Date of Completion/Discontinuation /Death on the Disposition form 09/Feb/2021. Please review and update as appropriate
Feb-19-2021 10:22:01 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Answered	site was notified of death 11feb2021
Feb-19-2021 10:22:01 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Feb/11/2021	site was notified of death 11feb2021
Feb-19-2021 02:01:32 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Reissued:Opened	CLINQUERY: per SAE report, date of death was clarified as 09Feb2021. Please clarify if the site was notified that day (09Feb2021). If not, please update "Date of Collection / Notification of Death:" on this death details CRF as

090177e196ae4002\Final\Final On: 01-Apr-2021 05:28 (GMT)

Header Text: C4591001

Visit: Disposition - Unscheduled

Form: DEATH DETAILS CODED - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1207

Site Name: (1207) Ankara University Medical Faculty

Subject No: 12071055

Subject Initials: ---

Generated By: (b) (4)

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

				appropriate.
Feb-19-2021 01:47:40 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Feb-17-2021 10:29:54 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Changed data per query
Feb-17-2021 10:26:06 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Answered	Changed data per query
Feb-17-2021 02:36:22 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Opened	CLINQUERY: please clarify if the Death Details Date of Collection / Notification of Death should be updated. Note the Disposition Follow Up (FUP) Date of Completion/Discontinuation /Death is 10/Feb/2021, and the stop of the fatal event is 10Feb2021.
Feb-17-2021 02:31:01 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	CLINQUERY: Please report cause of death. Note: Bacterial Pneumonia is reported with a fatal outcome.
Feb-15-2021 14:17:51 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Feb/9/2021	Transcription Error
Feb-15-2021 10:24:44 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Feb/10/2021	Initial Entry
Feb-15-2021 10:23:34 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>	Initial Entry
Jan-18-2021 16:28:53 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

2.a

Date	Location	User	Value	Reason
Feb-17-2021 10:29:27 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Cause of Death</b> PRIMARY CAUSE <b>h Status:</b> OF DEATH <b>Cause of Death</b> Bacterial pneumonia <b>h:</b>	Initial Entry

2.a Cause of Death Status:

Date	Location	User	Value	Reason
Feb-17-2021 10:29:27	ACV0PFEINFP6000	(b) (6)	<b>Data Entry:</b>	Initial Entry

090177e196ae4002\Final\Final On: 01-Apr-2021 05:28 (GMT)

**Header Text:** C4591001

**Visit:** Disposition - Unscheduled

**Form Version:** 22-Apr-2020 21:03

**Site No:** 1207

**Subject No:** 12071055

**Generated By:** (b) (4)

**Form:** DEATH DETAILS CODED - eCRF Audit Trail History

**Form Status:** Data Complete, Frozen, Verified

**Site Name:** (1207) Ankara University Medical Faculty

**Subject Initials:** ---

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

(UTC+03:00) Istanbul		(b) (4)	PRIMARY CAUSE OF DEATH	
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**2.a Cause of Death:**

Date	Location	User	Value	Reason
Feb-17-2021 10:29:27 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Bacterial pneumonia	Initial Entry

Header Text C4591001

Visit: V101\_VAX3

Form Version: 22-Apr-2020 21:02

Site No: 1207

Subject No: 12071055

Generated By: (b) (4)

Form: DATE OF VISIT - eCRF Audit Trail History

Form Status: Data Complete, Verified

Site Name: (1207) Ankara University Medical Faculty

Subject Initials: ---

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

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**I. Date of Visit**

Date	Location	User	Value	Reason
Mar-09-2021 14:04:16 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry
Mar-09-2021 14:02:22 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>	Initial Entry
Mar-05-2021 20:56:39 (UTC+03:00) Istanbul	ACV0PFEINFP6000	Rivkah Rosen (b) (4)	Query 1: Closed	Response satisfies query
Mar-04-2021 10:15:43 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	form 1 was completed on 18jan2021 subject unblinded was done. but V101 could not done due to subject page. Disposition page can not be erased because this procedure is done already instead of deleting page V101 page filled as not done.
Mar-03-2021 20:39:16 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reissued:Opened	DM Q: If not occurred, kindly erase the data from DISP RESCR form and add form level comment as Not Done or Not Applicable or else clarify.
Mar-03-2021 15:28:05 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	V101 visit haven't done because of subject death but before the subject's death, disposition page was already filled. Should i still delete the page?
Mar-02-2021 15:15:03 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	DOV is marked as Not Done. Please confirm if this visit occurred. If yes, update the DOV as appropriate. If not occurred, kindly erase the data from DISP RESCR form and add form level comment as

090177e196ae4002\Final\Final On: 01-Apr-2021 05:28 (GMT)

**Header Text:** C4591001

**Visit:** V101\_VAX3

**Form Version:** 22-Apr-2020 21:02

**Site No:** 1207

**Subject No:** 12071055

**Generated By:** (b) (4)

**Form:** DATE OF VISIT - eCRF Audit Trail History

**Form Status:** Data Complete, Verified

**Site Name:** (1207) Ankara University Medical Faculty

**Subject Initials:** ---

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

				Not Done or Not Applicable or else clarify.
Feb-11-2021 12:26:54 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

**2. Erroneous Visit**

Date	Location	User	Value	Reason
Mar-09-2021 14:04:16 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry
Mar-09-2021 14:02:22 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>	Initial Entry
Feb-11-2021 12:26:54 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry



**Header Text:** C4591001

**Visit:** V101\_VAX3

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

**Form Version:** 10-Dec-2020 02:31

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1207

**Site Name:** (1207) Ankara University Medical Faculty

**Subject No:** 12071055

**Subject Initials:** ---

**Generated By:** (b) (4)

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

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*I. Consent Was:*

Date	Location	User	Value	Reason
Feb-11-2021 12:27:16 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	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, Verified

Site No: 1207

Site Name: (1207) Ankara University Medical Faculty

Subject No: 12071055

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-18-2021 18:07:49 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Feb-18-2021 11:22:33 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Transcription Error
Feb-18-2021 11:22:33 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Feb/9/2021	Transcription Error
Feb-18-2021 10:57:06 (UTC+03:00) Istanbul	ACV0PFEINFP6000	Balaji Prabu R (b) (4)	Query 1: Opened	Date is reported at disposition follow up CRF is 09Feb2021, hence, please confirm whether this dates needs to be updated to 09Feb2021. Else clarify.
Feb-11-2021 12:28:08 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Feb/10/2021	Initial Entry

**2. Phase of Disposition:**

Date	Location	User	Value	Reason
Feb-11-2021 12:28:08 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> REPEAT SCREENING 1	Initial Entry

**3. Status:**

Date	Location	User	Value	Reason
Mar-12-2021 18:36:05 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 4: Closed	Response satisfies query
Mar-12-2021 14:57:31 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 4: Answered	Subject died but disposition was done before his death.
Mar-12-2021 14:40:59 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 4: Opened	DM: Status reported as Death. However, Death details are present on DEATH DTL and DISP FUP forms. As this visit is not occur, kindly consider to erase data from this form and mark this form as Not

090177e196ae4002\Final\Final On: 01-Apr-2021 05:28 (GMT)

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, Verified

Site No: 1207

Site Name: (1207) Ankara University Medical Faculty

Subject No: 12071055

Subject Initials: ---

Generated By: (b) (4)

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

				Done/Not Applicable at form level comment else, clarify.
Mar-09-2021 20:01:49 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Closed	Response satisfies query
Mar-09-2021 20:00:09 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Closed	Response satisfies query
Mar-09-2021 14:06:07 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Answered	visit did not occur but this page needs to be filled according to data manager.
Mar-09-2021 14:05:31 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Answered	subject died due to SAE
Mar-09-2021 14:03:57 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto query (autoquery)	Query 3: Opened	Response to "Status" is DEATH but "Specify Status" is Provided.
Mar-08-2021 12:54:44 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Opened	DM: DOV form is marked as Not Done. Please confirm if this visit occurred. If yes, update the DOV form as appropriate. If not occurred, kindly erase the data from this form and add form level comment as Not Done or Not Applicable or else clarify.
Feb-16-2021 22:29:48 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Feb-16-2021 09:28:01 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Changed data per query
Feb-15-2021 19:37:33 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reissued:Opened	DM: The Death Details page is located under Disposition.
Feb-12-2021 11:37:23 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Death detail page is not available on crf. could you please add the relevant page?
Feb-12-2021 02:13:52 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reissued:Opened	DM RQ: Per the CRFCR, if a participant ends the study due to death, The Death Details Coded (DEATH DTL)

090177e196ae4002\Final\Final On: 01-Apr-2021 05:28 (GMT)

**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, Verified

**Site No:** 1207

**Site Name:** (1207) Ankara University Medical Faculty

**Subject No:** 12071055

**Subject Initials:** ---

**Generated By:** (b) (4)

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

				CRF is required to be completed. Currently, the CRF is not completed. Please review and update accordingly.
Feb-11-2021 12:32:03 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	SAE FU report will be submitted within today
Feb-11-2021 12:28:08 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	'Response to 'Status' is 'Death' on Disposition-Follow up, but 'Death' CRF is not yet initiated. Please review and update as appropriate.
Feb-11-2021 12:28:08 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> DEATH	Initial Entry

**4. Specify Status:**

Date	Location	User	Value	Reason
Mar-09-2021 14:03:57 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> visit did not occur because of subject death. this page needs to be complete.	Initial Entry

090177e196ae4002\Final\Final On: 01-Apr-2021 05:28 (GMT)

Header Text C4591001

Visit: Subject Status - Unscheduled

Form: SUBJECT STATUS - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Verified

Site No: 1207

Site Name: (1207) Ankara University Medical Faculty

Subject No: 12071055

Subject Initials: ---

Generated By: (b) (4)

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

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**1. Subject Status**

Date	Location	User	Value	Reason
Feb-11-2021 12:29:00 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> DISCONTINUED	Initial Entry
Feb-11-2021 11:54:33 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> FOLLOW-UP	Transcription Error
Feb-11-2021 11:53:22 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> DISCONTINUED	New Information
Jan-19-2021 12:48:30 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> FOLLOW-UP	Initial Entry
Nov-05-2020 14:47:23 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> ENROLLED/RANDOMIZED	Initial Entry
Nov-05-2020 14:39:45 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SCREENED	Initial Entry

**2. Subject Status Date**

Date	Location	User	Value	Reason
Feb-17-2021 10:25:28 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> Feb/9/2021	Transcription Error
Feb-11-2021 12:29:00 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> Feb/10/2021	Initial Entry
Feb-11-2021 11:54:33 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> Jan/14/2021	Transcription Error
Feb-11-2021 11:54:18 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> Jan/14/2021	Transcription Error
Feb-11-2021 11:53:22 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> Feb/10/2021	New Information
Feb-11-2021 11:52:52 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> Feb/10/2021	New Information
Jan-19-2021 12:48:47 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> Jan/14/2021	Transcription Error
Jan-19-2021 12:48:30 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> Jan/19/2021	Initial Entry
Nov-05-2020 14:47:23 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> Nov/5/2020	Initial Entry
Nov-05-2020 14:39:45 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> Nov/5/2020	Initial Entry

090177e196ae4002\Final\Final On: 01-Apr-2021 05:28 (GMT)

**Header Text** C4591001

**Visit:** Investigator Signature - Unscheduled

**Form:** CASEBOOK SIGNATURE FORM - eCRF Audit Trail History

**Form Version:** 22-Apr-2020 21:04

**Form Status:** Data Complete, Signed, Verified

**Site No:** 1207

**Site Name:** (1207) Ankara University Medical Faculty

**Subject No:** 12071055

**Subject Initials:** ---

**Generated By:** (b) (4)

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

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*I. Casebook Signature*

Date	Location	User	Value	Reason
Nov-09-2020 22:03:09 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <a href="#">Click Here to Enable</a>	Initial Entry