

Header Text: c4591001

Visit: COHORT_SELECTION

Form: COHORT_SELECTION

Form Version: 10-Oct-2020 16:01

Form Status: Data Complete, Frozen, Verified

Site No: 1217

Site Name: (1217) Kocaeli University Faculty of Medicine

Subject No: 12171039

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 19-Apr-2021 21:04

[eCRF Audit Trail History](#)

Cohort Selection

DO NOT USE THE OPTIONS STAGE 1 NONSENTINEL and STAGE 2 from this CRF. As per protocol amendment 5, STAGE 3 option is equivalent to PHASE 2/3.

1.	Select appropriate response - Protocol version	08 SEP 2020
2.	Select appropriate response - What cohort does the subject belong to?	STAGE 3 COHORTS

Header Text: c4591001

Visit: COHORT_SELECTION

Form Version: 22-Apr-2020 21:02

Site No: 1217

Subject No: 12171039

Generated By: (b) (4)

Form: MAIN INFORMED CONSENT

Form Status: Data Complete, Frozen, Verified

Site Name: (1217) Kocaeli University Faculty of Medicine

Subject Initials: ---

Generated Time (GMT): 19-Apr-2021 21:04

[eCRF Audit Trail History](#)

Informed Consent

1.	Consent Was:	OBTAINED Date Written Consent Obtained Nov/4/2020
----	--------------	---

Header Text: c4591001

Visit: COHORT_SELECTION

Form: DEMOGRAPHY

Form Version: 15-Sep-2020 21:54

Form Status: Data Complete, Frozen, Verified

Site No: 1217

Site Name: (1217) Kocaeli University Faculty of Medicine

Subject No: 12171039

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 19-Apr-2021 21:04

[eCRF Audit Trail History](#)

Demography

1.	Subject ID	[12171039]
2.	Birth Date:	(b) (6)/1983
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:	

090177e196d89024\Final\Final On: 22-Apr-2021 02:12 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:02

Site No: 1217

Subject No: 12171039

Generated By: (b) (4)

Form: DATE OF VISIT

Form Status: Data Complete, Frozen, Verified

Site Name: (1217) Kocaeli University Faculty of Medicine

Subject Initials: ---

Generated Time (GMT): 19-Apr-2021 21:04

[eCRF Audit Trail History](#)

Date of Visit

1.	Date of Visit	Nov/4/2020
2.	Erroneous Visit	

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 10-Oct-2020 16:00

Site No: 1217

Subject No: 12171039

Generated By: (b) (4)

Form: INCLUSION/EXCLUSION CRITERIA

Form Status: Data Complete, Frozen, Verified

Site Name: (1217) Kocaeli University Faculty of Medicine

Subject Initials: ---

Generated Time (GMT): 19-Apr-2021 21:04

Form Comments

Inclusion Criteria Not Met

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

2.	Description of Exclusion Criterion Met	Not Applicable _____
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090177e196d89024\Final\Final On: 22-Apr-2021 02:12 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 15-Sep-2020 21:52

Site No: 1217

Subject No: 12171039

Generated By: (b) (4)

Form: DISPOSITION - SCREENING

Form Status: Data Complete, Frozen, Verified

Site Name: (1217) Kocaeli University Faculty of Medicine

Subject Initials: ---

Generated Time (GMT): 19-Apr-2021 21:04

[eCRF Audit Trail History](#)

Disposition - Screening

1.	Date of Completion/Discontinuation/Death	Nov/4/2020
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: 1217

Subject No: 12171039

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY

Form Status: Data Complete, Frozen, Verified

Site Name: (1217) Kocaeli University Faculty of Medicine

Subject Initials: ---

Generated Time (GMT): 19-Apr-2021 21:04

[eCRF Audit Trail History](#)

Medical History Details

1.a	Line/MH Number:	[1]
	Disease/Syndrome /Surgery/Non-Drug Allergies/Drug Allergies:	[hypercholesterol]
	Start Date:	Jan/UNK/2020
	Ongoing:	YES

090177e196d89024\Final\Final On: 22-Apr-2021 02:12 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 15-Sep-2020 21:57

Site No: 1217

Subject No: 12171039

Generated By: (b) (4)

Form: HIV STATUS

Form Status: Data Complete, Frozen, Verified

Site Name: (1217) Kocaeli University Faculty of Medicine

Subject Initials: ---

Generated Time (GMT): 19-Apr-2021 21:04

[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: 1217

Subject No: 12171039

Generated By: (b) (4)

Form: VITAL SIGNS - BASELINE

Form Status: Data Complete, Frozen, Verified

Site Name: (1217) Kocaeli University Faculty of Medicine

Subject Initials: ---

Generated Time (GMT): 19-Apr-2021 21:04

[eCRF Audit Trail History](#)

Vital Signs

1.	Date:	Nov/4/2020
2.	Weight:	[75.0]
3.	Unit:	kg
4.	Height:	[176.0]
5.	Unit:	cm
6.	Body Mass Index:	[24.2]

Vital Signs Details

7.a	Record Identifier:	1
	Temperature:	[37.1]
	Unit:	C
	Temperature Location:	FOREHEAD

090177e196d89024\Final\Final On: 22-Apr-2021 02:12 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1217

Subject No: 12171039

Generated By: (b) (4)

Form: RANDOMIZATION

Form Status: Data Complete, Frozen, Verified

Site Name: (1217) Kocaeli University Faculty of Medicine

Subject Initials: ---

Generated Time (GMT): 19-Apr-2021 21:04

[eCRF Audit Trail History](#)

Disposition

1.	Randomization Date :	Nov/4/2020
2.	Randomization Number:	[115336]
3.	Randomization Group:	[]

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1217

Site Name: (1217) Kocaeli University Faculty of Medicine

Subject No: 12171039

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 19-Apr-2021 21:04

[eCRF Audit Trail History](#)

Electronic Sample Tracking

1.	Data Origin	SITE
2.	Sample Type	SERUM
3.	Sample Collected?	YES Date of Collection: Nov/4/2020
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	[BPZ96Y]
5.b	Sample ID	[BPZ96Z]
5.c	Sample ID	[BS2S40]
5.d	Sample ID	[BS2S41]

090177e196d89024\Final\Final On: 22-Apr-2021 02:12 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1217

Site Name: (1217) Kocaeli University Faculty of Medicine

Subject No: 12171039

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 19-Apr-2021 21:04

[eCRF Audit Trail History](#)

Electronic Sample Tracking

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB
3.	Sample Collected?	YES Date of Collection: Nov/4/2020
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	[BPZ9F7]
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Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:04

Site No: 1217

Subject No: 12171039

Generated By: (b) (4)

Form: VACCINATION

Form Status: Data Complete, Frozen, Verified

Site Name: (1217) Kocaeli University Faculty of Medicine

Subject Initials: ---

Generated Time (GMT): 19-Apr-2021 21:04

[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/4/2020 09:50
5.	Anatomical Location:	DELTOID MUSCLE
6.	Body Side:	RIGHT
7.	Route:	INTRAMUSCULAR
8.	Actual Dose:	[]
9.	Unit:	
10.	Timeframe Subject Was Observed	THE PROTOCOL SPECIFIED OBSERVATION PERIOD
11.	Was the subject observed for at least the protocol specified observation period after investigational product administration?	YES

090177e196d89024\Final\Final On: 22-Apr-2021 02:12 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 06-Jul-2020 21:53

Site No: 1217

Subject No: 12171039

Generated By: (b) (4)

Form: REACTOGENICITY DIARY

Form Status: Data Complete, Frozen, Verified

Site Name: (1217) Kocaeli University Faculty of Medicine

Subject Initials: ---

Generated Time (GMT): 19-Apr-2021 21:04

[eCRF Audit Trail History](#)

Reactogenicity Diary

1.	Select appropriate response - Reactogenicity diary collection	YES - REACTOGENICITY E-DIARY COLLECTED FOR THIS SUBJECT
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Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:02

Site No: 1217

Subject No: 12171039

Generated By: (b) (4)

Form: DATE OF VISIT

Form Status: Data Complete, Frozen, Verified

Site Name: (1217) Kocaeli University Faculty of Medicine

Subject Initials: ---

Generated Time (GMT): 19-Apr-2021 21:04

[eCRF Audit Trail History](#)

Date of Visit

1.	Date of Visit	Nov/25/2020
2.	Erroneous Visit	

Header Text: c4591001

Visit: V2_VAX2_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES

Form Version: 10-Oct-2020 16:03

Form Status: Data Complete, Frozen, Verified

Site No: 1217

Site Name: (1217) Kocaeli University Faculty of Medicine

Subject No: 12171039

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 19-Apr-2021 21:04

[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?	YES Ongoing? NO Stop Date: Nov/10/2020

090177e196d89024\Final\Final On: 22-Apr-2021 02:12 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES

Form Version: 10-Oct-2020 16:03

Form Status: Data Complete, Frozen, Verified

Site No: 1217

Site Name: (1217) Kocaeli University Faculty of Medicine

Subject No: 12171039

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 19-Apr-2021 21:04

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

090177e196d89024\Final\Final On: 22-Apr-2021 02:12 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES

Form Version: 10-Oct-2020 16:03

Form Status: Data Complete, Frozen, Verified

Site No: 1217

Site Name: (1217) Kocaeli University Faculty of Medicine

Subject No: 12171039

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 19-Apr-2021 21:04

3.	Injection Site Location:	DELTOID MUSCLE
4.	Injection Site Body Side:	RIGHT
5.a	Injection Site Reaction:	REDNESS
	Were injection site reactions present on the last day the Subject Diary was completed?	NO
5.b	Injection Site Reaction:	SWELLING
	Were injection site reactions present on the last day the Subject Diary was completed?	NO
5.c	Injection Site Reaction:	PAIN AT INJECTION SITE
	Were injection site reactions present on the last day the Subject Diary was completed?	NO

090177e196d89024\Final\Final On: 22-Apr-2021 02:12 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 10-Oct-2020 16:01

Site No: 1217

Subject No: 12171039

Generated By: (b) (4)

Form: VITAL SIGNS - TEMP

Form Status: Data Complete, Frozen, Verified

Site Name: (1217) Kocaeli University Faculty of Medicine

Subject Initials: ---

Generated Time (GMT): 19-Apr-2021 21:04

[eCRF Audit Trail History](#)

Vital Signs

1.	Date:	Nov/25/2020
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Vital Signs Details

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

090177e196d89024\Final\Final On: 22-Apr-2021 02:12 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1217

Site Name: (1217) Kocaeli University Faculty of Medicine

Subject No: 12171039

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 19-Apr-2021 21:04

[eCRF Audit Trail History](#)

Electronic Sample Tracking

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB
3.	Sample Collected?	YES Date of Collection: Nov/25/2020
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	[BR510Z]
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Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:04

Site No: 1217

Subject No: 12171039

Generated By: (b) (4)

Form: VACCINATION

Form Status: Data Complete, Frozen, Verified

Site Name: (1217) Kocaeli University Faculty of Medicine

Subject Initials: ---

Generated Time (GMT): 19-Apr-2021 21:04

[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/25/2020 10:30
5.	Anatomical Location:	DELTOID MUSCLE
6.	Body Side:	RIGHT
7.	Route:	INTRAMUSCULAR
8.	Actual Dose:	[]
9.	Unit:	
10.	Timeframe Subject Was Observed	THE PROTOCOL SPECIFIED OBSERVATION PERIOD
11.	Was the subject observed for at least the protocol specified observation period after investigational product administration?	YES

090177e196d89024\Final\Final On: 22-Apr-2021 02:12 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L **Form:** DATE OF VISIT

Form Version: 22-Apr-2020 21:02 **Form Status:** Data Complete, Frozen, Verified

Site No: 1217 **Site Name:** (1217) Kocaeli University Faculty of Medicine

Subject No: 12171039 **Subject Initials:** ---

Generated By: (b) (4) **Generated Time (GMT):** 19-Apr-2021 21:04

[eCRF Audit Trail History](#)

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

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L **Form:** VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES

Form Version: 10-Oct-2020 16:03 **Form Status:** Data Complete, Frozen, Verified

Site No: 1217 **Site Name:** (1217) Kocaeli University Faculty of Medicine

Subject No: 12171039 **Subject Initials:** ---

Generated By: (b) (4) **Generated Time (GMT):** 19-Apr-2021 21:04

[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

090177e196d89024\Final\Final On: 22-Apr-2021 02:12 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L **Form:** VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES

Form Version: 10-Oct-2020 16:03 **Form Status:** Data Complete, Frozen, Verified

Site No: 1217 **Site Name:** (1217) Kocaeli University Faculty of Medicine

Subject No: 12171039 **Subject Initials:** ---

Generated By: (b) (4) **Generated Time (GMT):** 19-Apr-2021 21:04

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

090177e196d89024\Final\Final On: 22-Apr-2021 02:12 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L **Form:** VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES

Form Version: 10-Oct-2020 16:03 **Form Status:** Data Complete, Frozen, Verified

Site No: 1217 **Site Name:** (1217) Kocaeli University Faculty of Medicine

Subject No: 12171039 **Subject Initials:** ---

Generated By: (b) (4) **Generated Time (GMT):** 19-Apr-2021 21:04

3.	Injection Site Location:	DELTOID MUSCLE
4.	Injection Site Body Side:	RIGHT
5.a	Injection Site Reaction:	REDNESS
	Were injection site reactions present on the last day the Subject Diary was completed?	NO
5.b	Injection Site Reaction:	SWELLING
	Were injection site reactions present on the last day the Subject Diary was completed?	NO
5.c	Injection Site Reaction:	PAIN AT INJECTION SITE
	Were injection site reactions present on the last day the Subject Diary was completed?	NO

090177e196d89024\Final\Final On: 22-Apr-2021 02:12 (GMT)

Header Text: c4591001**Visit:** V3_MONTH1_POSTVAX2_L **Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY**Form Version:** 22-Apr-2020 21:03 **Form Status:** Data Complete, Frozen, Verified**Site No:** 1217**Site Name:** (1217) Kocaeli University Faculty of Medicine**Subject No:** 12171039**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 19-Apr-2021 21:04[eCRF Audit Trail History](#)**Electronic Sample Tracking**

1.	Data Origin	SITE
2.	Sample Type	SERUM
3.	Sample Collected?	YES Date of Collection: Dec/23/2020
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[]

Aliquot

Please enter barcode for each aliquot.

5.a	Sample ID	[BPZ9BX]
5.b	Sample ID	[BPZ9BY]
5.c	Sample ID	[BS2S6X]
5.d	Sample ID	[BS2S6Y]

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: 1217

Site Name: (1217) Kocaeli University Faculty of
Medicine

Subject No: 12171039

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 19-Apr-2021 21:04

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 Version: 20-Feb-2021 02:17

Site No: 1217

Subject No: 12171039

Generated By: (b) (4)

Form: SIGNS AND SYMPTOMS OF POTENTIAL
COVID-19

Form Status: Not Started

Site Name: (1217) Kocaeli University Faculty of
Medicine

Subject Initials: ---

Generated Time (GMT): 19-Apr-2021 21:04

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 Version: 22-Apr-2020 21:03

Site No: 1217

Subject No: 12171039

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING - NASAL
SWAB SELF

Form Status: Not Started

Site Name: (1217) Kocaeli University Faculty of
Medicine

Subject Initials: ---

Generated Time (GMT): 19-Apr-2021 21:04

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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090177e196d89024\Final\Final On: 22-Apr-2021 02:12 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL - New
Unscheduled Visit

Form Version: 22-Apr-2020 21:03

Site No: 1217

Subject No: 12171039

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING - NASAL
SWAB

Form Status: Not Started

Site Name: (1217) Kocaeli University Faculty of
Medicine

Subject Initials: ---

Generated Time (GMT): 19-Apr-2021 21:04

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: 1217

Site Name: (1217) Kocaeli University Faculty of
Medicine

Subject No: 12171039

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 19-Apr-2021 21:04

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?	
----	--	--

090177e196d89024\Final\Final On: 22-Apr-2021 02:12 (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: 1217

Site Name: (1217) Kocaeli University Faculty of
Medicine

Subject No: 12171039

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 19-Apr-2021 21:04

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: 1217

Site Name: (1217) Kocaeli University Faculty of
Medicine

Subject No: 12171039

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 19-Apr-2021 21:04

Date of Visit

1.	Date of Visit	//
2.	Erroneous Visit	

COVID-19 Illness Visit

3.	COVID-19 Illness Visit:	
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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: 1217

Site Name: (1217) Kocaeli University Faculty of
Medicine

Subject No: 12171039

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 19-Apr-2021 21:04

Electronic Sample Tracking

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

Aliquot

Please enter barcode for each aliquot.

5.	Sample ID	[]
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Header Text: c4591001

Visit: POT_COVID_REPEAT_SWAB **Form:** DATE OF VISIT - REPEAT SWAB
- New Unscheduled Visit

Form Version: 10-Oct-2020 15:57 **Form Status:** Not Started

Site No: 1217

Site Name: (1217) Kocaeli University Faculty of
Medicine

Subject No: 12171039

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 19-Apr-2021 21:04

Date of Visit

1.	Date of Visit	//
2.	Erroneous Visit	

COVID-19 Repeat Swab

3.	COVID-19 Repeat Swab:	
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090177e196d89024\Final\Final On: 22-Apr-2021 02:12 (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: 1217 **Site Name:** (1217) Kocaeli University Faculty of Medicine

Subject No: 12171039 **Subject Initials:** ---

Generated By: (b) (4) **Generated Time (GMT):** 19-Apr-2021 21:04

Electronic Sample Tracking

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

Aliquot

Please enter barcode for each aliquot.

5.	Sample ID	[]
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Header Text: c4591001

Visit: Logs

Form: ADVERSE EVENT REPORT

Form Version: 22-Apr-2020 21:02

Site No: 1217

Site Name: (1217) Kocaeli University Faculty of Medicine

Subject No: 12171039

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 19-Apr-2021 21:04

#	Category	AE Identifier	Adverse Event	Start Date	Is the Adverse Event Still Ongoing	Form Instance
1.	ADVERSE EVENT	1	Tinnitus in right ear	Jan/8/2021 UNK:UNK	NO End Date Time: Jan/18/2021 UNK:UNK	Repeating Pages
2.	ADVERSE EVENT	2	Acute hearing loss in right ear	Jan/UNK/2021 UNK:UNK	NO End Date Time: Jan/18/2021 UNK:UNK	Repeating Pages

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Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1217

Subject No: 12171039

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Frozen

Site Name: (1217) Kocaeli University Faculty of Medicine

Subject Initials: ---

Generated Time (GMT): 19-Apr-2021 21:04

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Adverse Event Report

1.	Category:	ADVERSE EVENT
2.	AE ID:	[1]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[Tinnitus in right ear]
4.	Start Date Time:	Jan/8/2021 UNK:UNK
5.	Is the adverse event still ongoing?	NO End Date Time: Jan/18/2021 UNK:UNK
6.	Toxicity Grade:	1

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Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1217

Subject No: 12171039

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Frozen

Site Name: (1217) Kocaeli University Faculty of Medicine

Subject Initials: ---

Generated Time (GMT): 19-Apr-2021 21:04

7.	Is the adverse event serious? If Yes, NOTIFY PFIZER IMMEDIATELY. Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).	NO
8.	Is this adverse event the result of a study Medication Error? If Yes, record the type of medication error on the Medication Error Log.	NO
9.	Is this event related to study treatment:	NOT RELATED If Not Related to study treatment(s), this event is due to: OTHER If Other, specify: [unknown]
10.	Latest Action Taken with Study Treatment:	NOT APPLICABLE

090177e196d89024\Final\Final On: 22-Apr-2021 02:12 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen

Site No: 1217

Site Name: (1217) Kocaeli University Faculty of Medicine

Subject No: 12171039

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 19-Apr-2021 21:04

11.	Was a Concomitant Medication given?	YES
12.	Was a Non-Drug Treatment given?	NO
13.	What was the outcome of this adverse event?:	RECOVERED/RESOLVED
14.	Did the adverse event cause the subject to be discontinued from the study?	NO
15.	Serious Adverse Event Number: For Pfizer Use Only	[]

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Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1217

Subject No: 12171039

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Frozen

Site Name: (1217) Kocaeli University Faculty of
Medicine

Subject Initials: ---

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Adverse Event Report

1.	Category:	ADVERSE EVENT
2.	AE ID:	[2]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[Acute hearing loss in right ear]
4.	Start Date Time:	Jan/UNK/2021 UNK:UNK
5.	Is the adverse event still ongoing?	NO End Date Time: Jan/18/2021 UNK:UNK
6.	Toxicity Grade:	1

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Header Text: c4591001

Visit: Logs - Unscheduled

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Site No: 1217

Subject No: 12171039

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Frozen

Site Name: (1217) Kocaeli University Faculty of Medicine

Subject Initials: ---

Generated Time (GMT): 19-Apr-2021 21:04

7.	Is the adverse event serious? If Yes, NOTIFY PFIZER IMMEDIATELY. Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).	NO
8.	Is this adverse event the result of a study Medication Error? If Yes, record the type of medication error on the Medication Error Log.	NO
9.	Is this event related to study treatment:	NOT RELATED If Not Related to study treatment(s), this event is due to: OTHER If Other, specify: [Unknown]
10.	Latest Action Taken with Study Treatment:	NOT APPLICABLE

090177e196d89024\Final\Final On: 22-Apr-2021 02:12 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen

Site No: 1217

Site Name: (1217) Kocaeli University Faculty of Medicine

Subject No: 12171039

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 19-Apr-2021 21:04

11.	Was a Concomitant Medication given?	YES
12.	Was a Non-Drug Treatment given?	NO
13.	What was the outcome of this adverse event?:	RECOVERED/RESOLVED
14.	Did the adverse event cause the subject to be discontinued from the study?	NO
15.	Serious Adverse Event Number: For Pfizer Use Only	[]

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Header Text: c4591001

Visit: Logs

Form: MEDICATION ERROR

Form Version: 17-Jul-2020 21:54

Site No: 1217

Site Name: (1217) Kocaeli University Faculty of Medicine

Subject No: 12171039

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 19-Apr-2021 21:04

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

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 17-Jul-2020 21:54

Site No: 1217

Subject No: 12171039

Generated By: (b) (4)

Form: MEDICATION ERROR

Form Status: Not Started

Site Name: (1217) Kocaeli University Faculty of Medicine

Subject Initials: ---

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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	[]

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Header Text: c4591001

Visit: Logs

Form: CONCOMITANT MEDICATIONS - NON STUDY VACCINATIONS

Form Version: 22-Apr-2020 21:03

Site No: 1217

Site Name: (1217) Kocaeli University Faculty of Medicine

Subject No: 12171039

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 19-Apr-2021 21:04

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

Header Text: c4591001

Visit: Logs - Unscheduled

Form: CONCOMITANT MEDICATIONS - NON STUDY VACCINATIONS

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1217

Site Name: (1217) Kocaeli University Faculty of Medicine

Subject No: 12171039

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 19-Apr-2021 21:04

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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:	//

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Header Text: c4591001

Visit: Logs

Form: CONCOMITANT MEDICATIONS - PROHIBITED

Form Version: 22-Apr-2020 21:03

Site No: 1217

Site Name: (1217) Kocaeli University Faculty of Medicine

Subject No: 12171039

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 19-Apr-2021 21:04

#	Sponsor-Defined Identifier	Category for Medication	Concomitant Medications Pre-specified	Name of Medication	Dose Description	Form Instance
1.	1	CORTICOSTEROIDS	NO	Prednol (methylprednisolone)	20	Repeating Pages
2.	2	CORTICOSTEROIDS	NO	Prednol (methylprednisolone)	16	Repeating Pages
3.	3	CORTICOSTEROIDS	NO	Prednol (methylprednisolone)	16	Repeating Pages
4.	4	CORTICOSTEROIDS	NO	Prednol (methylprednisolone)	16	Repeating Pages
5.	5	CORTICOSTEROIDS	NO	Prednol (methylprednisolone)	16	Repeating Pages
6.	6	CORTICOSTEROIDS	NO	Prednol (methylprednisolone)	8	Repeating Pages

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Header Text: c4591001

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Form: CONCOMITANT MEDICATIONS - PROHIBITED

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1217

Site Name: (1217) Kocaeli University Faculty of Medicine

Subject No: 12171039

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Concomitant Medications

1.	What is the medication identifier?	[1]
2.	Category:	CORTICOSTEROIDS
3.	Concomitant Medications Pre-specified:	NO
4.	Medication: Provide the complete generic drug name (including salt form, where applicable). Where generic name is unknown, enter the full trade or proprietary name. Include clarifying information in the Medication text (e.g., Ingredient(s), route, use, formulation).	[Prednol (methylprednisolone)]
5.	Dose:	[20]
6.	Dose Unit:	mg
7.	Dose Frequency:	QID
8.	Route:	ORAL
9.	Start Date:	Jan/15/2021

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Header Text: c4591001

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Form: CONCOMITANT MEDICATIONS - PROHIBITED

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1217

Site Name: (1217) Kocaeli University Faculty of Medicine

Subject No: 12171039

Subject Initials: ---

Generated By: (b) (4)

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10.	Ongoing?	NO End Date: Jan/17/2021
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Header Text: c4591001

Visit: Logs - Unscheduled

Form: CONCOMITANT MEDICATIONS - PROHIBITED

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Form Status: Data Complete, Frozen, Verified

Site No: 1217

Site Name: (1217) Kocaeli University Faculty of Medicine

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Subject Initials: ---

Generated By: (b) (4)

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Concomitant Medications

1.	What is the medication identifier?	[2]
2.	Category:	CORTICOSTEROIDS
3.	Concomitant Medications Pre-specified:	NO
4.	Medication: Provide the complete generic drug name (including salt form, where applicable). Where generic name is unknown, enter the full trade or proprietary name. Include clarifying information in the Medication text (e.g., Ingredient(s), route, use, formulation).	[Prednol (methylprednisolone)]
5.	Dose:	[16]
6.	Dose Unit:	mg
7.	Dose Frequency:	QID
8.	Route:	ORAL
9.	Start Date:	Jan/18/2021

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Header Text: c4591001

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Form: CONCOMITANT MEDICATIONS - PROHIBITED

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1217

Site Name: (1217) Kocaeli University Faculty of Medicine

Subject No: 12171039

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 19-Apr-2021 21:04

10.	Ongoing?	NO End Date: Jan/20/2021
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Header Text: c4591001

Visit: Logs - Unscheduled

Form: CONCOMITANT MEDICATIONS - PROHIBITED

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1217

Site Name: (1217) Kocaeli University Faculty of Medicine

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Generated By: (b) (4)

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Concomitant Medications

1.	What is the medication identifier?	[3]
2.	Category:	CORTICOSTEROIDS
3.	Concomitant Medications Pre-specified:	NO
4.	Medication: Provide the complete generic drug name (including salt form, where applicable). Where generic name is unknown, enter the full trade or proprietary name. Include clarifying information in the Medication text (e.g., Ingredient(s), route, use, formulation).	[Prednol (methylprednisolone)]
5.	Dose:	[16]
6.	Dose Unit:	mg
7.	Dose Frequency:	TID
8.	Route:	ORAL
9.	Start Date:	Jan/21/2021

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Header Text: c4591001

Visit: Logs - Unscheduled

Form: CONCOMITANT MEDICATIONS - PROHIBITED

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1217

Site Name: (1217) Kocaeli University Faculty of Medicine

Subject No: 12171039

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 19-Apr-2021 21:04

10.	Ongoing?	NO End Date: Jan/23/2021
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Header Text: c4591001

Visit: Logs - Unscheduled

Form: CONCOMITANT MEDICATIONS - PROHIBITED

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1217

Site Name: (1217) Kocaeli University Faculty of Medicine

Subject No: 12171039

Subject Initials: ---

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Concomitant Medications

1.	What is the medication identifier?	[4]
2.	Category:	CORTICOSTEROIDS
3.	Concomitant Medications Pre-specified:	NO
4.	Medication: Provide the complete generic drug name (including salt form, where applicable). Where generic name is unknown, enter the full trade or proprietary name. Include clarifying information in the Medication text (e.g., Ingredient(s), route, use, formulation).	[Prednol (methylprednisolone)]
5.	Dose:	[16]
6.	Dose Unit:	mg
7.	Dose Frequency:	BID
8.	Route:	ORAL
9.	Start Date:	Jan/24/2021

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Header Text: c4591001

Visit: Logs - Unscheduled

Form: CONCOMITANT MEDICATIONS - PROHIBITED

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1217

Site Name: (1217) Kocaeli University Faculty of Medicine

Subject No: 12171039

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 19-Apr-2021 21:04

10.	Ongoing?	NO End Date: Jan/26/2021
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Header Text: c4591001

Visit: Logs - Unscheduled

Form: CONCOMITANT MEDICATIONS - PROHIBITED

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1217

Site Name: (1217) Kocaeli University Faculty of Medicine

Subject No: 12171039

Subject Initials: ---

Generated By: (b) (4)

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Concomitant Medications

1.	What is the medication identifier?	[5]
2.	Category:	CORTICOSTEROIDS
3.	Concomitant Medications Pre-specified:	NO
4.	Medication: Provide the complete generic drug name (including salt form, where applicable). Where generic name is unknown, enter the full trade or proprietary name. Include clarifying information in the Medication text (e.g., Ingredient(s), route, use, formulation).	[Prednol (methylprednisolone)]
5.	Dose:	[16]
6.	Dose Unit:	mg
7.	Dose Frequency:	QD
8.	Route:	ORAL
9.	Start Date:	Jan/27/2021

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Header Text: c4591001

Visit: Logs - Unscheduled

Form: CONCOMITANT MEDICATIONS - PROHIBITED

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1217

Site Name: (1217) Kocaeli University Faculty of Medicine

Subject No: 12171039

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 19-Apr-2021 21:04

10.	Ongoing?	NO End Date: Jan/29/2021
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Header Text: c4591001

Visit: Logs - Unscheduled

Form: CONCOMITANT MEDICATIONS - PROHIBITED

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1217

Site Name: (1217) Kocaeli University Faculty of Medicine

Subject No: 12171039

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 19-Apr-2021 21:04

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Concomitant Medications

1.	What is the medication identifier?	[6]
2.	Category:	CORTICOSTEROIDS
3.	Concomitant Medications Pre-specified:	NO
4.	Medication: Provide the complete generic drug name (including salt form, where applicable). Where generic name is unknown, enter the full trade or proprietary name. Include clarifying information in the Medication text (e.g., Ingredient(s), route, use, formulation).	[Prednol (methylprednisolone)]
5.	Dose:	[8]
6.	Dose Unit:	mg
7.	Dose Frequency:	QD
8.	Route:	ORAL
9.	Start Date:	Jan/30/2021

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Header Text: c4591001

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Form: CONCOMITANT MEDICATIONS - PROHIBITED

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1217

Site Name: (1217) Kocaeli University Faculty of Medicine

Subject No: 12171039

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 19-Apr-2021 21:04

10.	Ongoing?	NO End Date: Feb/1/2021
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Header Text: c4591001

Visit: Logs

Form: RADIATION TREATMENT

Form Version: 22-Apr-2020 21:02

Site No: 1217

Site Name: (1217) Kocaeli University Faculty of Medicine

Subject No: 12171039

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 19-Apr-2021 21:04

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

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Header Text: c4591001

Visit: Logs - Unscheduled

Form: RADIATION TREATMENT

Form Version: 22-Apr-2020 21:02

Form Status: Not Started

Site No: 1217

Site Name: (1217) Kocaeli University Faculty of Medicine

Subject No: 12171039

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 19-Apr-2021 21:04

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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?	

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Header Text: c4591001

Visit: Logs

Form: TRANSFUSIONS

Form Version: 22-Apr-2020 21:03

Site No: 1217

Site Name: (1217) Kocaeli University Faculty of
Medicine

Subject No: 12171039

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 19-Apr-2021 21:04

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

Header Text: c4591001

Visit: Logs - Unscheduled

Form: TRANSFUSIONS

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1217

Site Name: (1217) Kocaeli University Faculty of
Medicine

Subject No: 12171039

Subject Initials: ---

Generated By: (b) (4)

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

Header Text: c4591001

Visit: Unplanned - New Unscheduled **Form:** DATE OF VISIT
Visit

Form Version: 22-Apr-2020 21:02 **Form Status:** Not Started

Site No: 1217 **Site Name:** (1217) Kocaeli University Faculty of
Medicine

Subject No: 12171039 **Subject Initials:** ---

Generated By: (b) (4) **Generated Time (GMT):** 19-Apr-2021 21:04

Date of Visit

1.	Date of Visit	//
2.	Erroneous Visit	

Header Text: c4591001

Visit: Unplanned - New Unscheduled Visit **Form:** UNPLANNED VISIT

Form Version: 22-Apr-2020 21:04 **Form Status:** Not Started

Site No: 1217 **Site Name:** (1217) Kocaeli University Faculty of Medicine

Subject No: 12171039 **Subject Initials:** ---

Generated By: (b) (4) **Generated Time (GMT):** 19-Apr-2021 21:04

Unplanned Assessments

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: 1217

Site Name: (1217) Kocaeli University Faculty of
Medicine

Subject No: 12171039

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 19-Apr-2021 21:04

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: 1217

Site Name: (1217) Kocaeli University Faculty of
Medicine

Subject No: 12171039

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 19-Apr-2021 21:04

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: 1217

Site Name: (1217) Kocaeli University Faculty of
Medicine

Subject No: 12171039

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 19-Apr-2021 21:04

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?	

090177e196d89024\Final\Final On: 22-Apr-2021 02:12 (GMT)

Header Text: c4591001

Visit: Unplanned Vaccination -
Unscheduled

Form: CONTACT OUTCOME - MONTH 1

Form Version: 10-Oct-2020 15:57

Form Status: Not Started

Site No: 1217

Site Name: (1217) Kocaeli University Faculty of
Medicine

Subject No: 12171039

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 19-Apr-2021 21:04

Contact Outcome

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

Header Text: c4591001

Visit: Unplanned Vaccination -
Unscheduled

Form: CONTACT OUTCOME - MONTH 6

Form Version: 10-Oct-2020 16:01

Form Status: Not Started

Site No: 1217

Site Name: (1217) Kocaeli University Faculty of
Medicine

Subject No: 12171039

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 19-Apr-2021 21:04

Contact Outcome

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

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: 1217

Site Name: (1217) Kocaeli University Faculty of Medicine

Subject No: 12171039

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 19-Apr-2021 21:04

[eCRF Audit Trail History](#)

Disposition - Treatment

1.	Date of Completion/Discontinuation /Death :	Dec/23/2020
2.	Phase of Disposition:	VACCINATION
3.	Status:	COMPLETED
4.	Specify Status:	[]

Header Text: c4591001

Visit: Potential ReVax Initial Contact - **Form:** DATE OF VISIT
Unscheduled

Form Version: 22-Apr-2020 21:02 **Form Status:** Data Complete, Frozen, Verified

Site No: 1217 **Site Name:** (1217) Kocaeli University Faculty of
Medicine

Subject No: 12171039 **Subject Initials:** ---

Generated By: (b) (4) **Generated Time (GMT):** 19-Apr-2021 21:04

[eCRF Audit Trail History](#)

Date of Visit

1.	Date of Visit	Feb/10/2021
2.	Erroneous Visit	

Header Text: c4591001

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

Form Version: 10-Dec-2020 02:25 **Form Status:** Data Complete, Frozen

Site No: 1217 **Site Name:** (1217) Kocaeli University Faculty of
Medicine

Subject No: 12171039 **Subject Initials:** ---

Generated By: (b) (4) **Generated Time (GMT):** 19-Apr-2021 21:04

[eCRF Audit Trail History](#)

Further Vaccination Confirmation

1.	Select appropriate response - Is participant willing to return for Vaccination 3?	Participant is willing to return for Vaccination 3 Participant is: eligible per local/national recommendations and confirmed to have received only placebo at Vaccination 1/2
----	---	--

Header Text: c4591001

Visit: Follow-Up - Unscheduled

Form: DISPOSITION - FOLLOW-UP

Form Version: 15-Sep-2020 21:53

Form Status: Not Started

Site No: 1217

Site Name: (1217) Kocaeli University Faculty of Medicine

Subject No: 12171039

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 19-Apr-2021 21:04

Disposition - Follow-Up

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

090177e196d89024\Final\Final On: 22-Apr-2021 02:12 (GMT)

Header Text: c4591001

Visit: Disposition - Unscheduled

Form: TREATMENT UNBLINDED

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1217

Site Name: (1217) Kocaeli University Faculty of Medicine

Subject No: 12171039

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 19-Apr-2021 21:04

[eCRF Audit Trail History](#)

Treatment Unblinded

1.	Date Treatment Unblinded :	Feb/10/2021
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: 1217

Subject No: 12171039

Generated By: (b) (4)

Form: WITHDRAWAL OF CONSENT

Form Status: Data Complete, Verified

Site Name: (1217) Kocaeli University Faculty of Medicine

Subject Initials: ---

Generated Time (GMT): 19-Apr-2021 21:04

[Form Comments](#)

[eCRF Audit Trail History](#)

Withdrawal Of Consent

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

Header Text: c4591001

Visit: Disposition - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1217

Subject No: 12171039

Generated By: (b) (4)

Form: DEATH DETAILS CODED

Form Status: Data Complete, Verified

Site Name: (1217) Kocaeli University Faculty of Medicine

Subject Initials: ---

Generated Time (GMT): 19-Apr-2021 21:04

[Form Comments](#)

[eCRF Audit Trail History](#)

Death Details

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

Cause of Death

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

Header Text: c4591001

Visit: V101_VAX3

Form: DATE OF VISIT

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen, Verified

Site No: 1217

Site Name: (1217) Kocaeli University Faculty of Medicine

Subject No: 12171039

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 19-Apr-2021 21:04

[eCRF Audit Trail History](#)

Date of Visit

1.	Date of Visit	Mar/3/2021
2.	Erroneous Visit	

Header Text: c4591001

Visit: V101_VAX3

Form: INFORMED CONSENT - FURTHER VACCINATION

Form Version: 10-Dec-2020 02:31

Form Status: Data Complete, Frozen, Verified

Site No: 1217

Site Name: (1217) Kocaeli University Faculty of Medicine

Subject No: 12171039

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 19-Apr-2021 21:04

[eCRF Audit Trail History](#)

Informed Consent - Further Vaccination

1.	Consent Was:	OBTAINED Date Written Consent Obtained Mar/3/2021
----	--------------	---

Header Text: c4591001

Visit: V101_VAX3

Form: INCLUSION/EXCLUSION CRITERIA - FURTHER VACCINATION

Form Version: 10-Dec-2020 02:30

Form Status: Data Complete, Frozen, Verified

Site No: 1217

Site Name: (1217) Kocaeli University Faculty of Medicine

Subject No: 12171039

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 19-Apr-2021 21:04

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

090177e196d89024\Final\Final On: 22-Apr-2021 02:12 (GMT)

Header Text: c4591001

Visit: V101_VAX3

Form: DISPOSITION - SCREENING FOR FURTHER VACCINATION

Form Version: 10-Dec-2020 02:31

Form Status: Data Complete, Frozen, Verified

Site No: 1217

Site Name: (1217) Kocaeli University Faculty of Medicine

Subject No: 12171039

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 19-Apr-2021 21:04

[eCRF Audit Trail History](#)

Disposition - Screening for Further Vaccination

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

Header Text: c4591001

Visit: V101_VAX3

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1217

Site Name: (1217) Kocaeli University Faculty of Medicine

Subject No: 12171039

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 19-Apr-2021 21:04

[eCRF Audit Trail History](#)

Electronic Sample Tracking

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

Aliquot

Please enter barcode for each aliquot.

5.a	Sample ID	[BN897X]
5.b	Sample ID	[BN897Y]
5.c	Sample ID	[BS2S9P]
5.d	Sample ID	[BS2S9R]

090177e196d89024\Final\Final On: 22-Apr-2021 02:12 (GMT)

Header Text: c4591001

Visit: V101_VAX3

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1217

Site Name: (1217) Kocaeli University Faculty of Medicine

Subject No: 12171039

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 19-Apr-2021 21:04

[eCRF Audit Trail History](#)

Electronic Sample Tracking

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

Aliquot

Please enter barcode for each aliquot.

5.a	Sample ID	[BN897W]
-----	-----------	----------

Header Text: c4591001

Visit: V101_VAX3

Form Version: 10-Dec-2020 02:26

Site No: 1217

Subject No: 12171039

Generated By: (b) (4)

Form: VACCINATION

Form Status: Data Complete, Frozen, Verified

Site Name: (1217) Kocaeli University Faculty of Medicine

Subject Initials: ---

Generated Time (GMT): 19-Apr-2021 21:04

[eCRF Audit Trail History](#)

Vaccination

1.	Was there a temporary delay of vaccination?	NO
2.	Treatment Name	[BNT162b2]
3.	Formulation:	INJECTION
4.	Dose Date Time:	Mar/3/2021 10:25
5.	Anatomical Location:	DELTOID MUSCLE
6.	Body Side:	RIGHT
7.	Route:	INTRAMUSCULAR
8.	Actual Dose:	[30.0]
9.	Unit:	ug
10.	Timeframe Subject Was Observed	30 MINUTES
11.	Was the subject observed for at least the protocol specified observation period after investigational product administration?	YES

090177e196d89024\Final\Final On: 22-Apr-2021 02:12 (GMT)

Header Text: c4591001

Visit: V102_VAX4

Form Version: 22-Apr-2020 21:02

Site No: 1217

Subject No: 12171039

Generated By: (b) (4)

Form: DATE OF VISIT

Form Status: Not Started

Site Name: (1217) Kocaeli University Faculty of
Medicine

Subject Initials: ---

Generated Time (GMT): 19-Apr-2021 21:04

Date of Visit

1.	Date of Visit	//
2.	Erroneous Visit	

Header Text: c4591001

Visit: V102_VAX4

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1217

Site Name: (1217) Kocaeli University Faculty of Medicine

Subject No: 12171039

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 19-Apr-2021 21:04

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

090177e196d89024\Final\Final On: 22-Apr-2021 02:12 (GMT)

Header Text: c4591001

Visit: V102_VAX4

Form Version: 10-Dec-2020 02:26

Site No: 1217

Subject No: 12171039

Generated By: (b) (4)

Form: VACCINATION

Form Status: Not Started

Site Name: (1217) Kocaeli University Faculty of Medicine

Subject Initials: ---

Generated Time (GMT): 19-Apr-2021 21:04

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?	

090177e196d89024\Final\Final On: 22-Apr-2021 02:12 (GMT)

Header Text: c4591001

Visit: V103_MONTH1

Form Version: 22-Apr-2020 21:02

Site No: 1217

Subject No: 12171039

Generated By: (b) (4)

Form: DATE OF VISIT

Form Status: Not Started

Site Name: (1217) Kocaeli University Faculty of
Medicine

Subject Initials: ---

Generated Time (GMT): 19-Apr-2021 21:04

Date of Visit

1.	Date of Visit	//
2.	Erroneous Visit	

Header Text: c4591001

Visit: V103_MONTH1

Form Version: 22-Apr-2020 21:04

Site No: 1217

Subject No: 12171039

Generated By: (b) (4)

Form: CONTACT OUTCOME

Form Status: Not Started

Site Name: (1217) Kocaeli University Faculty of
Medicine

Subject Initials: ---

Generated Time (GMT): 19-Apr-2021 21:04

Contact Outcome

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

Header Text: c4591001

Visit: V104_MONTH6

Form Version: 22-Apr-2020 21:02

Site No: 1217

Subject No: 12171039

Generated By: (b) (4)

Form: DATE OF VISIT

Form Status: Not Started

Site Name: (1217) Kocaeli University Faculty of
Medicine

Subject Initials: ---

Generated Time (GMT): 19-Apr-2021 21:04

Date of Visit

1.	Date of Visit	//
2.	Erroneous Visit	

Header Text: c4591001

Visit: V104_MONTH6

Form Version: 22-Apr-2020 21:04

Site No: 1217

Subject No: 12171039

Generated By: (b) (4)

Form: CONTACT OUTCOME

Form Status: Not Started

Site Name: (1217) Kocaeli University Faculty of
Medicine

Subject Initials: ---

Generated Time (GMT): 19-Apr-2021 21:04

Contact Outcome

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

Header Text: c4591001

Visit: V105_MONTH18

Form Version: 22-Apr-2020 21:02

Site No: 1217

Subject No: 12171039

Generated By: (b) (4)

Form: DATE OF VISIT

Form Status: Not Started

Site Name: (1217) Kocaeli University Faculty of
Medicine

Subject Initials: ---

Generated Time (GMT): 19-Apr-2021 21:04

Date of Visit

1.	Date of Visit	//
2.	Erroneous Visit	

Header Text: c4591001

Visit: V105_MONTH18

Form Version: 22-Apr-2020 21:04

Site No: 1217

Subject No: 12171039

Generated By: (b) (4)

Form: CONTACT OUTCOME

Form Status: Not Started

Site Name: (1217) Kocaeli University Faculty of
Medicine

Subject Initials: ---

Generated Time (GMT): 19-Apr-2021 21:04

Contact Outcome

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

Header Text: c4591001

Visit:
FURTHER_VACCINATION_EOT -
Unscheduled

Form: DISPOSITION - TREATMENT

Form Version: 20-Feb-2021 02:26

Form Status: Not Started

Site No: 1217

Site Name: (1217) Kocaeli University Faculty of
Medicine

Subject No: 12171039

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 19-Apr-2021 21:04

Disposition - Treatment

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

090177e196d89024\Final\Final On: 22-Apr-2021 02:12 (GMT)

Header Text: c4591001

Visit: Subject Status - Unscheduled

Form: SUBJECT STATUS

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Verified

Site No: 1217

Site Name: (1217) Kocaeli University Faculty of Medicine

Subject No: 12171039

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 19-Apr-2021 21:04

[eCRF Audit Trail History](#)

Subject Status

1.	Subject Status	FOLLOW-UP
2.	Subject Status Date	Dec/23/2020

Header Text: c4591001

Visit: Investigator Signature -
Unscheduled

Form: CASEBOOK SIGNATURE FORM

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Signed, Verified

Site No: 1217

Site Name: (1217) Kocaeli University Faculty of
Medicine

Subject No: 12171039

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 19-Apr-2021 21:04

[eCRF Audit Trail History](#)

Casebook Signature Form

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

Header Text: c4591001

Visit: Investigator Signature -
Unscheduled

Form: CASEBOOK SIGNATURE FORM

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Signed, Verified

Site No: 1217

Site Name: (1217) Kocaeli University Faculty of
Medicine

Subject No: 12171039

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 19-Apr-2021 21:04

[Audit Trail](#)

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

- CRF_Sign

Name	Signature Meaning	Date	Type	Action
Sila Akhan	Approved	Mar-03-2021 12:16:26 (UTC+03:00) Istanbul	BOOK	Signed

Affidavit:

By my dated signature below, I, SilaAkhan, 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: INCLUSION/EXCLUSION CRITERIA -
Comments

Form Version: 10-Oct-2020 16:00

Form Status: Data Complete, Frozen, Verified

Site No: 1217

Site Name: (1217) Kocaeli University Faculty of
Medicine

Subject No: 12171039

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 19-Apr-2021 21:04

[Back to Form](#)

Item	Date	User	Comment
Form	Nov-04-2020 09:12:51 (UTC+03:00) Istanbul	(b) (4), (b) (6) [REDACTED]	Not Applicable

Header Text: c4591001

Visit: Disposition - Unscheduled

Form: WITHDRAWAL OF CONSENT - Comments

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Verified

Site No: 1217

Site Name: (1217) Kocaeli University Faculty of Medicine

Subject No: 12171039

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 19-Apr-2021 21:04

[Back to Form](#)

Item	Date	User	Comment
Form	Feb-10-2021 14:02:55 (UTC+03:00) Istanbul	(b) (4), (b) (6) [Redacted]	Not Applicable

Header Text: c4591001

Visit: Disposition

Form: WITHDRAWAL OF CONSENT - Comments

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Verified

Site No: 1217

Site Name: (1217) Kocaeli University Faculty of Medicine

Subject No: 12171039

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 19-Apr-2021 21:04

[Back to Form](#)

Item	Date	User	Comment
1	Feb-10-2021 14:02:55 (UTC+03:00) Istanbul	(b) (4), (b) (6) [Redacted]	Not Applicable

090177e196d89024\Final\Final On: 22-Apr-2021 02:12 (GMT)

Header Text: c4591001

Visit: Disposition - Unscheduled

Form: DEATH DETAILS CODED - Comments

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Verified

Site No: 1217

Site Name: (1217) Kocaeli University Faculty of Medicine

Subject No: 12171039

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 19-Apr-2021 21:04

[Back to Form](#)

Item	Date	User	Comment
Form	Feb-10-2021 14:03:14 (UTC+03:00) Istanbul	(b) (4), (b) (6) [Redacted]	Not Applicable

Header Text: c4591001

Visit: Disposition

Form: DEATH DETAILS CODED - Comments

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Verified

Site No: 1217

Site Name: (1217) Kocaeli University Faculty of Medicine

Subject No: 12171039

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 19-Apr-2021 21:04

[Back to Form](#)

Item	Date	User	Comment
1	Feb-10-2021 14:03:14 (UTC+03:00) Istanbul	(b) (4), (b) (6) [REDACTED]	Not Applicable

Header Text: c4591001

Visit: V101_VAX3

Form: INCLUSION/EXCLUSION CRITERIA - FURTHER VACCINATION - Comments

Form Version: 10-Dec-2020 02:30

Form Status: Data Complete, Frozen, Verified

Site No: 1217

Site Name: (1217) Kocaeli University Faculty of Medicine

Subject No: 12171039

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 19-Apr-2021 21:04

[Back to Form](#)

Item	Date	User	Comment
Form	Mar-03-2021 11:02:23 (UTC+03:00) Istanbul	(b) (4), (b) (6) [Redacted]	Not Applicable

Header Text: c4591001

Visit: Investigator Signature -
Unscheduled

Form: CASEBOOK SIGNATURE FORM - Signature
History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Signed, Verified

Site No: 1217

Site Name: (1217) Kocaeli University Faculty of
Medicine

Subject No: 12171039

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 19-Apr-2021 21:04

[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
Sila Akhan	Approved	Mar-03-2021 12:16:26 (UTC+03:00) Istanbul	BOOK	Signed

Affidavit:

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

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

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

(b) (6)	N/A	Mar-03-2021 11:02:01 (UTC+03:00) Istanbul		Edit - All signatures invalidated
---------	-----	--	--	---

Affidavit:

N/A

Sila Akhan	Approved	Feb-10-2021 14:15:23 (UTC+03:00) Istanbul	BOOK	Signed
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090177e196d89024\Final\Final On: 22-Apr-2021 02:12 (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: 1217

Site Name: (1217) Kocaeli University Faculty of
Medicine

Subject No: 12171039

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 19-Apr-2021 21:04

Affidavit:

By my dated signature below, I, SilaAkhan, 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 14:02:42 (UTC+03:00) Istanbul		Edit - All signatures invalidated
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Affidavit:

N/A

Sila Akhan	Approved	Feb-03-2021 16:23:28 (UTC+03:00) Istanbul	BOOK	Signed
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090177e196d89024\Final\Final On: 22-Apr-2021 02:12 (GMT)

Header Text: c4591001

Visit: Investigator Signature -
Unscheduled

Form: CASEBOOK SIGNATURE FORM - Signature
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Form Version: 22-Apr-2020 21:04

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Site No: 1217

Site Name: (1217) Kocaeli University Faculty of
Medicine

Subject No: 12171039

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 19-Apr-2021 21:04

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(b) (6)	N/A	Feb-03-2021 16:02:02 (UTC+03:00) Istanbul		Edit - All signatures invalidated
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Affidavit:

N/A

Sila Akhan	Approved	Jan-22-2021 22:24:30 (UTC+03:00) Istanbul	BOOK	Signed
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090177e196d89024\Final\Final On: 22-Apr-2021 02:12 (GMT)

Header Text: c4591001

Visit: Investigator Signature -
Unscheduled

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History

Form Version: 22-Apr-2020 21:04

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Medicine

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

(b) (6)	N/A	Jan-22-2021 22:17:53 (UTC+03:00) Istanbul		Edit - All signatures invalidated
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Affidavit:

N/A

Sila Akhan	Approved	Jan-22-2021 16:27:22 (UTC+03:00) Istanbul	BOOK	Signed
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090177e196d89024\Final\Final On: 22-Apr-2021 02:12 (GMT)

Header Text: c4591001

Visit: Investigator Signature -
Unscheduled

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History

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Site Name: (1217) Kocaeli University Faculty of
Medicine

Subject No: 12171039

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 19-Apr-2021 21:04

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

(b) (6)	N/A	Jan-22-2021 16:02:54 (UTC+03:00) Istanbul		Edit - All signatures invalidated
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Affidavit:

N/A

Sila Akhan	Approved	Jan-20-2021 15:30:13 (UTC+03:00) Istanbul	BOOK	Signed
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090177e196d89024\Final\Final On: 22-Apr-2021 02:12 (GMT)

Header Text: c4591001

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Unscheduled

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History

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(b) (6)	N/A	Jan-19-2021 15:53:24 (UTC+03:00) Istanbul		Edit - All signatures invalidated
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Affidavit:

N/A

Sila Akhan	Approved	Jan-19-2021 13:30:57 (UTC+03:00) Istanbul	BOOK	Signed
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090177e196d89024\Final\Final On: 22-Apr-2021 02:12 (GMT)

Header Text: c4591001

Visit: Investigator Signature -
Unscheduled

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History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Signed, Verified

Site No: 1217

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Generated Time (GMT): 19-Apr-2021 21:04

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

(b) (6)	N/A	Jan-19-2021 13:18:48 (UTC+03:00) Istanbul		Edit - All signatures invalidated
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Affidavit:

N/A

Sila Akhan	Approved	Dec-23-2020 12:21:41 (UTC+03:00) Istanbul	BOOK	Signed
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090177e196d89024\Final\Final On: 22-Apr-2021 02:12 (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: 1217

Site Name: (1217) Kocaeli University Faculty of
Medicine

Subject No: 12171039

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 19-Apr-2021 21:04

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

(b) (6)	N/A	Dec-23-2020 12:01:57 (UTC+03:00) Istanbul		Edit - All signatures invalidated
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Affidavit:

N/A

Sila Akhan	Approved	Dec-02-2020 20:58:20 (UTC+03:00) Istanbul	BOOK	Signed
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090177e196d89024\Final\Final On: 22-Apr-2021 02:12 (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: 1217

Site Name: (1217) Kocaeli University Faculty of
Medicine

Subject No: 12171039

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 19-Apr-2021 21:04

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

(b) (6)	N/A	Nov-19-2020 16:00:45 (UTC+03:00) Istanbul		Edit - All signatures invalidated
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Affidavit:

N/A

Sila Akhan	Approved	Nov-18-2020 09:27:28 (UTC+03:00) Istanbul	BOOK	Signed
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090177e196d89024\Final\Final On: 22-Apr-2021 02:12 (GMT)

Header Text: c4591001

Visit: Investigator Signature -
Unscheduled

Form Version: 22-Apr-2020 21:04

Site No: 1217

Subject No: 12171039

Generated By: (b) (4)

Form: CASEBOOK SIGNATURE FORM - Signature
History

Form Status: Data Complete, Signed, Verified

Site Name: (1217) Kocaeli University Faculty of
Medicine

Subject Initials: ---

Generated Time (GMT): 19-Apr-2021 21:04

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

Header Text: c4591001

Visit: COHORT_SELECTION

Form: COHORT SELECTION - eCRF Audit Trail History

Form Version: 10-Oct-2020 16:01

Form Status: Data Complete, Frozen, Verified

Site No: 1217

Site Name: (1217) Kocaeli University Faculty of Medicine

Subject No: 12171039

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 19-Apr-2021 21:04

[Back to Form](#)

1. Select appropriate response - Protocol version

Date	Location	User	Value	Reason
Nov-04-2020 08:56:36 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 08 SEP 2020	Initial Entry

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

Date	Location	User	Value	Reason
Nov-04-2020 08:56:36 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: STAGE 3 COHORTS	Initial Entry

090177e196d89024\Final\Final On: 22-Apr-2021 02:12 (GMT)

Header Text: c4591001

Visit: COHORT_SELECTION

Form: MAIN INFORMED CONSENT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen, Verified

Site No: 1217

Site Name: (1217) Kocaeli University Faculty of Medicine

Subject No: 12171039

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 19-Apr-2021 21:04

[Back to Form](#)

1. Consent Was:

Date	Location	User	Value	Reason
Nov-04-2020 08:56:57 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: OBTAINED Date Written Consent Obtained Nov/4/2020	Initial Entry

090177e196d89024\Final\Final On: 22-Apr-2021 02:12 (GMT)

Header Text: c4591001

Visit: COHORT_SELECTION

Form Version: 15-Sep-2020 21:54

Site No: 1217

Subject No: 12171039

Generated By: (b) (4)

Form: DEMOGRAPHY - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1217) Kocaeli University Faculty of Medicine

Subject Initials: ---

Generated Time (GMT): 19-Apr-2021 21:04

[Back to Form](#)

1. Subject ID

Date	Location	User	Value	Reason
Nov-04-2020 08:56:23 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 12171039	Item copied from previous form

2. Birth Date:

Date	Location	User	Value	Reason
Nov-04-2020 08:56:16 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: (b) (6) 1983	Enrollment Entry

3. Sex:

Date	Location	User	Value	Reason
Nov-04-2020 08:57:59 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: MALE	Initial Entry

4. Ethnicity:

Date	Location	User	Value	Reason
Nov-04-2020 08:57:59	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NOT HISPANIC OR	Initial Entry

090177e196d89024\Final\Final On: 22-Apr-2021 02:12 (GMT)

Header Text: c4591001

Visit: COHORT_SELECTION

Form: DEMOGRAPHY - eCRF Audit Trail History

Form Version: 15-Sep-2020 21:54

Form Status: Data Complete, Frozen, Verified

Site No: 1217

Site Name: (1217) Kocaeli University Faculty of Medicine

Subject No: 12171039

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 19-Apr-2021 21:04

(UTC+03:00) Istanbul		(b) (4), (b) (6)	LATINO(A) OR OF S PANISH ORIGIN	
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5. Race: (Check X all that apply):

Date	Location	User	Value	Reason
Nov-04-2020 08:57:59 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: WHITE	Initial Entry

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:02

Site No: 1217

Subject No: 12171039

Generated By: (b) (4)

Form: DATE OF VISIT - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1217) Kocaeli University Faculty of Medicine

Subject Initials: ---

Generated Time (GMT): 19-Apr-2021 21:04

[Back to Form](#)

1. Date of Visit

Date	Location	User	Value	Reason
Nov-04-2020 09:12:40 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Nov/4/2020	Initial Entry

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 15-Sep-2020 21:52

Site No: 1217

Subject No: 12171039

Generated By: (b) (4)

Form: DISPOSITION - SCREENING - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1217) Kocaeli University Faculty of Medicine

Subject Initials: ---

Generated Time (GMT): 19-Apr-2021 21:04

[Back to Form](#)

1. Date of Completion/Discontinuation/Death

Date	Location	User	Value	Reason
Nov-04-2020 09:13:19 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Nov/4/2020	Initial Entry

2. Phase of Disposition:

Date	Location	User	Value	Reason
Nov-04-2020 09:13:19 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SCREENING	Initial Entry

3. Status:

Date	Location	User	Value	Reason
Nov-04-2020 09:13:19 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: COMPLETED	Initial Entry

090177e196d89024\Final\Final On: 22-Apr-2021 02:12 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1217

Site Name: (1217) Kocaeli University Faculty of Medicine

Subject No: 12171039

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 19-Apr-2021 21:04

[Back to Form](#)

1.a

Date	Location	User	Value	Reason
Nov-04-2020 10:21:32 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Line/MH Number: 1 Medical History Term: hypercholesterolemia Start Date: Jan/UNK/2020 Ongoing: YES	Changed Information
Nov-04-2020 10:20:39 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 1 Medical History Term: hypercholesterolemia Start Date: UNK/UNK/2019 Ongoing: YES	Initial Entry

1.a Line/MH Number:

Date	Location	User	Value	Reason
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090177e196d89024\Final\Final On: 22-Apr-2021 02:12 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1217

Site Name: (1217) Kocaeli University Faculty of Medicine

Subject No: 12171039

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 19-Apr-2021 21:04

Nov-04-2020 10:20:39 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 1	Initial Entry
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1.a Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:

Date	Location	User	Value	Reason
Nov-04-2020 10:20:39 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: hypercholesterol	Initial Entry

1.a Start Date:

Date	Location	User	Value	Reason
Nov-04-2020 10:21:32 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Jan/UNK/2020	Changed Information
Nov-04-2020 10:20:39 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: UNK/UNK/2019	Initial Entry

1.a Ongoing:

Date	Location	User	Value	Reason
Nov-04-2020 10:20:39 (UTC+03:00)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

090177e196d89024\Final\Final On: 22-Apr-2021 02:12 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1217

Site Name: (1217) Kocaeli University Faculty of Medicine

Subject No: 12171039

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 19-Apr-2021 21:04

Istanbul				
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Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 15-Sep-2020 21:57

Site No: 1217

Subject No: 12171039

Generated By: (b) (4)

Form: HIV STATUS - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1217) Kocaeli University Faculty of Medicine

Subject Initials: ---

Generated Time (GMT): 19-Apr-2021 21:04

[Back to Form](#)

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

Date	Location	User	Value	Reason
Nov-04-2020 09:13:34 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: The subject is NOT known to be HIV POSITIVE	Initial Entry

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 10-Oct-2020 16:04

Site No: 1217

Subject No: 12171039

Generated By: (b) (4)

Form: VITAL SIGNS - BASELINE - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1217) Kocaeli University Faculty of Medicine

Subject Initials: ---

Generated Time (GMT): 19-Apr-2021 21:04

[Back to Form](#)

1. Date:

Date	Location	User	Value	Reason
Nov-04-2020 10:09:17 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Nov/4/2020	Initial Entry

2. Weight:

Date	Location	User	Value	Reason
Nov-04-2020 10:09:17 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 75.0	Initial Entry

3. Unit:

Date	Location	User	Value	Reason
Nov-04-2020 10:09:17 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: kg	Initial Entry

4. Height:

Date	Location	User	Value	Reason
Nov-04-2020	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Initial Entry

090177e196d89024\Final\Final On: 22-Apr-2021 02:12 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: VITAL SIGNS - BASELINE - eCRF Audit Trail History

Form Version: 10-Oct-2020 16:04

Form Status: Data Complete, Frozen, Verified

Site No: 1217

Site Name: (1217) Kocaeli University Faculty of Medicine

Subject No: 12171039

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 19-Apr-2021 21:04

10:09:17 (UTC+03:00) Istanbul		(b) (4), (b) (6)	176.0	
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5. Unit:

Date	Location	User	Value	Reason
Nov-04-2020 10:09:17 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: cm	Initial Entry

6. Body Mass Index:

Date	Location	User	Value	Reason
Nov-04-2020 10:09:17 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 24.2	Initial Entry

7.a

Date	Location	User	Value	Reason
Nov-04-2020 10:09:17 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Record Identifier: Temperature 37.1 : Temperature C Unit:	Initial Entry

090177e196d89024\Final\Final On: 22-Apr-2021 02:12 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: VITAL SIGNS - BASELINE - eCRF Audit Trail History

Form Version: 10-Oct-2020 16:04

Form Status: Data Complete, Frozen, Verified

Site No: 1217

Site Name: (1217) Kocaeli University Faculty of Medicine

Subject No: 12171039

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 19-Apr-2021 21:04

			Temperature FORE Location:: HEAD	
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7.a Record Identifier:

Date	Location	User	Value	Reason
Nov-04-2020 10:09:17 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 1	Initial Entry

7.a Temperature:

Date	Location	User	Value	Reason
Nov-04-2020 10:09:17 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 37.1	Initial Entry

7.a Unit:

Date	Location	User	Value	Reason
Nov-04-2020 10:09:17 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: C	Initial Entry

7.a Temperature Location:

Date	Location	User	Value	Reason
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090177e196d89024\Final\Final On: 22-Apr-2021 02:12 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: VITAL SIGNS - BASELINE - eCRF Audit Trail History

Form Version: 10-Oct-2020 16:04

Form Status: Data Complete, Frozen, Verified

Site No: 1217

Site Name: (1217) Kocaeli University Faculty of Medicine

Subject No: 12171039

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 19-Apr-2021 21:04

Nov-04-2020 10:09:17 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: FOREHEAD	Initial Entry
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Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1217

Subject No: 12171039

Generated By: (b) (4)

Form: RANDOMIZATION - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1217) Kocaeli University Faculty of Medicine

Subject Initials: ---

Generated Time (GMT): 19-Apr-2021 21:04

[Back to Form](#)

1. Randomization Date :

Date	Location	User	Value	Reason
Nov-04-2020 15:28:19 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Nov/4/2020	Initial Entry

2. Randomization Number:

Date	Location	User	Value	Reason
Nov-04-2020 15:28:19 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 115336	Initial Entry

090177e196d89024\Final\Final On: 22-Apr-2021 02:12 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1217

Subject No: 12171039

Generated By: (b) (4)

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

Form Status: Data Complete, Frozen, Verified

Site Name: (1217) Kocaeli University Faculty of Medicine

Subject Initials: ---

Generated Time (GMT): 19-Apr-2021 21:04

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1. Data Origin

Date	Location	User	Value	Reason
Nov-04-2020 15:03:56 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Nov-04-2020 15:03:56 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SERUM	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Nov-04-2020 15:27:05 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Nov-04-2020 15:03:56 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered.

090177e196d89024\Final\Final On: 22-Apr-2021 02:12 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1217

Site Name: (1217) Kocaeli University Faculty of Medicine

Subject No: 12171039

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 19-Apr-2021 21:04

				Please review and correct as appropriate.
Nov-04-2020 15:03:56 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Date of Collection: Nov/4/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Nov-04-2020 15:27:05 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BPZ96Y	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Nov-04-2020 15:27:05 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BPZ96Y	Initial Entry

5.b

Date	Location	User	Value	Reason
Nov-04-2020 15:27:18 (UTC+03:00)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BPZ96Z	Initial Entry

090177e196d89024\Final\Final On: 22-Apr-2021 02:12 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1217

Site Name: (1217) Kocaeli University Faculty of Medicine

Subject No: 12171039

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 19-Apr-2021 21:04

Istanbul				
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5.b Sample ID

Date	Location	User	Value	Reason
Nov-04-2020 15:27:18 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BPZ96Z	Initial Entry

5.c

Date	Location	User	Value	Reason
Nov-19-2020 16:00:45 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BS2S40	Initial Entry

5.c Sample ID

Date	Location	User	Value	Reason
Nov-19-2020 16:00:45 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BS2S40	Initial Entry

5.d

Date	Location	User	Value	Reason
Nov-19-2020 16:00:58	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Initial Entry

090177e196d89024\Final\Final On: 22-Apr-2021 02:12 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1217

Site Name: (1217) Kocaeli University Faculty of Medicine

Subject No: 12171039

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 19-Apr-2021 21:04

(UTC+03:00) Istanbul		(b) (4), (b) (6)	Sample ID: BS2S41	
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5.d Sample ID

Date	Location	User	Value	Reason
Nov-19-2020 16:00:58 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BS2S41	Initial Entry

090177e196d89024\Final\Final On: 22-Apr-2021 02:12 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1217

Site Name: (1217) Kocaeli University Faculty of Medicine

Subject No: 12171039

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 19-Apr-2021 21:04

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1. Data Origin

Date	Location	User	Value	Reason
Nov-04-2020 15:27:38 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Nov-04-2020 15:27:38 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: NASAL_SWAB	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Nov-04-2020 15:27:55 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Nov-04-2020 15:27:38 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered.

090177e196d89024\Final\Final On: 22-Apr-2021 02:12 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1217

Site Name: (1217) Kocaeli University Faculty of Medicine

Subject No: 12171039

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 19-Apr-2021 21:04

				Please review and correct as appropriate.
Nov-04-2020 15:27:38 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Date of Collection: Nov/4/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Nov-04-2020 15:27:55 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BPZ9F7	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Nov-04-2020 15:27:55 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BPZ9F7	Initial Entry

090177e196d89024\Final\Final On: 22-Apr-2021 02:12 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:04

Site No: 1217

Subject No: 12171039

Generated By: (b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1217) Kocaeli University Faculty of Medicine

Subject Initials: ---

Generated Time (GMT): 19-Apr-2021 21:04

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1. Was there a temporary delay of vaccination?

Date	Location	User	Value	Reason
Nov-04-2020 15:28:42 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2. Treatment Name

Date	Location	User	Value	Reason
Nov-04-2020 15:28:42 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: BLINDED THERAPY	Initial Entry

3. Formulation:

Date	Location	User	Value	Reason
Nov-04-2020 15:28:42 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: INJECTION	Initial Entry

4. Dose Date Time:

Date	Location	User	Value	Reason
Nov-04-2020 15:28:42	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Nov/4/2020 09:50	Initial Entry

090177e196d89024\Final\Final On: 22-Apr-2021 02:12 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: VACCINATION - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Frozen, Verified

Site No: 1217

Site Name: (1217) Kocaeli University Faculty of Medicine

Subject No: 12171039

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 19-Apr-2021 21:04

(UTC+03:00) Istanbul		(b) (4), (b) (6)		
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5. Anatomical Location:

Date	Location	User	Value	Reason
Nov-04-2020 15:28:42 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: DELTOID MUSCLE	Initial Entry

6. Body Side:

Date	Location	User	Value	Reason
Nov-04-2020 15:28:42 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: RIGHT	Initial Entry

7. Route:

Date	Location	User	Value	Reason
Nov-04-2020 15:28:42 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: INTRAMUSCULAR	Initial Entry

10. Timeframe Subject Was Observed

Date	Location	User	Value	Reason
Nov-04-2020 15:28:42	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: THE PROTOCOL SPE	Initial Entry

090177e196d89024\Final\Final On: 22-Apr-2021 02:12 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: VACCINATION - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Frozen, Verified

Site No: 1217

Site Name: (1217) Kocaeli University Faculty of Medicine

Subject No: 12171039

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 19-Apr-2021 21:04

(UTC+03:00) Istanbul			CIFIED OBSERVATIO N PERIOD	
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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-04-2020 15:28:42 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 06-Jul-2020 21:53

Site No: 1217

Subject No: 12171039

Generated By: (b) (4)

Form: REACTOGENICITY DIARY - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1217) Kocaeli University Faculty of Medicine

Subject Initials: ---

Generated Time (GMT): 19-Apr-2021 21:04

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1. Select appropriate response - Reactogenicity diary collection

Date	Location	User	Value	Reason
Nov-04-2020 10:34:39 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES - REACTOGENI CITY E-DIARY COL LECTED FOR THIS SUBJECT	Initial Entry

090177e196d89024\Final\Final On: 22-Apr-2021 02:12 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:02

Site No: 1217

Subject No: 12171039

Generated By: (b) (4)

Form: DATE OF VISIT - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1217) Kocaeli University Faculty of Medicine

Subject Initials: ---

Generated Time (GMT): 19-Apr-2021 21:04

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1. Date of Visit

Date	Location	User	Value	Reason
Nov-25-2020 10:11:03 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Nov/25/2020	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: 1217

Site Name: (1217) Kocaeli University Faculty of Medicine

Subject No: 12171039

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 19-Apr-2021 21:04

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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-25-2020 10:12:45 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2.a

Date	Location	User	Value	Reason
Nov-25-2020 10:12:45 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom:: F E V E R Were fever or sys N temic symptoms O present on the las t day the Subject Diary was compl eted?:	Initial Entry

2.a Symptom:

Date	Location	User	Value	Reason
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090177e196d89024\Final\Final On: 22-Apr-2021 02:12 (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: 1217

Site Name: (1217) Kocaeli University Faculty of Medicine

Subject No: 12171039

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 19-Apr-2021 21:04

Nov-25-2020 10:12:45 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: FEVER	Initial Entry
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2.a Were fever or systemic symptoms present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Nov-25-2020 10:12:45 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2.b

Date	Location	User	Value	Reason
Nov-25-2020 10:12:45 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom:: FA TI G U E Were fever or sy N stemic symptoms O present on the la st day the Subjec t Diary was com pleted?:	Initial Entry

090177e196d89024\Final\Final On: 22-Apr-2021 02:12 (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: 1217

Site Name: (1217) Kocaeli University Faculty of
Medicine

Subject No: 12171039

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 19-Apr-2021 21:04

2.b Symptom:

Date	Location	User	Value	Reason
Nov-25-2020 10:12:45 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: FATIGUE	Initial Entry

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

Date	Location	User	Value	Reason
Nov-25-2020 10:12:45 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2.c

Date	Location	User	Value	Reason
Nov-25-2020 10:12:45 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom:: HEADACHE	Initial Entry

090177e196d89024\Final\Final On: 22-Apr-2021 02:12 (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: 1217

Site Name: (1217) Kocaeli University Faculty of
Medicine

Subject No: 12171039

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 19-Apr-2021 21:04

			<p>Were fever or systemic symptoms present on the last day of the Subject Diary was completed?:</p> <p>YES Ongoing?</p> <p>NO</p> <p>Stop Date:</p> <p>No v/ 10 /2 02 0</p>	
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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: 1217

Site Name: (1217) Kocaeli University Faculty of Medicine

Subject No: 12171039

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 19-Apr-2021 21:04

2.c Symptom:

Date	Location	User	Value	Reason
Nov-25-2020 10:12:45 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: HEADACHE	Initial Entry

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

Date	Location	User	Value	Reason
Nov-25-2020 10:12:45 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Ongoing? NO Stop Date: Nov/10/2020	Initial Entry

2.d

Date	Location	User	Value	Reason
Nov-25-2020 10:12:45 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom:: C HI L LS	Initial Entry

090177e196d89024\Final\Final On: 22-Apr-2021 02:12 (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: 1217

Site Name: (1217) Kocaeli University Faculty of Medicine

Subject No: 12171039

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 19-Apr-2021 21:04

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

Date	Location	User	Value	Reason
Nov-25-2020 10:12:45 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: CHILLS	Initial Entry

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

Date	Location	User	Value	Reason
Nov-25-2020 10:12:45 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2.e

Date	Location	User	Value	Reason
Nov-25-2020 10:12:45 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom:: VO MI TI	Initial Entry

090177e196d89024\Final\Final On: 22-Apr-2021 02:12 (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: 1217

Site Name: (1217) Kocaeli University Faculty of Medicine

Subject No: 12171039

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 19-Apr-2021 21:04

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

Date	Location	User	Value	Reason
Nov-25-2020 10:12:45 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: VOMITING	Initial Entry

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

Date	Location	User	Value	Reason
Nov-25-2020 10:12:45 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2.f

Date	Location	User	Value	Reason
Nov-25-2020 10:12:45 (UTC+03:00)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom:: DI AR	Initial Entry

090177e196d89024\Final\Final On: 22-Apr-2021 02:12 (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: 1217

Site Name: (1217) Kocaeli University Faculty of Medicine

Subject No: 12171039

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 19-Apr-2021 21:04

Istanbul			RH EA Were fever or sy stemic symptom s present on the last day the Subj ect Diary was co mpleted?:	
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2.f Symptom:

Date	Location	User	Value	Reason
Nov-25-2020 10:12:45 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: DIARRHEA	Initial Entry

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

Date	Location	User	Value	Reason
Nov-25-2020 10:12:45 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2.g

Date	Location	User	Value	Reason
Nov-25-2020 10:12:45	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom:: NEW	Initial Entry

090177e196d89024\Final\Final On: 22-Apr-2021 02:12 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

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

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Form Status: Data Complete, Frozen, Verified

Site No: 1217

Site Name: (1217) Kocaeli University Faculty of Medicine

Subject No: 12171039

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 19-Apr-2021 21:04

(UTC+03:00) Istanbul		(b) (4), (b) (6)	OR W ORSE NED MUSC LE PA IN Were fever o r systemic sy mptoms pres ent on the las t day the Sub ject Diary wa s completed? :	
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2.g Symptom:

Date	Location	User	Value	Reason
Nov-25-2020 10:12:45 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NEW OR WORSENE D MUSCLE PAIN	Initial Entry

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

Date	Location	User	Value	Reason
Nov-25-2020 10:12:45 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

090177e196d89024\Final\Final On: 22-Apr-2021 02:12 (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: 1217

Site Name: (1217) Kocaeli University Faculty of Medicine

Subject No: 12171039

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 19-Apr-2021 21:04

2.h

Date	Location	User	Value	Reason
Nov-25-2020 10:12:45 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<p>Data Entry:</p> <p>Symptom:: NEW OR W ORSE NED J OINT PAIN</p> <p>Were fever or systemic symptoms present on the last day the Subject Diary was completed? NO :</p>	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: 1217

Site Name: (1217) Kocaeli University Faculty of Medicine

Subject No: 12171039

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 19-Apr-2021 21:04

2.h Symptom:

Date	Location	User	Value	Reason
Nov-25-2020 10:12:45 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NEW OR WORSENE D 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-25-2020 10:12:45 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

3. Injection Site Location:

Date	Location	User	Value	Reason
Nov-25-2020 10:12:45 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: DELTOID MUSCLE	Initial Entry

4. Injection Site Body Side:

Date	Location	User	Value	Reason
Nov-25-2020 10:13:32 (UTC+03:00)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: RIGHT	Initial Entry

090177e196d89024\Final\Final On: 22-Apr-2021 02:12 (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: 1217

Site Name: (1217) Kocaeli University Faculty of Medicine

Subject No: 12171039

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 19-Apr-2021 21:04

Istanbul

5.a

Date	Location	User	Value	Reason
Nov-25-2020 10:12:45 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Injection Site Reaction: REDNESS 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-25-2020 10:12:45 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: REDNESS	Initial Entry

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

Date	Location	User	Value	Reason
Nov-25-2020 10:12:45	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

090177e196d89024\Final\Final On: 22-Apr-2021 02:12 (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: 1217

Site Name: (1217) Kocaeli University Faculty of Medicine

Subject No: 12171039

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 19-Apr-2021 21:04

(UTC+03:00)
Istanbul

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

5.b

Date	Location	User	Value	Reason
Nov-25-2020 10:12:45 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Injection Site Reaction: SW EL LI NG Were injections present on the last day the Subject Diary was completed?: NO	Initial Entry

090177e196d89024\Final\Final On: 22-Apr-2021 02:12 (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: 1217

Site Name: (1217) Kocaeli University Faculty of
Medicine

Subject No: 12171039

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 19-Apr-2021 21:04

5.b Injection Site Reaction:

Date	Location	User	Value	Reason
Nov-25-2020 10:12:45 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: SWELLING	Initial Entry

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

Date	Location	User	Value	Reason
Nov-25-2020 10:12:45 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

5.c

Date	Location	User	Value	Reason
Nov-25-2020 10:12:45 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Injection Site PAIN Reaction:: AT I NJE CTI ON S ITE	Initial Entry

090177e196d89024\Final\Final On: 22-Apr-2021 02:12 (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: 1217

Site Name: (1217) Kocaeli University Faculty of Medicine

Subject No: 12171039

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 19-Apr-2021 21:04

			Were injection NO site reactions present on the last day the Subject Diary was completed?:	
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5.c Injection Site Reaction:

Date	Location	User	Value	Reason
Nov-25-2020 10:12:45 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: PAIN AT INJECTION SITE	Initial Entry

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

Date	Location	User	Value	Reason
Nov-25-2020 10:12:45 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

090177e196d89024\Final\Final On: 22-Apr-2021 02:12 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 10-Oct-2020 16:01

Site No: 1217

Subject No: 12171039

Generated By: (b) (4)

Form: VITAL SIGNS - TEMP - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1217) Kocaeli University Faculty of Medicine

Subject Initials: ---

Generated Time (GMT): 19-Apr-2021 21:04

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1. Date:

Date	Location	User	Value	Reason
Nov-25-2020 10:13:57 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Nov/25/2020	Initial Entry

2.a

Date	Location	User	Value	Reason
Nov-25-2020 10:13:57 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Record Identifier:: Temperature 36.3 : Temperature C Unit: Temperature FORE Location:: HEAD	Initial Entry

2.a Record Identifier:

Date	Location	User	Value	Reason
Nov-25-2020 10:13:57 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 1	Initial Entry

090177e196d89024\Final\Final On: 22-Apr-2021 02:12 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 10-Oct-2020 16:01

Site No: 1217

Subject No: 12171039

Generated By: (b) (4)

Form: VITAL SIGNS - TEMP - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1217) Kocaeli University Faculty of Medicine

Subject Initials: ---

Generated Time (GMT): 19-Apr-2021 21:04

2.a Temperature:

Date	Location	User	Value	Reason
Nov-25-2020 10:13:57 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 36.3	Initial Entry

2.a Unit:

Date	Location	User	Value	Reason
Nov-25-2020 10:13:57 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: C	Initial Entry

2.a Temperature Location:

Date	Location	User	Value	Reason
Nov-25-2020 10:13:57 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: FOREHEAD	Initial Entry

090177e196d89024\Final\Final On: 22-Apr-2021 02:12 (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: 1217

Site Name: (1217) Kocaeli University Faculty of Medicine

Subject No: 12171039

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 19-Apr-2021 21:04

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1. Data Origin

Date	Location	User	Value	Reason
Nov-25-2020 10:14:10 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Nov-25-2020 10:14:10 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: NASAL_SWAB	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Nov-25-2020 11:16:40 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Nov-25-2020 10:14:10 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered.

090177e196d89024\Final\Final On: 22-Apr-2021 02:12 (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: 1217

Site Name: (1217) Kocaeli University Faculty of Medicine

Subject No: 12171039

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 19-Apr-2021 21:04

				Please review and correct as appropriate.
Nov-25-2020 10:14:10 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Date of Collection: Nov/25/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Nov-25-2020 11:16:40 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BR510Z	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Nov-25-2020 11:16:40 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BR510Z	Initial Entry

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Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:04

Site No: 1217

Subject No: 12171039

Generated By: (b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1217) Kocaeli University Faculty of Medicine

Subject Initials: ---

Generated Time (GMT): 19-Apr-2021 21:04

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1. Was there a temporary delay of vaccination?

Date	Location	User	Value	Reason
Nov-25-2020 10:16:34 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2. Treatment Name

Date	Location	User	Value	Reason
Nov-25-2020 10:16:34 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: BLINDED THERAPY	Initial Entry

3. Formulation:

Date	Location	User	Value	Reason
Nov-25-2020 10:16:34 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: INJECTION	Initial Entry

4. Dose Date Time:

Date	Location	User	Value	Reason
Nov-25-2020 11:17:25	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Nov/25/2020 10:30	Changed Information

090177e196d89024\Final\Final On: 22-Apr-2021 02:12 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form: VACCINATION - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Frozen, Verified

Site No: 1217

Site Name: (1217) Kocaeli University Faculty of Medicine

Subject No: 12171039

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 19-Apr-2021 21:04

(UTC+03:00) Istanbul		(b) (4), (b) (6)		
Nov-25-2020 10:16:34 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Nov/25/2020 10:16	Initial Entry

5. Anatomical Location:

Date	Location	User	Value	Reason
Nov-25-2020 10:16:34 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: DELTOID MUSCLE	Initial Entry

6. Body Side:

Date	Location	User	Value	Reason
Nov-25-2020 11:17:41 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: RIGHT	Initial Entry

7. Route:

Date	Location	User	Value	Reason
Nov-25-2020 10:16:34 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: INTRAMUSCULAR	Initial Entry

090177e196d89024\Final\Final On: 22-Apr-2021 02:12 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form: VACCINATION - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Frozen, Verified

Site No: 1217

Site Name: (1217) Kocaeli University Faculty of Medicine

Subject No: 12171039

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 19-Apr-2021 21:04

10. Timeframe Subject Was Observed

Date	Location	User	Value	Reason
Nov-25-2020 10:16:34 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: THE PROTOCOL SPECIFIED OBSERVATION PERIOD	Initial Entry

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

Date	Location	User	Value	Reason
Nov-25-2020 10:16:34 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

090177e196d89024\Final\Final On: 22-Apr-2021 02:12 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L **Form:** DATE OF VISIT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02 **Form Status:** Data Complete, Frozen, Verified

Site No: 1217 **Site Name:** (1217) Kocaeli University Faculty of Medicine

Subject No: 12171039 **Subject Initials:** ---

Generated By: (b) (4) **Generated Time (GMT):** 19-Apr-2021 21:04

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1. Date of Visit

Date	Location	User	Value	Reason
Dec-23-2020 12:01:57 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Dec/23/2020	Initial Entry

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L **Form:** VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

Form Version: 10-Oct-2020 16:03 **Form Status:** Data Complete, Frozen, Verified

Site No: 1217 **Site Name:** (1217) Kocaeli University Faculty of Medicine

Subject No: 12171039 **Subject Initials:** ---

Generated By: (b) (4) **Generated Time (GMT):** 19-Apr-2021 21:04

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

Date	Location	User	Value	Reason
Dec-23-2020 12:02:18 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2.a

Date	Location	User	Value	Reason
Dec-23-2020 12:02:18 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom:: F E V E R Were fever or sys N temic symptoms O present on the las t day the Subject Diary was compl eted?:	Initial Entry

2.a Symptom:

Date	Location	User	Value	Reason
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090177e196d89024\Final\Final On: 22-Apr-2021 02:12 (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: 1217 **Site Name:** (1217) Kocaeli University Faculty of Medicine

Subject No: 12171039 **Subject Initials:** ---

Generated By: (b) (4) **Generated Time (GMT):** 19-Apr-2021 21:04

Dec-23-2020 12:02:18 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: FEVER	Initial Entry
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2.a Were fever or systemic symptoms present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Dec-23-2020 12:02:18 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2.b

Date	Location	User	Value	Reason
Dec-23-2020 12:02:18 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom:: FA TI G U E Were fever or sy N stemic symptoms O present on the la st day the Subjec t Diary was com pleted?:	Initial Entry

090177e196d89024\Final\Final On: 22-Apr-2021 02:12 (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: 1217 Site Name: (1217) Kocaeli University Faculty of Medicine

Subject No: 12171039 Subject Initials: ---

Generated By: (b) (4) Generated Time (GMT): 19-Apr-2021 21:04

2.b Symptom:

Date	Location	User	Value	Reason
Dec-23-2020 12:02:18 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: FATIGUE	Initial Entry

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

Date	Location	User	Value	Reason
Dec-23-2020 12:02:18 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2.c

Date	Location	User	Value	Reason
Dec-23-2020 12:02:18 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom:: HE AD AC HE Were fever or sy NO stemic symptom s present on the last day the Sub ject Diary was c ompleted?:	Initial Entry

090177e196d89024\Final\Final On: 22-Apr-2021 02:12 (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: 1217 Site Name: (1217) Kocaeli University Faculty of Medicine

Subject No: 12171039 Subject Initials: ---

Generated By: (b) (4) Generated Time (GMT): 19-Apr-2021 21:04

2.c Symptom:

Date	Location	User	Value	Reason
Dec-23-2020 12:02:18 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: HEADACHE	Initial Entry

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

Date	Location	User	Value	Reason
Dec-23-2020 12:02:18 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2.d

Date	Location	User	Value	Reason
Dec-23-2020 12:02:18 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom:: C HI L LS Were fever or sys N temic symptoms O present on the la st day the Subjec t Diary was com pleted?:	Initial Entry

090177e196d89024\Final\Final On: 22-Apr-2021 02:12 (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: 1217 Site Name: (1217) Kocaeli University Faculty of Medicine

Subject No: 12171039 Subject Initials: ---

Generated By: (b) (4) Generated Time (GMT): 19-Apr-2021 21:04

2.d Symptom:

Date	Location	User	Value	Reason
Dec-23-2020 12:02:18 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: CHILLS	Initial Entry

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

Date	Location	User	Value	Reason
Dec-23-2020 12:02:18 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2.e

Date	Location	User	Value	Reason
Dec-23-2020 12:02:18 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom:: VO MI TI NG Were fever or sy NO stemic symptom s present on the last day the Sub ject Diary was c ompleted?:	Initial Entry

090177e196d89024\Final\Final On: 22-Apr-2021 02:12 (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: 1217 Site Name: (1217) Kocaeli University Faculty of Medicine

Subject No: 12171039 Subject Initials: ---

Generated By: (b) (4) Generated Time (GMT): 19-Apr-2021 21:04

2.e Symptom:

Date	Location	User	Value	Reason
Dec-23-2020 12:02:18 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: VOMITING	Initial Entry

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

Date	Location	User	Value	Reason
Dec-23-2020 12:02:18 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2.f

Date	Location	User	Value	Reason
Dec-23-2020 12:02:18 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom:: DI AR RH EA Were fever or sy NO stemic symptom s present on the last day the Subj ect Diary was co mpleted?:	Initial Entry

090177e196d89024\Final\Final On: 22-Apr-2021 02:12 (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: 1217 **Site Name:** (1217) Kocaeli University Faculty of Medicine

Subject No: 12171039 **Subject Initials:** ---

Generated By: (b) (4) **Generated Time (GMT):** 19-Apr-2021 21:04

2.f Symptom:

Date	Location	User	Value	Reason
Dec-23-2020 12:02:18 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: DIARRHEA	Initial Entry

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

Date	Location	User	Value	Reason
Dec-23-2020 12:02:18 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2.g

Date	Location	User	Value	Reason
Dec-23-2020 12:02:18 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom:: NEW OR W ORSE NED MUSC LE PA IN	Initial Entry

090177e196d89024\Final\Final On: 22-Apr-2021 02:12 (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: 1217 Site Name: (1217) Kocaeli University Faculty of Medicine

Subject No: 12171039 Subject Initials: ---

Generated By: (b) (4) Generated Time (GMT): 19-Apr-2021 21:04

			Were fever or NO r systemic sy mptoms pres ent on the las t day the Sub ject Diary wa s completed? :	
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2.g Symptom:

Date	Location	User	Value	Reason
Dec-23-2020 12:02:18 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NEW OR WORSENE D MUSCLE PAIN	Initial Entry

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

Date	Location	User	Value	Reason
Dec-23-2020 12:02:18 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2.h

Date	Location	User	Value	Reason
Dec-23-2020 12:02:18	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom:: NEW	Initial Entry

090177e196d89024\Final\Final On: 22-Apr-2021 02:12 (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: 1217 Site Name: (1217) Kocaeli University Faculty of Medicine

Subject No: 12171039 Subject Initials: ---

Generated By: (b) (4) Generated Time (GMT): 19-Apr-2021 21:04

(UTC+03:00) Istanbul		(b) (4), (b) (6)	OR W ORSE NED J OINT PAIN Were fever o r systemic sy mptoms pres ent on the las t day the Sub ject Diary wa s completed? :	
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2.h Symptom:

Date	Location	User	Value	Reason
Dec-23-2020 12:02:18 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NEW OR WORSENE D JOINT PAIN	Initial Entry

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

Date	Location	User	Value	Reason
Dec-23-2020 12:02:18 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

090177e196d89024\Final\Final On: 22-Apr-2021 02:12 (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: 1217 Site Name: (1217) Kocaeli University Faculty of Medicine

Subject No: 12171039 Subject Initials: ---

Generated By: (b) (4) Generated Time (GMT): 19-Apr-2021 21:04

3. Injection Site Location:

Date	Location	User	Value	Reason
Dec-23-2020 12:02:18 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: DELTOID MUSCLE	Initial Entry

4. Injection Site Body Side:

Date	Location	User	Value	Reason
Dec-23-2020 12:02:35 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: RIGHT	Initial Entry

5.a

Date	Location	User	Value	Reason
Dec-23-2020 12:02:18 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Injection Site Re RE action:: D NE SS Were injection si N te reactions pres O ent on the last d ay the Subject D iary was complet ed?:	Initial Entry

090177e196d89024\Final\Final On: 22-Apr-2021 02:12 (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: 1217 **Site Name:** (1217) Kocaeli University Faculty of Medicine

Subject No: 12171039 **Subject Initials:** ---

Generated By: (b) (4) **Generated Time (GMT):** 19-Apr-2021 21:04

5.a Injection Site Reaction:

Date	Location	User	Value	Reason
Dec-23-2020 12:02:18 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: REDNESS	Initial Entry

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

Date	Location	User	Value	Reason
Dec-23-2020 12:02:18 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

5.b

Date	Location	User	Value	Reason
Dec-23-2020 12:02:18 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Injection Site Reaction: SW EL LI NG Were injection site reactions present on the last day the Subject Diary was completed?: NO	Initial Entry

090177e196d89024\Final\Final On: 22-Apr-2021 02:12 (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: 1217 **Site Name:** (1217) Kocaeli University Faculty of Medicine

Subject No: 12171039 **Subject Initials:** ---

Generated By: (b) (4) **Generated Time (GMT):** 19-Apr-2021 21:04

5.b Injection Site Reaction:

Date	Location	User	Value	Reason
Dec-23-2020 12:02:18 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: SWELLING	Initial Entry

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

Date	Location	User	Value	Reason
Dec-23-2020 12:02:18 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

5.c

Date	Location	User	Value	Reason
Dec-23-2020 12:02:18 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Injection Site PAIN Reaction:: AT I NJE CTI ON S ITE	Initial Entry

090177e196d89024\Final\Final On: 22-Apr-2021 02:12 (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: 1217 **Site Name:** (1217) Kocaeli University Faculty of Medicine

Subject No: 12171039 **Subject Initials:** ---

Generated By: (b) (4) **Generated Time (GMT):** 19-Apr-2021 21:04

			Were injection NO site reactions present on the last day the Subject Diary was completed?:	
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5.c Injection Site Reaction:

Date	Location	User	Value	Reason
Dec-23-2020 12:02:18 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: PAIN AT INJECTION SITE	Initial Entry

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

Date	Location	User	Value	Reason
Dec-23-2020 12:02:18 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

090177e196d89024\Final\Final On: 22-Apr-2021 02:12 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L **Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03 **Form Status:** Data Complete, Frozen, Verified

Site No: 1217 **Site Name:** (1217) Kocaeli University Faculty of Medicine

Subject No: 12171039 **Subject Initials:** ---

Generated By: (b) (4) **Generated Time (GMT):** 19-Apr-2021 21:04

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1. Data Origin

Date	Location	User	Value	Reason
Dec-23-2020 12:02:48 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Dec-23-2020 12:02:48 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SERUM	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Dec-23-2020 12:03:54 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Dec-23-2020 12:02:48 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered.

090177e196d89024\Final\Final On: 22-Apr-2021 02:12 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03 Form Status: Data Complete, Frozen, Verified

Site No: 1217 Site Name: (1217) Kocaeli University Faculty of Medicine

Subject No: 12171039 Subject Initials: ---

Generated By: (b) (4) Generated Time (GMT): 19-Apr-2021 21:04

				Please review and correct as appropriate.
Dec-23-2020 12:02:48 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Date of Collection: Dec/23/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Dec-23-2020 12:03:54 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BPZ9BX	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Dec-23-2020 12:03:54 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BPZ9BX	Initial Entry

5.b

Date	Location	User	Value	Reason
Dec-23-2020 12:04:04 (UTC+03:00)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BPZ9BY	Initial Entry

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Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03 Form Status: Data Complete, Frozen, Verified

Site No: 1217 Site Name: (1217) Kocaeli University Faculty of Medicine

Subject No: 12171039 Subject Initials: ---

Generated By: (b) (4) Generated Time (GMT): 19-Apr-2021 21:04

Istanbul				
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5.b Sample ID

Date	Location	User	Value	Reason
Dec-23-2020 12:04:04 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BPZ9BY	Initial Entry

5.c

Date	Location	User	Value	Reason
Dec-23-2020 12:04:42 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BS2S6X	Initial Entry

5.c Sample ID

Date	Location	User	Value	Reason
Dec-23-2020 12:04:42 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BS2S6X	Initial Entry

5.d

Date	Location	User	Value	Reason
Dec-23-2020 12:04:53	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Initial Entry

090177e196d89024\Final\Final On: 22-Apr-2021 02:12 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L **Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03 **Form Status:** Data Complete, Frozen, Verified

Site No: 1217 **Site Name:** (1217) Kocaeli University Faculty of Medicine

Subject No: 12171039 **Subject Initials:** ---

Generated By: (b) (4) **Generated Time (GMT):** 19-Apr-2021 21:04

(UTC+03:00) Istanbul		(b) (4), (b) (6)	Sample ID: BS2S6Y	
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5.d Sample ID

Date	Location	User	Value	Reason
Dec-23-2020 12:04:53 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BS2S6Y	Initial Entry

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Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - Audit Trail

Form Version: 22-Apr-2020 21:02

Form Status:

Site No: 1217

Site Name: (1217) Kocaeli University Faculty of Medicine

Subject No: 12171039

Subject Initials: ---

Generated By: (b) (4)

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Date	Location	User	Value	Reason
Jan-19-2021 13:18:48 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Created	

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - Audit Trail

Form Version: 22-Apr-2020 21:02

Form Status:

Site No: 1217

Site Name: (1217) Kocaeli University Faculty of Medicine

Subject No: 12171039

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 19-Apr-2021 21:04

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Date	Location	User	Value	Reason
Jan-19-2021 15:53:24 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Created	

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen

Site No: 1217

Site Name: (1217) Kocaeli University Faculty of Medicine

Subject No: 12171039

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 19-Apr-2021 21:04

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1. Category:

Date	Location	User	Value	Reason
Jan-19-2021 13:18:48 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: ADVERSE EVENT	Initial Entry

2. AE ID:

Date	Location	User	Value	Reason
Jan-19-2021 13:18:48 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 1	Initial Entry

3. Adverse Event:

(If possible specify diagnosis, not individual symptoms)

Date	Location	User	Value	Reason
Jan-22-2021 16:39:52 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Jan-22-2021 16:02:54 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	data is updated as per query

090177e196d89024\Final\Final On: 22-Apr-2021 02:12 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen

Site No: 1217

Site Name: (1217) Kocaeli University Faculty of Medicine

Subject No: 12171039

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 19-Apr-2021 21:04

Jan-22-2021 16:02:54 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Data Entry: Tinnitus in right ear	data is updated as per query
Jan-22-2021 15:57:50 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Query 1: Reissued: Opened	clinical: thanks, but if tinnitus in the R ear only, pls update AE term to reflect this.
Jan-22-2021 15:47:54 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Query 1: Answered	the volunteer experienced hearing loss in the right ear only
Jan-22-2021 14:43:04 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Query 1: Opened	clinical: pls update term to indicate if right, left or both ears. Thanks
Jan-19-2021 13:18:48 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Data Entry: tinnitus	Initial Entry

4. Start Date Time:

Date	Location	User	Value	Reason
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Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

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Site No: 1217

Site Name: (1217) Kocaeli University Faculty of Medicine

Subject No: 12171039

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 19-Apr-2021 21:04

Jan-19-2021 13:18:48 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Jan/8/2021 UNK:UN K	Initial Entry
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5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Jan-19-2021 13:18:48 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO End Date Time: Jan/18/2021 UNK: UNK	Initial Entry

6. Toxicity Grade:

Date	Location	User	Value	Reason
Jan-19-2021 13:18:48 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 1	Initial Entry

7. Is the adverse event serious?

If Yes, NOTIFY PFIZER IMMEDIATELY.

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

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Header Text: c4591001

Visit: Logs - Unscheduled

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Form Status: Data Complete, Frozen

Site No: 1217

Site Name: (1217) Kocaeli University Faculty of Medicine

Subject No: 12171039

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 19-Apr-2021 21:04

Date	Location	User	Value	Reason
Jan-19-2021 13:18:48 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

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

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

Date	Location	User	Value	Reason
Jan-19-2021 13:18:48 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

9. Is this event related to study treatment:

Date	Location	User	Value	Reason
Jan-19-2021 13:18:48 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NOT RELATED If Not Related to study treatment(s), this event is due to: OTHER <i>If Other, specify:</i> unknown	Initial Entry

10. Latest Action Taken with Study Treatment:

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Header Text: c4591001

Visit: Logs - Unscheduled

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Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen

Site No: 1217

Site Name: (1217) Kocaeli University Faculty of Medicine

Subject No: 12171039

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 19-Apr-2021 21:04

Date	Location	User	Value	Reason
Jan-19-2021 13:18:48 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NOT APPLICABLE	Initial Entry

11. Was a Concomitant Medication given?

Date	Location	User	Value	Reason
Jan-19-2021 13:18:48 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Jan-19-2021 13:18:48 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

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

Date	Location	User	Value	Reason
Jan-19-2021 13:18:48 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: RECOVERED/RESO LVED	Initial Entry

090177e196d89024\Final\Final On: 22-Apr-2021 02:12 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

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Form Status: Data Complete, Frozen

Site No: 1217

Site Name: (1217) Kocaeli University Faculty of Medicine

Subject No: 12171039

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 19-Apr-2021 21:04

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

Date	Location	User	Value	Reason
Jan-19-2021 13:18:48 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

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Form Status: Data Complete, Frozen

Site No: 1217

Site Name: (1217) Kocaeli University Faculty of Medicine

Subject No: 12171039

Subject Initials: ---

Generated By: (b) (4)

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1. Category:

Date	Location	User	Value	Reason
Jan-19-2021 15:53:24 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: ADVERSE EVENT	Initial Entry

2. AE ID:

Date	Location	User	Value	Reason
Jan-19-2021 15:53:24 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 2	Initial Entry

3. Adverse Event:

(If possible specify diagnosis, not individual symptoms)

Date	Location	User	Value	Reason
Feb-08-2021 00:53:59 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Closed	Response satisfies query
Feb-06-2021 15:12:40 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Answered	The volunteer has no known history.

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Header Text: c4591001

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Site No: 1217

Site Name: (1217) Kocaeli University Faculty of Medicine

Subject No: 12171039

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 19-Apr-2021 21:04

Feb-05-2021 19:19:15 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Opened	clinical: pls confirm subject has no past history of hearing loss, episodes of hearing loss, tinnitis or other ear problems or update MedHx CRF accordingly. Thanks
Jan-24-2021 19:24:50 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Closed	Response satisfies query
Jan-23-2021 12:34:39 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Answered	As a result of the test conducted on January 18, 2021, it was stated that the hearing loss returned to normal.
Jan-23-2021 01:24:15 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Reissued :Opened	clinical: pls confirm, hearing on repeat audiometry was

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Site No: 1217

Site Name: (1217) Kocaeli University Faculty of Medicine

Subject No: 12171039

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 19-Apr-2021 21:04

				back to normal? was the hearing loss determined to be sensorineural or not? Thanks
Jan-22-2021 22:42:37 (UTC+03:00) Istanbul	ACV0PFEINFP6000	Binnur Yildirim (b) (4)	Query 2: Answered	Complaints in repeated audiometry on January 18 ended.
Jan-22-2021 22:24:39 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Reissued :Opened	clinical: Thanks, but pls advise if audiometry revealed sensorineural hearing loss and if there was any improvement on the repeat audiometry done 18 Jan.
Jan-22-2021 22:19:08 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Acute hearing loss in right ear	Changed Information
Jan-22-2021 22:17:53	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Answered	Changed Information

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Header Text: c4591001

Visit: Logs - Unscheduled

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Form Status: Data Complete, Frozen

Site No: 1217

Site Name: (1217) Kocaeli University Faculty of Medicine

Subject No: 12171039

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 19-Apr-2021 21:04

(UTC+03:00) Istanbul				
Jan-22-2021 22:17:53 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Acute hearing loss	Changed Information
Jan-22-2021 16:44:36 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	reissued
Jan-22-2021 16:44:25 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Opened	clinical: Thanks, but pls update AE term to indicate which ear(s) affected and advise if hearing has improved on repeat audiometry, and update AE term to indicate if sensorineural or conductive hearing loss
Jan-22-2021 16:42:22 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reissued :Opened	clinical: Thanks, but pls update AE term to indicate

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				which ear(s) affected and advise if hearing has improved on repeat audiometry.
Jan-22-2021 16:14:15 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Control audiometry refers to pure tone audiometry for right ear. Subject started to take prednol 16 mg PO 5x1 on 15Jan2021. Medication is still ongoing but dose is decreasing day by day. But AE was terminated according to the control test.
Jan-22-2021 14:41:21 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reissued :Opened	clinical: pls update AE term to indicate whether R, L or both ears involved. Pls clarify what

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				'control audiometry' refers to, and the severity of hearing loss on the audiometry. Has subject received any treatment or improvement?
Jan-22-2021 11:40:59 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Subject was seen ENT on 15Jan2021 and an audiometry was performed. According to the result, acute hearing loss was diagnosed. Then control audiometry was performed on 18Jan2021. AE was closed
Jan-21-2021 18:33:02 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	clin: pls confirm no prior hx tinnitus, hearing issues. Advise how dx made ie subjective vs

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				audiometry, degree of hearing loss, and has subject seen ENT? Thanks
Jan-19-2021 15:53:24 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: sudden hearing loss	Initial Entry

4. Start Date Time:

Date	Location	User	Value	Reason
Jan-26-2021 18:28:09 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Jan-26-2021 10:59:38 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	the date of onset of hearing loss is unknown.
Jan-25-2021 19:16:50 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	clinical: pls enter start DAY. Thanks
Jan-19-2021 15:53:24 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Jan/UNK/2021 UNK:UNK	Initial Entry

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Subject No: 12171039

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Generated By: (b) (4)

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5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Jan-19-2021 15:53:24 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO End Date Time: Jan/18/2021 UNK: UNK	Initial Entry

6. Toxicity Grade:

Date	Location	User	Value	Reason
Jan-19-2021 15:53:24 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 1	Initial Entry

7. Is the adverse event serious?

If Yes, NOTIFY PFIZER IMMEDIATELY.

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

Date	Location	User	Value	Reason
Jan-19-2021 15:53:24 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

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

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

Date	Location	User	Value	Reason
Jan-19-2021 15:53:24 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

9. Is this event related to study treatment:

Date	Location	User	Value	Reason
Feb-08-2021 00:42:10 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Feb-06-2021 15:17:55 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Acute hearing loss
Feb-05-2021 19:19:34 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	clinical: causality is listed as non-related, other =UNK. Please provide specific causality if possible. Thanks

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Subject Initials: ---

Generated By: (b) (4)

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Jan-19-2021 15:54:39 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NOT RELATED If Not Related to study treatment(s), this event is due to: OTHER <i>If Other, specify:</i> Unknown	Transcription Error
Jan-19-2021 15:54:25 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NOT RELATED	Transcription Error
Jan-19-2021 15:53:24 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: RELATED	Initial Entry

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Jan-19-2021 15:53:24 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NOT APPLICABLE	Initial Entry

11. Was a Concomitant Medication given?

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Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 19-Apr-2021 21:04

Date	Location	User	Value	Reason
Jan-19-2021 15:53:24 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Jan-19-2021 15:53:24 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

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

Date	Location	User	Value	Reason
Jan-19-2021 15:53:24 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: RECOVERED/RESOLVED	Initial Entry

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

Date	Location	User	Value	Reason
Jan-19-2021 15:53:24 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

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Date	Location	User	Value	Reason
Feb-03-2021 16:05:06 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Created	

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Feb-03-2021 16:09:06 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Created	

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Date	Location	User	Value	Reason
Feb-03-2021 16:10:01 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Created	

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Feb-03-2021 16:21:04 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Created	

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1. What is the medication identifier?

Date	Location	User	Value	Reason
Feb-03-2021 16:02:02 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 1	Initial Entry

2. Category:

Date	Location	User	Value	Reason
Feb-03-2021 16:02:02 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: CORTICOSTEROIDS	Initial Entry

3. Concomitant Medications Pre-specified:

Date	Location	User	Value	Reason
Feb-03-2021 16:02:02 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: NO	Initial Entry

4. Medication:

Provide the complete generic drug name (including salt form, where applicable). Where generic name is unknown, enter the full trade or proprietary name. Include clarifying information in the Medication text (e.g., Ingredient(s), route, use, formulation).

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Subject Initials: ---

Generated By: (b) (4)

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Date	Location	User	Value	Reason
Feb-12-2021 01:16:02 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Deleted	Query is invalid or does not apply
Feb-12-2021 00:58:46 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Candidate	CLINQUERY: Per Protocol Section 6.5.1. Prohibited During the Study - Receipt of Systemic Corticosteroids (≥ 20 mg/day of prednisone or equivalent) for ≥ 14 days is prohibited. This ConMed Record does not meet this Criteria. Please confirm and DELETE Record.
Feb-03-2021 16:02:02 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Prednol (methylprednisolone)	Initial Entry

5. Dose:

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Date	Location	User	Value	Reason
Feb-03-2021 16:07:26 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 20	New Information
Feb-03-2021 16:02:02 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 80	Initial Entry

6. Dose Unit:

Date	Location	User	Value	Reason
Feb-03-2021 16:02:02 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: mg	Initial Entry

7. Dose Frequency:

Date	Location	User	Value	Reason
Feb-03-2021 16:07:41 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: QID	New Information
Feb-03-2021 16:02:02 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: TID	Initial Entry

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8. Route:

Date	Location	User	Value	Reason
Feb-03-2021 16:02:02 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: ORAL	Initial Entry

9. Start Date:

Date	Location	User	Value	Reason
Feb-03-2021 16:02:02 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Jan/15/2021	Initial Entry

10. Ongoing?

Date	Location	User	Value	Reason
Feb-03-2021 16:02:02 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO End Date: Jan/17/2021	Initial Entry

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1. What is the medication identifier?

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Feb-03-2021 16:04:02 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 2	Initial Entry

2. Category:

Date	Location	User	Value	Reason
Feb-03-2021 16:04:02 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: CORTICOSTEROIDS	Initial Entry

3. Concomitant Medications Pre-specified:

Date	Location	User	Value	Reason
Feb-03-2021 16:04:02 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: NO	Initial Entry

4. Medication:

Provide the complete generic drug name (including salt form, where applicable). Where generic name is unknown, enter the full trade or proprietary name. Include clarifying information in the Medication text (e.g., Ingredient(s), route, use, formulation).

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Date	Location	User	Value	Reason
Feb-12-2021 01:16:02 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Deleted	Query is invalid or does not apply
Feb-12-2021 00:59:01 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Candidate	CLINQUERY: Per Protocol Section 6.5.1. Prohibited During the Study - Receipt of Systemic Corticosteroids (≥ 20 mg/day of prednisone or equivalent) for ≥ 14 days is prohibited. This ConMed Record does not meet this Criteria. Please confirm and DELETE Record.
Feb-03-2021 16:04:02 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Prednol (methylprednisolone)	Initial Entry

5. Dose:

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Generated By: (b) (4)

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Date	Location	User	Value	Reason
Feb-03-2021 16:08:01 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 16	New Information
Feb-03-2021 16:04:02 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 64	Initial Entry

6. Dose Unit:

Date	Location	User	Value	Reason
Feb-03-2021 16:04:02 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: mg	Initial Entry

7. Dose Frequency:

Date	Location	User	Value	Reason
Feb-03-2021 16:08:13 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: QID	Changed Information
Feb-03-2021 16:04:02 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: TID	Initial Entry

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8. Route:

Date	Location	User	Value	Reason
Feb-03-2021 16:04:02 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: ORAL	Initial Entry

9. Start Date:

Date	Location	User	Value	Reason
Feb-03-2021 16:04:02 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Jan/18/2021	Initial Entry

10. Ongoing?

Date	Location	User	Value	Reason
Feb-03-2021 16:04:02 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO End Date: Jan/20/2021	Initial Entry

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1. What is the medication identifier?

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Feb-03-2021 16:05:06 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 3	Initial Entry

2. Category:

Date	Location	User	Value	Reason
Feb-03-2021 16:05:06 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: CORTICOSTEROIDS	Initial Entry

3. Concomitant Medications Pre-specified:

Date	Location	User	Value	Reason
Feb-03-2021 16:05:06 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: NO	Initial Entry

4. Medication:

Provide the complete generic drug name (including salt form, where applicable). Where generic name is unknown, enter the full trade or proprietary name. Include clarifying information in the Medication text (e.g., Ingredient(s), route, use, formulation).

090177e196d89024\Final\Final On: 22-Apr-2021 02:12 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1217

Subject No: 12171039

Generated By: (b) (4)

Form: CONCOMITANT MEDICATIONS - PROHIBITED - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1217) Kocaeli University Faculty of Medicine

Subject Initials: ---

Generated Time (GMT): 19-Apr-2021 21:04

Date	Location	User	Value	Reason
Feb-12-2021 01:16:02 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Deleted	Query is invalid or does not apply
Feb-12-2021 00:59:16 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Candidate	CLINQUERY: Per Protocol Section 6.5.1. Prohibited During the Study - Receipt of Systemic Corticosteroids (≥ 20 mg/day of prednisone or equivalent) for ≥ 14 days is prohibited. This ConMed Record does not meet this Criteria. Please confirm and DELETE Record.
Feb-03-2021 16:05:06 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Prednol (methylprednisolone)	Initial Entry

5. Dose:

090177e196d89024\Final\Final On: 22-Apr-2021 02:12 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: CONCOMITANT MEDICATIONS - PROHIBITED - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1217

Site Name: (1217) Kocaeli University Faculty of Medicine

Subject No: 12171039

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 19-Apr-2021 21:04

Date	Location	User	Value	Reason
Feb-03-2021 16:05:57 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 16	Transcription Error
Feb-03-2021 16:05:06 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 48	Initial Entry

6. Dose Unit:

Date	Location	User	Value	Reason
Feb-03-2021 16:05:06 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: mg	Initial Entry

7. Dose Frequency:

Date	Location	User	Value	Reason
Feb-03-2021 16:05:06 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: TID	Initial Entry

8. Route:

Date	Location	User	Value	Reason
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090177e196d89024\Final\Final On: 22-Apr-2021 02:12 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: CONCOMITANT MEDICATIONS - PROHIBITED - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1217

Site Name: (1217) Kocaeli University Faculty of Medicine

Subject No: 12171039

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 19-Apr-2021 21:04

Feb-03-2021 16:05:06 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: ORAL	Initial Entry
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9. Start Date:

Date	Location	User	Value	Reason
Feb-03-2021 16:05:06 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Jan/21/2021	Initial Entry

10. Ongoing?

Date	Location	User	Value	Reason
Feb-03-2021 16:05:06 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO End Date: Jan/23/2021	Initial Entry

090177e196d89024\Final\Final On: 22-Apr-2021 02:12 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1217

Subject No: 12171039

Generated By: (b) (4)

Form: CONCOMITANT MEDICATIONS - PROHIBITED - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1217) Kocaeli University Faculty of Medicine

Subject Initials: ---

Generated Time (GMT): 19-Apr-2021 21:04

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1. What is the medication identifier?

Date	Location	User	Value	Reason
Feb-03-2021 16:09:06 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 4	Initial Entry

2. Category:

Date	Location	User	Value	Reason
Feb-03-2021 16:09:06 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: CORTICOSTEROIDS	Initial Entry

3. Concomitant Medications Pre-specified:

Date	Location	User	Value	Reason
Feb-03-2021 16:09:06 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: NO	Initial Entry

4. Medication:

Provide the complete generic drug name (including salt form, where applicable). Where generic name is unknown, enter the full trade or proprietary name. Include clarifying information in the Medication text (e.g., Ingredient(s), route, use, formulation).

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Header Text: c4591001

Visit: Logs - Unscheduled

Form: CONCOMITANT MEDICATIONS - PROHIBITED - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1217

Site Name: (1217) Kocaeli University Faculty of Medicine

Subject No: 12171039

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 19-Apr-2021 21:04

Date	Location	User	Value	Reason
Feb-12-2021 01:16:02 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Deleted	Query is invalid or does not apply
Feb-12-2021 00:59:29 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Candidate	CLINQUERY: Per Protocol Section 6.5.1. Prohibited During the Study - Receipt of Systemic Corticosteroids (≥ 20 mg/day of prednisone or equivalent) for ≥ 14 days is prohibited. This ConMed Record does not meet this Criteria. Please confirm and DELETE Record.
Feb-03-2021 16:09:06 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Prednol (methylprednisolone)	Initial Entry

5. Dose:

090177e196d89024\Final\Final On: 22-Apr-2021 02:12 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: CONCOMITANT MEDICATIONS - PROHIBITED - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1217

Site Name: (1217) Kocaeli University Faculty of Medicine

Subject No: 12171039

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 19-Apr-2021 21:04

Date	Location	User	Value	Reason
Feb-03-2021 16:09:06 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 16	Initial Entry

6. Dose Unit:

Date	Location	User	Value	Reason
Feb-03-2021 16:09:06 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: mg	Initial Entry

7. Dose Frequency:

Date	Location	User	Value	Reason
Feb-03-2021 16:09:06 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BID	Initial Entry

8. Route:

Date	Location	User	Value	Reason
Feb-03-2021 16:09:06 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: ORAL	Initial Entry

090177e196d89024\Final\Final On: 22-Apr-2021 02:12 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: CONCOMITANT MEDICATIONS - PROHIBITED - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1217

Site Name: (1217) Kocaeli University Faculty of Medicine

Subject No: 12171039

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 19-Apr-2021 21:04

9. Start Date:

Date	Location	User	Value	Reason
Feb-03-2021 16:09:06 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Jan/24/2021	Initial Entry

10. Ongoing?

Date	Location	User	Value	Reason
Feb-03-2021 16:09:06 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO End Date: Jan/26/2021	Initial Entry

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Header Text: c4591001

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Site No: 1217

Subject No: 12171039

Generated By: (b) (4)

Form: CONCOMITANT MEDICATIONS - PROHIBITED - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1217) Kocaeli University Faculty of Medicine

Subject Initials: ---

Generated Time (GMT): 19-Apr-2021 21:04

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1. What is the medication identifier?

Date	Location	User	Value	Reason
Feb-03-2021 16:10:01 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 5	Initial Entry

2. Category:

Date	Location	User	Value	Reason
Feb-03-2021 16:10:01 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: CORTICOSTEROIDS	Initial Entry

3. Concomitant Medications Pre-specified:

Date	Location	User	Value	Reason
Feb-03-2021 16:10:01 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: NO	Initial Entry

4. Medication:

Provide the complete generic drug name (including salt form, where applicable). Where generic name is unknown, enter the full trade or proprietary name. Include clarifying information in the Medication text (e.g., Ingredient(s), route, use, formulation).

Header Text: c4591001

Visit: Logs - Unscheduled

Form: CONCOMITANT MEDICATIONS - PROHIBITED - eCRF Audit Trail History

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Form Status: Data Complete, Frozen, Verified

Site No: 1217

Site Name: (1217) Kocaeli University Faculty of Medicine

Subject No: 12171039

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 19-Apr-2021 21:04

Date	Location	User	Value	Reason
Feb-12-2021 01:16:02 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Deleted	Query is invalid or does not apply
Feb-12-2021 00:59:54 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Candidate	CLINQUERY: Per Protocol Section 6.5.1. Prohibited During the Study - Receipt of Systemic Corticosteroids (≥ 20 mg/day of prednisone or equivalent) for ≥ 14 days is prohibited. This ConMed Record does not meet this Criteria. Please confirm and DELETE Record.
Feb-03-2021 16:10:01 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Prednol (methylprednisolone)	Initial Entry

5. Dose:

090177e196d89024\Final\Final On: 22-Apr-2021 02:12 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: CONCOMITANT MEDICATIONS - PROHIBITED - eCRF Audit Trail History

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Form Status: Data Complete, Frozen, Verified

Site No: 1217

Site Name: (1217) Kocaeli University Faculty of Medicine

Subject No: 12171039

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 19-Apr-2021 21:04

Date	Location	User	Value	Reason
Feb-03-2021 16:10:01 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 16	Initial Entry

6. Dose Unit:

Date	Location	User	Value	Reason
Feb-03-2021 16:10:01 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: mg	Initial Entry

7. Dose Frequency:

Date	Location	User	Value	Reason
Feb-03-2021 16:10:01 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: QD	Initial Entry

8. Route:

Date	Location	User	Value	Reason
Feb-03-2021 16:10:01 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: ORAL	Initial Entry

090177e196d89024\Final\Final On: 22-Apr-2021 02:12 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: CONCOMITANT MEDICATIONS - PROHIBITED - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1217

Site Name: (1217) Kocaeli University Faculty of Medicine

Subject No: 12171039

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 19-Apr-2021 21:04

9. Start Date:

Date	Location	User	Value	Reason
Feb-03-2021 16:10:01 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Jan/27/2021	Initial Entry

10. Ongoing?

Date	Location	User	Value	Reason
Feb-03-2021 16:10:01 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO End Date: Jan/29/2021	Initial Entry

090177e196d89024\Final\Final On: 22-Apr-2021 02:12 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

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Site No: 1217

Subject No: 12171039

Generated By: (b) (4)

Form: CONCOMITANT MEDICATIONS - PROHIBITED - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1217) Kocaeli University Faculty of Medicine

Subject Initials: ---

Generated Time (GMT): 19-Apr-2021 21:04

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1. What is the medication identifier?

Date	Location	User	Value	Reason
Feb-03-2021 16:21:04 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 6	Initial Entry

2. Category:

Date	Location	User	Value	Reason
Feb-03-2021 16:21:04 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: CORTICOSTEROIDS	Initial Entry

3. Concomitant Medications Pre-specified:

Date	Location	User	Value	Reason
Feb-03-2021 16:21:04 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: NO	Initial Entry

4. Medication:

Provide the complete generic drug name (including salt form, where applicable). Where generic name is unknown, enter the full trade or proprietary name. Include clarifying information in the Medication text (e.g., Ingredient(s), route, use, formulation).

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Header Text: c4591001

Visit: Logs - Unscheduled

Form: CONCOMITANT MEDICATIONS - PROHIBITED - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1217

Site Name: (1217) Kocaeli University Faculty of Medicine

Subject No: 12171039

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 19-Apr-2021 21:04

Date	Location	User	Value	Reason
Feb-12-2021 01:16:02 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Deleted	Query is invalid or does not apply
Feb-12-2021 01:00:09 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Candidate	CLINQUERY: Per Protocol Section 6.5.1. Prohibited During the Study - Receipt of Systemic Corticosteroids (≥ 20 mg/day of prednisone or equivalent) for ≥ 14 days is prohibited. This ConMed Record does not meet this Criteria. Please confirm and DELETE Record.
Feb-03-2021 16:21:04 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Prednol (methylprednisolone)	Initial Entry

5. Dose:

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Header Text: c4591001

Visit: Logs - Unscheduled

Form: CONCOMITANT MEDICATIONS - PROHIBITED - eCRF Audit Trail History

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Form Status: Data Complete, Frozen, Verified

Site No: 1217

Site Name: (1217) Kocaeli University Faculty of Medicine

Subject No: 12171039

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 19-Apr-2021 21:04

Date	Location	User	Value	Reason
Feb-03-2021 16:21:04 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 8	Initial Entry

6. Dose Unit:

Date	Location	User	Value	Reason
Feb-03-2021 16:21:04 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: mg	Initial Entry

7. Dose Frequency:

Date	Location	User	Value	Reason
Feb-03-2021 16:21:04 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: QD	Initial Entry

8. Route:

Date	Location	User	Value	Reason
Feb-03-2021 16:21:04 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: ORAL	Initial Entry

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Header Text: c4591001

Visit: Logs - Unscheduled

Form: CONCOMITANT MEDICATIONS - PROHIBITED - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1217

Site Name: (1217) Kocaeli University Faculty of Medicine

Subject No: 12171039

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 19-Apr-2021 21:04

9. Start Date:

Date	Location	User	Value	Reason
Feb-03-2021 16:21:04 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Jan/30/2021	Initial Entry

10. Ongoing?

Date	Location	User	Value	Reason
Feb-03-2021 16:21:04 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO End Date: Feb/1/2021	Initial Entry

090177e196d89024\Final\Final On: 22-Apr-2021 02:12 (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: 1217 **Site Name:** (1217) Kocaeli University Faculty of Medicine

Subject No: 12171039 **Subject Initials:** ---

Generated By: (b) (4) **Generated Time (GMT):** 19-Apr-2021 21:04

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1. Date of Completion/Discontinuation/Death :

Date	Location	User	Value	Reason
Dec-23-2020 12:05:17 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Dec/23/2020	Initial Entry

2. Phase of Disposition:

Date	Location	User	Value	Reason
Dec-23-2020 12:05:17 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: VACCINATION	Initial Entry

3. Status:

Date	Location	User	Value	Reason
Dec-23-2020 12:05:17 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: COMPLETED	Initial Entry

090177e196d89024\Final\Final On: 22-Apr-2021 02:12 (GMT)

Header Text: c4591001

Visit: Potential ReVax Initial Contact - **Form:** DATE OF VISIT - eCRF Audit Trail History
Unscheduled

Form Version: 22-Apr-2020 21:02 **Form Status:** Data Complete, Frozen, Verified

Site No: 1217 **Site Name:** (1217) Kocaeli University Faculty of
Medicine

Subject No: 12171039 **Subject Initials:** ---

Generated By: (b) (4) **Generated Time (GMT):** 19-Apr-2021 21:04

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1. Date of Visit

Date	Location	User	Value	Reason
Feb-10-2021 14:06:49 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Feb/10/2021	Initial Entry

090177e196d89024\Final\Final On: 22-Apr-2021 02:12 (GMT)

Header Text: c4591001

Visit: Potential ReVax Initial Contact - **Form:** FURTHER VACCINATION CONFIRMATION -
Unscheduled eCRF Audit Trail History

Form Version: 10-Dec-2020 02:25 **Form Status:** Data Complete, Frozen

Site No: 1217 **Site Name:** (1217) Kocaeli University Faculty of
Medicine

Subject No: 12171039 **Subject Initials:** ---

Generated By: (b) (4) **Generated Time (GMT):** 19-Apr-2021 21:04

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1. Select appropriate response - Is participant willing to return for Vaccination 3?

Date	Location	User	Value	Reason
Feb-10-2021 14:12:10 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Participant is willing to return for Vaccinati on 3 Participant is: eligible per local/n ational recommen dations and confir med to have receiv ed only placebo at Vaccination 1/2	New Information
Feb-10-2021 14:07:03 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Participant is willing to return for Vaccinati on 3 Participant is: eligible per other p rotocol allowance(s) and confirmed t o have received on ly placebo at Vacci nation 1/2	Initial Entry

090177e196d89024\Final\Final On: 22-Apr-2021 02:12 (GMT)

Header Text: c4591001

Visit: Disposition - Unscheduled

Form: TREATMENT UNBLINDED - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1217

Site Name: (1217) Kocaeli University Faculty of Medicine

Subject No: 12171039

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 19-Apr-2021 21:04

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1. Date Treatment Unblinded :

Date	Location	User	Value	Reason
Feb-10-2021 14:02:42 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Feb/10/2021	Initial Entry

2. Primary Reason for Unblinding:

Date	Location	User	Value	Reason
Feb-10-2021 14:02:42 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: ASSESS ELIGIBILIT Y FOR ADDITIONA L VACCINATION	Initial Entry

090177e196d89024\Final\Final On: 22-Apr-2021 02:12 (GMT)

Header Text: c4591001

Visit: Disposition - Unscheduled

Form: WITHDRAWAL OF CONSENT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Verified

Site No: 1217

Site Name: (1217) Kocaeli University Faculty of Medicine

Subject No: 12171039

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 19-Apr-2021 21:04

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1. Withdrawal of Consent Date :

Date	Location	User	Value	Reason
Feb-10-2021 14:02:55 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

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, Verified

Site No: 1217

Site Name: (1217) Kocaeli University Faculty of Medicine

Subject No: 12171039

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 19-Apr-2021 21:04

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1. Date of Collection / Notification of Death:

Date	Location	User	Value	Reason
Feb-10-2021 14:03:14 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

090177e196d89024\Final\Final On: 22-Apr-2021 02:12 (GMT)

Header Text: c4591001

Visit: V101_VAX3

Form Version: 22-Apr-2020 21:02

Site No: 1217

Subject No: 12171039

Generated By: (b) (4)

Form: DATE OF VISIT - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1217) Kocaeli University Faculty of Medicine

Subject Initials: ---

Generated Time (GMT): 19-Apr-2021 21:04

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1. Date of Visit

Date	Location	User	Value	Reason
Mar-03-2021 11:02:01 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Mar/3/2021	Initial Entry

Header Text: c4591001

Visit: V101_VAX3

Form: INFORMED CONSENT - FURTHER VACCINATION - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:31

Form Status: Data Complete, Frozen, Verified

Site No: 1217

Site Name: (1217) Kocaeli University Faculty of Medicine

Subject No: 12171039

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 19-Apr-2021 21:04

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1. Consent Was:

Date	Location	User	Value	Reason
Mar-03-2021 11:02:12 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: OBTAINED Date Written Consent Obtained Mar/3/2021	Initial Entry

090177e196d89024\Final\Final On: 22-Apr-2021 02:12 (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, Frozen, Verified

Site No: 1217

Site Name: (1217) Kocaeli University Faculty of Medicine

Subject No: 12171039

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 19-Apr-2021 21:04

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1. Date of Completion/Discontinuation/Death :

Date	Location	User	Value	Reason
Mar-03-2021 11:02:48 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Mar/3/2021	Initial Entry

2. Phase of Disposition:

Date	Location	User	Value	Reason
Mar-03-2021 11:02:48 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: REPEAT SCREENIN G 1	Initial Entry

3. Status:

Date	Location	User	Value	Reason
Mar-03-2021 11:02:48 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: COMPLETED	Initial Entry

090177e196d89024\Final\Final On: 22-Apr-2021 02:12 (GMT)

Header Text: c4591001

Visit: V101_VAX3

Form Version: 22-Apr-2020 21:03

Site No: 1217

Subject No: 12171039

Generated By: (b) (4)

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

Form Status: Data Complete, Frozen, Verified

Site Name: (1217) Kocaeli University Faculty of Medicine

Subject Initials: ---

Generated Time (GMT): 19-Apr-2021 21:04

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1. Data Origin

Date	Location	User	Value	Reason
Mar-03-2021 12:11:57 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Mar-03-2021 12:11:57 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SERUM	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Mar-03-2021 12:12:15 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Mar-03-2021 12:11:57 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered.

090177e196d89024\Final\Final On: 22-Apr-2021 02:12 (GMT)

Header Text: c4591001

Visit: V101_VAX3

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1217

Site Name: (1217) Kocaeli University Faculty of Medicine

Subject No: 12171039

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 19-Apr-2021 21:04

				Please review and correct as appropriate.
Mar-03-2021 12:11:57 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Date of Collection: Mar/3/2021	Initial Entry

5.a

Date	Location	User	Value	Reason
Mar-03-2021 12:12:15 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BN897X	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Mar-03-2021 12:12:15 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BN897X	Initial Entry

5.b

Date	Location	User	Value	Reason
Mar-03-2021 12:12:28 (UTC+03:00)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BN897Y	Initial Entry

090177e196d89024\Final\Final On: 22-Apr-2021 02:12 (GMT)

Header Text: c4591001

Visit: V101_VAX3

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1217

Site Name: (1217) Kocaeli University Faculty of Medicine

Subject No: 12171039

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 19-Apr-2021 21:04

Istanbul				
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5.b Sample ID

Date	Location	User	Value	Reason
Mar-03-2021 12:12:28 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BN897Y	Initial Entry

5.c

Date	Location	User	Value	Reason
Mar-03-2021 12:12:41 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BS2S9P	Initial Entry

5.c Sample ID

Date	Location	User	Value	Reason
Mar-03-2021 12:12:41 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BS2S9P	Initial Entry

5.d

Date	Location	User	Value	Reason
Mar-03-2021 12:12:53	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Initial Entry

090177e196d89024\Final\Final On: 22-Apr-2021 02:12 (GMT)

Header Text: c4591001

Visit: V101_VAX3

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1217

Site Name: (1217) Kocaeli University Faculty of Medicine

Subject No: 12171039

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 19-Apr-2021 21:04

(UTC+03:00) Istanbul		(b) (4), (b) (6)	Sample ID: BS2S9R	
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5.d Sample ID

Date	Location	User	Value	Reason
Mar-03-2021 12:12:53 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BS2S9R	Initial Entry

090177e196d89024\Final\Final On: 22-Apr-2021 02:12 (GMT)

Header Text: c4591001

Visit: V101_VAX3

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1217

Site Name: (1217) Kocaeli University Faculty of Medicine

Subject No: 12171039

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 19-Apr-2021 21:04

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1. Data Origin

Date	Location	User	Value	Reason
Mar-03-2021 12:13:12 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Mar-03-2021 12:13:12 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: NASAL_SWAB	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Mar-03-2021 12:13:50 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Mar-03-2021 12:13:12 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered.

090177e196d89024\Final\Final On: 22-Apr-2021 02:12 (GMT)

Header Text: c4591001

Visit: V101_VAX3

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1217

Site Name: (1217) Kocaeli University Faculty of Medicine

Subject No: 12171039

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 19-Apr-2021 21:04

				Please review and correct as appropriate.
Mar-03-2021 12:13:12 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Date of Collection: Mar/3/2021	Initial Entry

5.a

Date	Location	User	Value	Reason
Mar-03-2021 12:13:50 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID BN897 : W	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Mar-03-2021 12:13:50 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BN897W	Initial Entry

090177e196d89024\Final\Final On: 22-Apr-2021 02:12 (GMT)

Header Text: c4591001

Visit: V101_VAX3

Form Version: 10-Dec-2020 02:26

Site No: 1217

Subject No: 12171039

Generated By: (b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1217) Kocaeli University Faculty of Medicine

Subject Initials: ---

Generated Time (GMT): 19-Apr-2021 21:04

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1. Was there a temporary delay of vaccination?

Date	Location	User	Value	Reason
Mar-03-2021 11:03:14 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2. Treatment Name

Date	Location	User	Value	Reason
Mar-03-2021 11:03:14 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: BNT162b2	Initial Entry

3. Formulation:

Date	Location	User	Value	Reason
Mar-03-2021 11:03:14 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: INJECTION	Initial Entry

4. Dose Date Time:

Date	Location	User	Value	Reason
Mar-03-2021 11:03:14	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Mar/3/2021 10:25	Initial Entry

090177e196d89024\Final\Final On: 22-Apr-2021 02:12 (GMT)

Header Text: c4591001

Visit: V101_VAX3

Form: VACCINATION - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:26

Form Status: Data Complete, Frozen, Verified

Site No: 1217

Site Name: (1217) Kocaeli University Faculty of Medicine

Subject No: 12171039

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 19-Apr-2021 21:04

(UTC+03:00) Istanbul		(b) (4), (b) (6)		
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5. Anatomical Location:

Date	Location	User	Value	Reason
Mar-03-2021 11:03:14 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: DELTOID MUSCLE	Initial Entry

6. Body Side:

Date	Location	User	Value	Reason
Mar-03-2021 11:03:14 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: RIGHT	Initial Entry

7. Route:

Date	Location	User	Value	Reason
Mar-03-2021 11:03:14 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: INTRAMUSCULAR	Initial Entry

8. Actual Dose:

Date	Location	User	Value	Reason
Mar-03-2021 11:03:14	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 30.0	Initial Entry

090177e196d89024\Final\Final On: 22-Apr-2021 02:12 (GMT)

Header Text: c4591001

Visit: V101_VAX3

Form: VACCINATION - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:26

Form Status: Data Complete, Frozen, Verified

Site No: 1217

Site Name: (1217) Kocaeli University Faculty of Medicine

Subject No: 12171039

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 19-Apr-2021 21:04

(UTC+03:00)
Istanbul

9. Unit:

Date	Location	User	Value	Reason
Mar-03-2021 11:03:14 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: ug	Initial Entry

10. Timeframe Subject Was Observed

Date	Location	User	Value	Reason
Mar-03-2021 11:03:14 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 30 MINUTES	Initial Entry

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

Date	Location	User	Value	Reason
Mar-03-2021 11:03:14 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

090177e196d89024\Final\Final On: 22-Apr-2021 02:12 (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: 1217

Site Name: (1217) Kocaeli University Faculty of Medicine

Subject No: 12171039

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 19-Apr-2021 21:04

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1. Subject Status

Date	Location	User	Value	Reason
Dec-23-2020 12:05:17 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: FOLLOW-UP	Initial Entry
Nov-04-2020 15:28:19 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: ENROLLED/RANDOMIZED	Initial Entry
Nov-04-2020 09:13:19 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SCREENED	Initial Entry

2. Subject Status Date

Date	Location	User	Value	Reason
Dec-23-2020 12:05:17 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Dec/23/2020	Initial Entry
Nov-04-2020 15:28:19 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Nov/4/2020	Initial Entry

090177e196d89024\Final\Final On: 22-Apr-2021 02:12 (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: 1217

Site Name: (1217) Kocaeli University Faculty of Medicine

Subject No: 12171039

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 19-Apr-2021 21:04

Nov-04-2020 09:13:19 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Nov/4/2020	Initial Entry
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Header Text: c4591001

Visit: Investigator Signature -
Unscheduled

Form Version: 22-Apr-2020 21:04

Site No: 1217

Subject No: 12171039

Generated By: (b) (4)

Form: CASEBOOK SIGNATURE FORM - eCRF Audit
Trail History

Form Status: Data Complete, Signed, Verified

Site Name: (1217) Kocaeli University Faculty of
Medicine

Subject Initials: ---

Generated Time (GMT): 19-Apr-2021 21:04

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1. Casebook Signature

Date	Location	User	Value	Reason
Nov-18-2020 09:12:16 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Click Here to Enable	Initial Entry