

**Header Text:** C4591001

**Visit:** COHORT\_SELECTION

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

**Site No:** 1217

**Subject No:** 12171031

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

**Form:** COHORT\_SELECTION

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

**Site Name:** (1217) Kocaeli University Faculty of Medicine

**Subject Initials:** ---

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

[eCRF Audit Trail History](#)

**Cohort Selection**

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

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

**Header Text:** C4591001

**Visit:** COHORT\_SELECTION

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

**Site No:** 1217

**Subject No:** 12171031

**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):** 29-Mar-2021 13:11

[eCRF Audit Trail History](#)

**Informed Consent**

1.	Consent Was:	OBTAINED Date Written Consent Obtained Oct/30/2020
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**Header Text:** C4591001

**Visit:** COHORT\_SELECTION

**Form Version:** 15-Sep-2020 21:54

**Site No:** 1217

**Subject No:** 12171031

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

**Form:** DEMOGRAPHY

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

**Site Name:** (1217) Kocaeli University Faculty of Medicine

**Subject Initials:** ---

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

[eCRF Audit Trail History](#)

**Demography**

1.	Subject ID	[12171031]
2.	Birth Date:	(b) (6) 1985
3.	Sex:	FEMALE
4.	Ethnicity:	NOT HISPANIC OR LATINO(A) OR OF SPANISH ORIGIN
5.	Race: (Check X all that apply):	WHITE
6.	Racial Designation:	

**Header Text:** C4591001

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

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

**Site No:** 1217

**Subject No:** 12171031

**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):** 29-Mar-2021 13:11

[eCRF Audit Trail History](#)

**Date of Visit**

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

**Header Text:** C4591001

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

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

**Site No:** 1217

**Subject No:** 12171031

**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):** 29-Mar-2021 13:11

**Form Comments**

**Inclusion Criteria Not Met**

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

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

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

**Form Version:** 15-Sep-2020 21:52

**Site No:** 1217

**Subject No:** 12171031

**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):** 29-Mar-2021 13:11

[eCRF Audit Trail History](#)

**Disposition - Screening**

1.	Date of Completion/Discontinuation /Death	Oct/30/2020
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:** 12171031

**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):** 29-Mar-2021 13:11

[Form Comments](#)

**Medical History Details**

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

090177e196ae2f27\Final\Final On: 01-Apr-2021 03:36 (GMT)

**Header Text:** C4591001

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

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

**Site No:** 1217

**Subject No:** 12171031

**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):** 29-Mar-2021 13:11

[eCRF Audit Trail History](#)

**HIV Status**

1.	Select appropriate response - What is the subject HIV status?	The subject is NOT known to be HIV POSITIVE
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**Header Text:** C4591001

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

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

**Site No:** 1217

**Subject No:** 12171031

**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):** 29-Mar-2021 13:11

[eCRF Audit Trail History](#)

**Vital Signs**

1.	Date:	Oct/30/2020
2.	Weight:	[65.0]
3.	Unit:	kg
4.	Height:	[155.0]
5.	Unit:	cm
6.	Body Mass Index:	[27.1]

**Vital Signs Details**

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

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**Header Text:** C4591001

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

**Form Version:** 10-Oct-2020 15:58

**Site No:** 1217

**Subject No:** 12171031

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

**Form:** LAB URINALYSIS - PREGNANCY TEST

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

**Site Name:** (1217) Kocaeli University Faculty of Medicine

**Subject Initials:** ---

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

[eCRF Audit Trail History](#)

**Lab Urinalysis**

1.	Lab Panel:	URINALYSIS
2.	Lab Sub-Panel:	PREGNANCY
3.	Collection Date:	Oct/30/2020
4.	Laboratory Name and Address (Derived)	[STUDY SITE]
5.	Specimen Type:	URINE

**Lab Result**

6.a	Sponsor ID:	[113]
	Test:	Choriogonadotropin Beta_PX113
	Result:	NEGATIVE
	Not Done:	

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**Header Text:** C4591001

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

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

**Site No:** 1217

**Subject No:** 12171031

**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):** 29-Mar-2021 13:11

[eCRF Audit Trail History](#)

**Disposition**

1.	Randomization Date :	Oct/30/2020
2.	Randomization Number:	[114923]
3.	Randomization Group:	[ ]

**Header Text:** C4591001

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

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

**Site No:** 1217

**Subject No:** 12171031

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

**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

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

**Site Name:** (1217) Kocaeli University Faculty of Medicine

**Subject Initials:** ---

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

[eCRF Audit Trail History](#)

**Electronic Sample Tracking**

1.	Data Origin	SITE
2.	Sample Type	SERUM
3.	Sample Collected?	YES Date of Collection: Oct/30/2020
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	[BPZ96W]
5.b	Sample ID	[BPZ96X]
5.c	Sample ID	[BS2S3V]
5.d	Sample ID	[BS2S3W]

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**Header Text:** C4591001

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

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

**Site No:** 1217

**Subject No:** 12171031

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

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

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

**Site Name:** (1217) Kocaeli University Faculty of Medicine

**Subject Initials:** ---

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

[eCRF Audit Trail History](#)

**Electronic Sample Tracking**

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB
3.	Sample Collected?	YES Date of Collection: Oct/30/2020
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	[BPZ96H]
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090177e196ae2f27\Final\Final On: 01-Apr-2021 03:36 (GMT)

**Header Text:** C4591001

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

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

**Site No:** 1217

**Subject No:** 12171031

**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):** 29-Mar-2021 13:11

[eCRF Audit Trail History](#)

**Vaccination**

1.	Was there a temporary delay of vaccination?	NO
2.	Treatment Name	[BLINDED THERAPY]
3.	Formulation:	INJECTION
4.	Dose Date Time:	Oct/30/2020 11:55
5.	Anatomical Location:	DELTOID MUSCLE
6.	Body Side:	LEFT
7.	Route:	INTRAMUSCULAR
8.	Actual Dose:	[ ]
9.	Unit:	
10.	Timeframe Subject Was Observed	THE PROTOCOL SPECIFIED OBSERVATION PERIOD
11.	Was the subject observed for at least the protocol specified observation period after investigational product administration?	YES

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**Header Text:** C4591001

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

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

**Site No:** 1217

**Subject No:** 12171031

**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):** 29-Mar-2021 13:11

[eCRF Audit Trail History](#)

**Reactogenicity Diary**

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

**Visit:** V2\_VAX2\_L

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

**Site No:** 1217

**Subject No:** 12171031

**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):** 29-Mar-2021 13:11

[eCRF Audit Trail History](#)

**Date of Visit**

1.	Date of Visit	Nov/19/2020
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: 12171031

Subject Initials: ---

Generated By: (b) (4)

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

[eCRF Audit Trail History](#)

**Vaccination Symptoms Diary - Symptom Resolved Dates**

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

090177e196ae2f27\Final\Final On: 01-Apr-2021 03:36 (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:** 12171031

**Subject Initials:** ---

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

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

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

090177e196ae2f27\Final\Final On: 01-Apr-2021 03:36 (GMT)

**Header Text:** C4591001

**Visit:** V2\_VAX2\_L

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

**Site No:** 1217

**Subject No:** 12171031

**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):** 29-Mar-2021 13:11

[eCRF Audit Trail History](#)

**Vital Signs**

1.	Date:	Nov/19/2020
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**Vital Signs Details**

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

**Header Text:** C4591001

**Visit:** V2\_VAX2\_L

**Form Version:** 10-Oct-2020 15:58

**Site No:** 1217

**Subject No:** 12171031

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

**Form:** LAB URINALYSIS - PREGNANCY TEST

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

**Site Name:** (1217) Kocaeli University Faculty of Medicine

**Subject Initials:** ---

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

[eCRF Audit Trail History](#)

**Lab Urinalysis**

1.	Lab Panel:	URINALYSIS
2.	Lab Sub-Panel:	PREGNANCY
3.	Collection Date:	Nov/19/2020
4.	Laboratory Name and Address (Derived)	[STUDY SITE]
5.	Specimen Type:	URINE

**Lab Result**

6.a	Sponsor ID:	[113]
	Test:	Choriogonadotropin Beta_PX113
	Result:	NEGATIVE
	Not Done:	

090177e196ae2f27\Final\Final On: 01-Apr-2021 03:36 (GMT)

**Header Text:** C4591001

**Visit:** V2\_VAX2\_L

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

**Site No:** 1217

**Subject No:** 12171031

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

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

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

**Site Name:** (1217) Kocaeli University Faculty of Medicine

**Subject Initials:** ---

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

[eCRF Audit Trail History](#)

**Electronic Sample Tracking**

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB
3.	Sample Collected?	YES Date of Collection: Nov/19/2020
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	[BPZ9GX]
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090177e196ae2f27\Final\Final On: 01-Apr-2021 03:36 (GMT)

**Header Text:** C4591001

**Visit:** V2\_VAX2\_L

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

**Site No:** 1217

**Subject No:** 12171031

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

**Form:** VACCINATION

**Form Status:** Data Complete, Verified

**Site Name:** (1217) Kocaeli University Faculty of Medicine

**Subject Initials:** ---

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

[eCRF Audit Trail History](#)

**Vaccination**

1.	Was there a temporary delay of vaccination?	YES Date of First Delay: Nov/19/2020  Reason(s) for Temporary Delay of Vaccination RECENT NON-STUDY VACCINATION	
2.	Treatment Name	[ ]	
3.	Formulation:		
4.	Dose Date Time:	Not Done _____ //	<a href="#">Comments</a>
5.	Anatomical Location:		
6.	Body Side:	Not Done _____	<a href="#">Comments</a>
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?	Not Done _____	<a href="#">Comments</a>

090177e196ae2f27\Final\Final On: 01-Apr-2021 03:36 (GMT)

**Header Text:** C4591001

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

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

**Site No:** 1217

**Subject No:** 12171031

**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):** 29-Mar-2021 13:11

[eCRF Audit Trail History](#)

**Date of Visit**

1.	Date of Visit	Dec/17/2020
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, Verified

Site No: 1217

Site Name: (1217) Kocaeli University Faculty of Medicine

Subject No: 12171031

Subject Initials: ---

Generated By: (b) (4)

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

[Form Comments](#)

[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?	Not Applicable	<a href="#">Comments</a>
2.a	Symptom:	FEVER	
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	Not Applicable	<a href="#">Comments</a>
2.b	Symptom:	FATIGUE	
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	Not Applicable	<a href="#">Comments</a>
2.c	Symptom:	HEADACHE	
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	Not Applicable	<a href="#">Comments</a>
2.d	Symptom:	CHILLS	
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	Not Applicable	<a href="#">Comments</a>
2.e	Symptom:	VOMITING	
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	Not Applicable	<a href="#">Comments</a>
2.f	Symptom:	DIARRHEA	
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	Not Applicable	<a href="#">Comments</a>

090177e196ae2f27\Final\Final On: 01-Apr-2021 03:36 (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, Verified

**Site No:** 1217

**Site Name:** (1217) Kocaeli University Faculty of Medicine

**Subject No:** 12171031

**Subject Initials:** ---

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

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

2.g	Symptom:	NEW OR WORSENERED MUSCLE PAIN	
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	Not Applicable	<a href="#">Comments</a>
2.h	Symptom:	NEW OR WORSENERED JOINT PAIN	
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	Not Applicable	<a href="#">Comments</a>
3.	Injection Site Location:	Not Applicable	<a href="#">Comments</a>
4.	Injection Site Body Side:	Not Applicable	<a href="#">Comments</a>
5.a	Injection Site Reaction:	REDNESS	
	Were injection site reactions present on the last day the Subject Diary was completed?	Not Applicable	<a href="#">Comments</a>
5.b	Injection Site Reaction:	SWELLING	
	Were injection site reactions present on the last day the Subject Diary was completed?	Not Applicable	<a href="#">Comments</a>
5.c	Injection Site Reaction:	PAIN AT INJECTION SITE	
	Were injection site reactions present on the last day the Subject Diary was completed?	Not Applicable	<a href="#">Comments</a>

090177e196ae2f27\Final\Final On: 01-Apr-2021 03:36 (GMT)

**Header Text:** C4591001

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

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

**Site No:** 1217

**Subject No:** 12171031

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

**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

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

**Site Name:** (1217) Kocaeli University Faculty of Medicine

**Subject Initials:** ---

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

[eCRF Audit Trail History](#)

**Electronic Sample Tracking**

1.	Data Origin	SITE
2.	Sample Type	SERUM
3.	Sample Collected?	YES Date of Collection: Dec/17/2020
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	[BPZ9CV]
5.b	Sample ID	[BPZ9CW]
5.c	Sample ID	[BNLZT7]
5.d	Sample ID	[BNLZT8]

090177e196ae2f27\Final\Final On: 01-Apr-2021 03:36 (GMT)

**Header Text:** C4591001

**Visit:** V4\_MONTH6\_L

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

**Site No:** 1217

**Subject No:** 12171031

**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):** 29-Mar-2021 13:11

**Date of Visit**

1.	Date of Visit	//
2.	Erroneous Visit	

**Header Text:** C4591001

**Visit:** V4\_MONTH6\_L

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

**Site No:** 1217

**Subject No:** 12171031

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

**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

**Form Status:** Not Started

**Site Name:** (1217) Kocaeli University Faculty of Medicine

**Subject Initials:** ---

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

**Electronic Sample Tracking**

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

**Aliquot**

Please enter barcode for each aliquot.

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

**Visit:** V5\_MONTH12\_L

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

**Site No:** 1217

**Subject No:** 12171031

**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):** 29-Mar-2021 13:11

**Date of Visit**

1.	Date of Visit	//
2.	Erroneous Visit	

**Header Text:** C4591001

**Visit:** V5\_MONTH12\_L

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

**Site No:** 1217

**Subject No:** 12171031

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

**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

**Form Status:** Not Started

**Site Name:** (1217) Kocaeli University Faculty of Medicine

**Subject Initials:** ---

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

**Electronic Sample Tracking**

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

**Aliquot**

Please enter barcode for each aliquot.

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

**Header Text:** C4591001

**Visit:** V6\_MONTH24\_L

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

**Site No:** 1217

**Subject No:** 12171031

**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):** 29-Mar-2021 13:11

**Date of Visit**

1.	Date of Visit	//
2.	Erroneous Visit	

**Header Text:** C4591001

**Visit:** V6\_MONTH24\_L

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

**Site No:** 1217

**Subject No:** 12171031

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

**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

**Form Status:** Not Started

**Site Name:** (1217) Kocaeli University Faculty of Medicine

**Subject Initials:** ---

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

**Electronic Sample Tracking**

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

**Aliquot**

Please enter barcode for each aliquot.

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

**Visit:** POT\_COVID\_ILL - New Unscheduled Visit **Form:** DATE OF VISIT - ILLNESS ONSET

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

**Form Status:** Not Started

**Site No:** 1217

**Site Name:** (1217) Kocaeli University Faculty of Medicine

**Subject No:** 12171031

**Subject Initials:** ---

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

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

Date of Visit		
1.	Date of Visit	//
2.	Erroneous Visit	
COVID-19 Illness Visit		
3.	COVID-19 Illness Visit:	

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL - New Unscheduled Visit **Form:** SIGNS AND SYMPTOMS OF POTENTIAL COVID-19

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

**Form Status:** Not Started

**Site No:** 1217

**Site Name:** (1217) Kocaeli University Faculty of Medicine

**Subject No:** 12171031

**Subject Initials:** ---

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

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

**Signs and Symptoms**

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

**Symptoms**

4.	Symptoms:	
	Was symptom present?	

**Symptoms - Other**

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

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL - New Unscheduled Visit **Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB SELF

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

**Form Status:** Not Started

**Site No:** 1217

**Site Name:** (1217) Kocaeli University Faculty of Medicine

**Subject No:** 12171031

**Subject Initials:** ---

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

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

**Electronic Sample Tracking**

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

**Aliquot**

Please enter barcode for each aliquot.

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

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL - New Unscheduled Visit **Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB

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

**Form Status:** Not Started

**Site No:** 1217

**Site Name:** (1217) Kocaeli University Faculty of Medicine

**Subject No:** 12171031

**Subject Initials:** ---

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

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

**Electronic Sample Tracking**

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

**Aliquot**

Please enter barcode for each aliquot.

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

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL - New Unscheduled Visit **Form:** HEALTH CARE UTILIZATION

**Form Version:** 20-Feb-2021 02:19

**Form Status:** Not Started

**Site No:** 1217

**Site Name:** (1217) Kocaeli University Faculty of Medicine

**Subject No:** 12171031

**Subject Initials:** ---

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

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

**Health Care Utilization**

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

**Health Care Utilization Other**

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

**Health Care Utilization**

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

090177e196ae2f27\Final\Final On: 01-Apr-2021 03:36 (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:** 12171031

**Subject Initials:** ---

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

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

**Illness Details**

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

**Header Text:** C4591001

**Visit:** POT\_COVID\_CONVA - New Unscheduled **Form:** DATE OF VISIT - ILLNESS CONVALESCENT 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:** 12171031

**Subject Initials:** ---

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

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

**Date of Visit**

1.	Date of Visit	//
2.	Erroneous Visit	

**COVID-19 Illness Visit**

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

**Header Text:** C4591001

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

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

**Form Status:** Not Started

**Site No:** 1217

**Site Name:** (1217) Kocaeli University Faculty of Medicine

**Subject No:** 12171031

**Subject Initials:** ---

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

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

**Electronic Sample Tracking**

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

**Aliquot**

Please enter barcode for each aliquot.

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

**Header Text:** C4591001

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

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

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

**Form Status:** Not Started

**Site No:** 1217

**Site Name:** (1217) Kocaeli University Faculty of Medicine

**Subject No:** 12171031

**Subject Initials:** ---

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

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

**Date of Visit**

1.	Date of Visit	//
2.	Erroneous Visit	

**COVID-19 Repeat Swab**

3.	COVID-19 Repeat Swab:	
----	-----------------------	--

**Header Text:** C4591001

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

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

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

**Form Status:** Not Started

**Site No:** 1217

**Site Name:** (1217) Kocaeli University Faculty of Medicine

**Subject No:** 12171031

**Subject Initials:** ---

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

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

**Electronic Sample Tracking**

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

**Aliquot**

Please enter barcode for each aliquot.

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

**Header Text:** C4591001

**Visit:** Logs

**Form:** ADVERSE EVENT REPORT

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

**Site No:** 1217

**Site Name:** (1217) Kocaeli University Faculty of Medicine

**Subject No:** 12171031

**Subject Initials:** ---

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

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

#	Category	AE Identifier	Adverse Event	Start Date	Is the Adverse Event Still Ongoing	Form Instance
1.	ADVERSE EVENT	1	exposure during pregnancy	Oct/30/2020 11:55	YES	<a href="#">Repeating Pages</a>

090177e196ae2f27\Final\Final On: 01-Apr-2021 03:36 (GMT)

Header Text: C4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1217

Subject No: 12171031

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Verified

Site Name: (1217) Kocaeli University Faculty of Medicine

Subject Initials: ---

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

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[Form Audit Trail](#)

**Adverse Event Report**

1.	Category:	ADVERSE EVENT	
2.	AE ID:	[1]	
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[exposure during pregnancy]	
4.	Start Date Time:	Oct/30/2020 11:55	<a href="#">Comments</a>
5.	Is the adverse event still ongoing?	YES	
6.	Toxicity Grade:	Not Applicable	<a href="#">Comments</a>
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	<a href="#">Comments</a>
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: [subject pregnant]	
10.	Latest Action Taken with Study Treatment:	DRUG WITHDRAWN	
11.	Was a Concomitant Medication given?	NO	
12.	Was a Non-Drug Treatment given?	NO	

090177e196ae2f27\Final\Final On: 01-Apr-2021 03:36 (GMT)

**Header Text:** C4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1217

**Subject No:** 12171031

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

**Form:** ADVERSE EVENT REPORT

**Form Status:** Data Complete, Verified

**Site Name:** (1217) Kocaeli University Faculty of Medicine

**Subject Initials:** ---

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

13.	What was the outcome of this adverse event?:	UNKNOWN	<a href="#">Comments</a>
14.	Did the adverse event cause the subject to be discontinued from the study?	NO	
15.	Serious Adverse Event Number: For Pfizer Use Only	[ ]	<a href="#">Comments</a>

090177e196ae2f27\Final\Final On: 01-Apr-2021 03:36 (GMT)

**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:** 12171031

**Subject Initials:** ---

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

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

#	Category	Medication Error	Start Date	Is the medication error Still On going	Study Medication Errors Action	Form Instance
1.						<a href="#">Repeating Pages</a>

**Header Text:** C4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1217

**Subject No:** 12171031

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

**Form:** MEDICATION ERROR

**Form Status:** Not Started

**Site Name:** (1217) Kocaeli University Faculty of Medicine

**Subject Initials:** ---

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

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**Medication Error**

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

090177e196ae2f27\Final\Final On: 01-Apr-2021 03:36 (GMT)

**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:** 12171031

**Subject Initials:** ---

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

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

#	Sponsor-Defined Identifier	Category for Medication	Concomitant Medications Pre-specified	Name of Medication	Start Date	Form Instance
1.	1	VACCINATIONS	NO	Hepatitis A Vaccination	Nov/9/2020	<a href="#">Repeating Pages</a>
2.	2	VACCINATIONS	NO	Hepatitis B Vaccination	Nov/9/2020	<a href="#">Repeating Pages</a>

**Header Text:** C4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1217

**Subject No:** 12171031

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

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

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

**Site Name:** (1217) Kocaeli University Faculty of Medicine

**Subject Initials:** ---

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

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**Concomitant Medications**

1.	What is the medication identifier?	[1]
2.	Category:	VACCINATIONS
3.	Concomitant Medications Pre-specified:	NO
4.	Medication:  Provide the complete generic drug name (including salt form, where applicable). Where generic name is unknown, enter the full trade or proprietary name. Include clarifying information in the Medication text (e.g., Ingredient(s), route, use, formulation).	[Hepatitis A Vaccination]
5.	Date:	Nov/9/2020

090177e196ae2f27\Final\Final On: 01-Apr-2021 03:36 (GMT)

**Header Text:** C4591001

**Visit:** Logs - Unscheduled

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

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

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

**Site No:** 1217

**Site Name:** (1217) Kocaeli University Faculty of Medicine

**Subject No:** 12171031

**Subject Initials:** ---

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

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

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**Concomitant Medications**

1.	What is the medication identifier?	[2]
2.	Category:	VACCINATIONS
3.	Concomitant Medications Pre-specified:	NO
4.	Medication:  Provide the complete generic drug name (including salt form, where applicable). Where generic name is unknown, enter the full trade or proprietary name. Include clarifying information in the Medication text (e.g., Ingredient(s), route, use, formulation).	[Hepatitis B Vaccination]
5.	Date:	Nov/9/2020

090177e196ae2f27\Final\Final On: 01-Apr-2021 03:36 (GMT)

**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:** 12171031

**Subject Initials:** ---

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

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

#	Sponsor-Defined Identifier	Category for Medication	Concomitant Medications Pre-specified	Name of Medication	Dose Description	Form Instance
1.						<a href="#">Repeating Pages</a>

090177e196ae2f27\Final\Final On: 01-Apr-2021 03:36 (GMT)

**Header Text:** C4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1217

**Subject No:** 12171031

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

**Form:** CONCOMITANT MEDICATIONS - PROHIBITED

**Form Status:** Not Started

**Site Name:** (1217) Kocaeli University Faculty of Medicine

**Subject Initials:** ---

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

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**Concomitant Medications**

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

090177e196ae2f27\Final\Final On: 01-Apr-2021 03:36 (GMT)

**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:** 12171031

**Subject Initials:** ---

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

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

#	Category	Treatment Identifier	Con Non-Drug Treatments Pre-specified	Treatment	Start Date	Form Instance
1.						<a href="#">Repeating Pages</a>

090177e196ae2f27\Final\Final On: 01-Apr-2021 03:36 (GMT)

**Header Text:** C4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1217

**Subject No:** 12171031

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

**Form:** RADIATION TREATMENT

**Form Status:** Not Started

**Site Name:** (1217) Kocaeli University Faculty of Medicine

**Subject Initials:** ---

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

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**Radiation Treatment**

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

**Header Text:** C4591001

**Visit:** Logs

**Form:** TRANSFUSIONS

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

**Site No:** 1217

**Site Name:** (1217) Kocaeli University Faculty of Medicine

**Subject No:** 12171031

**Subject Initials:** ---

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

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

#	Transfusion Type	Date of Transfusion	Form Instance
1.			<a href="#">Repeating Pages</a>

090177e196ae2f27\Final\Final On: 01-Apr-2021 03:36 (GMT)

**Header Text:** C4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1217

**Subject No:** 12171031

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

**Form:** TRANSFUSIONS

**Form Status:** Not Started

**Site Name:** (1217) Kocaeli University Faculty of Medicine

**Subject Initials:** ---

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

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

**Header Text:** C4591001

**Visit:** Unplanned 1 - Unscheduled Visit on  
Nov/03/2020

**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:** 12171031

**Subject Initials:** ---

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

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

[eCRF Audit Trail History](#)

**Date of Visit**

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

**Header Text:** C4591001

**Visit:** Unplanned 1 - Unscheduled Visit on  
Nov/03/2020

**Form:** UNPLANNED VISIT

**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:** 12171031

**Subject Initials:** ---

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

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

[eCRF Audit Trail History](#)

**Unplanned Assessments**

1.	Assessments	CONTACT OUTCOME
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**Header Text:** C4591001

**Visit:** Unplanned 1 - Unscheduled Visit on  
Nov/03/2020

**Form:** CONTACT OUTCOME - UNPLANNED

**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:** 12171031

**Subject Initials:** ---

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

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

[eCRF Audit Trail History](#)

**Contact Outcome**

1.	Contact Type:	TELEPHONE VISIT
2.	Was contact made?	YES Date of Contact: Nov/3/2020  Contact Outcome: VISIT NOT REQUIRED, INVESTIGATOR DECISION
3.	Comments:	[ ]

090177e196ae2f27\Final\Final On: 01-Apr-2021 03:36 (GMT)

**Header Text:** C4591001

**Visit:** Unplanned Vaccination - Unscheduled

**Form:** DATE OF VISIT

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

**Form Status:** Not Started

**Site No:** 1217

**Site Name:** (1217) Kocaeli University Faculty of Medicine

**Subject No:** 12171031

**Subject Initials:** ---

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

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

**Date of Visit**

1.	Date of Visit	//
2.	Erroneous Visit	

**Header Text:** C4591001

**Visit:** Unplanned Vaccination - Unscheduled

**Form:** VITAL SIGNS - TEMP

**Form Version:** 20-Feb-2021 02:16

**Form Status:** Not Started

**Site No:** 1217

**Site Name:** (1217) Kocaeli University Faculty of Medicine

**Subject No:** 12171031

**Subject Initials:** ---

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

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

**Vital Signs**

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

**Vital Signs Details**

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

**Header Text:** C4591001

**Visit:** Unplanned Vaccination - Unscheduled

**Form:** LAB URINALYSIS - PREGNANCY TEST

**Form Version:** 20-Feb-2021 02:14

**Form Status:** Not Started

**Site No:** 1217

**Site Name:** (1217) Kocaeli University Faculty of Medicine

**Subject No:** 12171031

**Subject Initials:** ---

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

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

**Lab Urinalysis**

1.	Lab Panel:	
2.	Lab Sub-Panel:	
3.	Collection Date:	//
4.	Laboratory Name and Address (Derived)	[ ]
5.	Specimen Type:	

**Lab Result**

6.	Sponsor ID:	[ ]
	Test:	
	Result:	
	Not Done:	

**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:** 12171031

**Subject Initials:** ---

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

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

**Vaccination**

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

090177e196ae2f27\Final\Final On: 01-Apr-2021 03:36 (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:** 12171031

**Subject Initials:** ---

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

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

**Contact Outcome**

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

**Header Text:** C4591001

**Visit:** Unplanned Vaccination - Unscheduled

**Form:** CONTACT OUTCOME - MONTH 6

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

**Form Status:** Not Started

**Site No:** 1217

**Site Name:** (1217) Kocaeli University Faculty of Medicine

**Subject No:** 12171031

**Subject Initials:** ---

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

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

**Contact Outcome**

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

**Header Text:** C4591001

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

**Form:** DATE OF VISIT

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

**Form Status:** Not Started

**Site No:** 1217

**Site Name:** (1217) Kocaeli University Faculty of Medicine

**Subject No:** 12171031

**Subject Initials:** ---

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

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

**Date of Visit**

1.	Date of Visit	//
2.	Erroneous Visit	

**Header Text:** C4591001

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

**Form:** INFORMED CONSENT - ASYMPTOMATIC SURVEILLANCE

**Form Version:** 14-Jan-2021 02:29

**Form Status:** Not Started

**Site No:** 1217

**Site Name:** (1217) Kocaeli University Faculty of Medicine

**Subject No:** 12171031

**Subject Initials:** ---

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

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

**Informed Consent - Asymptomatic Surveillance**

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

090177e196ae2f27\Final\Final On: 01-Apr-2021 03:36 (GMT)

**Header Text:** C4591001

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

**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

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

**Form Status:** Not Started

**Site No:** 1217

**Site Name:** (1217) Kocaeli University Faculty of Medicine

**Subject No:** 12171031

**Subject Initials:** ---

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

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

**Electronic Sample Tracking**

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

**Aliquot**

Please enter barcode for each aliquot.

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

**Header Text:** C4591001

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

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

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

**Form Status:** Not Started

**Site No:** 1217

**Site Name:** (1217) Kocaeli University Faculty of Medicine

**Subject No:** 12171031

**Subject Initials:** ---

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

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

**Electronic Sample Tracking**

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

**Aliquot**

Please enter barcode for each aliquot.

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

090177e196ae2f27\Final\Final On: 01-Apr-2021 03:36 (GMT)

**Header Text:** C4591001

**Visit:** End of Treatment - Unscheduled

**Form Version:** 15-Sep-2020 21:55

**Site No:** 1217

**Subject No:** 12171031

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

**Form:** DISPOSITION - TREATMENT

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

**Site Name:** (1217) Kocaeli University Faculty of Medicine

**Subject Initials:** ---

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

[eCRF Audit Trail History](#)

**Disposition - Treatment**

1.	Date of Completion/Discontinuation /Death :	Dec/7/2020
2.	Phase of Disposition:	VACCINATION
3.	Status:	PREGNANCY
4.	Specify Status:	[ ]

**Header Text:** C4591001

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

**Form:** DATE OF VISIT

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

**Form Status:** Not Started

**Site No:** 1217

**Site Name:** (1217) Kocaeli University Faculty of Medicine

**Subject No:** 12171031

**Subject Initials:** ---

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

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

**Date of Visit**

1.	Date of Visit	//
2.	Erroneous Visit	

**Header Text:** C4591001

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

**Form:** FURTHER VACCINATION CONFIRMATION

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

**Form Status:** Not Started

**Site No:** 1217

**Site Name:** (1217) Kocaeli University Faculty of Medicine

**Subject No:** 12171031

**Subject Initials:** ---

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

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

**Further Vaccination Confirmation**

1.	Select appropriate response - Is participant willing to return for Vaccination 3?	
----	---	--

**Header Text:** C4591001

**Visit:** Follow-Up - Unscheduled

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

**Site No:** 1217

**Subject No:** 12171031

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

**Form:** DISPOSITION - FOLLOW-UP

**Form Status:** Not Started

**Site Name:** (1217) Kocaeli University Faculty of Medicine

**Subject Initials:** ---

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

**Disposition - Follow-Up**

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

**Header Text:** C4591001

**Visit:** Disposition - Unscheduled

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

**Site No:** 1217

**Subject No:** 12171031

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

**Form:** TREATMENT UNBLINDED

**Form Status:** Data Complete, Verified

**Site Name:** (1217) Kocaeli University Faculty of Medicine

**Subject Initials:** ---

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

[Form Comments](#)

[eCRF Audit Trail History](#)

**Treatment Unblinded**

1.	Date Treatment Unblinded :	Not Applicable _____ //	<a href="#">Comments</a>
2.	Primary Reason for Unblinding:	Not Applicable _____	<a href="#">Comments</a>

**Header Text:** C4591001

**Visit:** Disposition - Unscheduled

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

**Site No:** 1217

**Subject No:** 12171031

**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):** 29-Mar-2021 13:11

[Form Comments](#)

[eCRF Audit Trail History](#)

**Withdrawal Of Consent**

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

**Header Text:** C4591001

**Visit:** Disposition - Unscheduled

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

**Site No:** 1217

**Subject No:** 12171031

**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):** 29-Mar-2021 13:11

[Form Comments](#)

[eCRF Audit Trail History](#)

**Death Details**

1.	Date of Collection / Notification of Death:	Not Applicable _____ //	<a href="#">Comments</a>
----	---	-------------------------------	--------------------------

**Cause of Death**

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

**Header Text:** C4591001

**Visit:** Subject Status - Unscheduled

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

**Site No:** 1217

**Subject No:** 12171031

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

**Form:** SUBJECT STATUS

**Form Status:** Data Complete, Verified

**Site Name:** (1217) Kocaeli University Faculty of Medicine

**Subject Initials:** ---

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

[eCRF Audit Trail History](#)

**Subject Status**

1.	Subject Status	DISCONTINUED
2.	Subject Status Date	Dec/7/2020

**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:** 12171031

**Subject Initials:** ---

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

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

[eCRF Audit Trail History](#)

**Casebook Signature Form**

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

**Header Text:** C4591001

**Visit:** Investigator Signature - Unscheduled

**Form:** CASEBOOK SIGNATURE FORM

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

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

**Site No:** 1217

**Site Name:** (1217) Kocaeli University Faculty of Medicine

**Subject No:** 12171031

**Subject Initials:** ---

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

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

[Audit Trail](#)

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

- CRF\_Sign

Name	Signature Meaning	Date	Type	Action
Sila Akhan	Approved	Jan-21-2021 13:29:41 (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.

090177e196ae2f27\Final\Final On: 01-Apr-2021 03:36 (GMT)

**Header Text:** C4591001

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

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

**Site No:** 1217

**Subject No:** 12171031

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

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

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

**Site Name:** (1217) Kocaeli University Faculty of Medicine

**Subject Initials:** ---

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

[Back to Form](#)

Item	Date	User	Comment
Form	Oct-30-2020 15:03:59 (UTC+03:00) Istanbul	(b) (4), (b) (6)	Not Applicable

**Header Text:** C4591001

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

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

**Site No:** 1217

**Subject No:** 12171031

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

**Form:** GENERAL MEDICAL HISTORY - Comments

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

**Site Name:** (1217) Kocaeli University Faculty of Medicine

**Subject Initials:** ---

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

[Back to Form](#)

Item	Date	User	Comment
Form	Oct-30-2020 15:43:15 (UTC+03:00) Istanbul	(b) (4), (b) (6)	Not Applicable

**Header Text:** C4591001

**Visit:** V2\_VAX2\_L

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

**Site No:** 1217

**Subject No:** 12171031

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

**Form:** VACCINATION - Comments

**Form Status:** Data Complete, Verified

**Site Name:** (1217) Kocaeli University Faculty of Medicine

**Subject Initials:** ---

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

[Back to Form](#)

Item	Date	User	Comment
4	Nov-24-2020 14:44:01 (UTC+03:00) Istanbul	(b) (4), (b) (6)	This section will be enter Not Done
4	Nov-24-2020 14:43:22 (UTC+03:00) Istanbul	(b) (4), (b) (6)	This section will be enter
4	Nov-24-2020 14:40:56 (UTC+03:00) Istanbul	(b) (4), (b) (6)	Not Applicable

**Header Text:** C4591001

**Visit:** V2\_VAX2\_L

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

**Site No:** 1217

**Subject No:** 12171031

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

**Form:** VACCINATION - Comments

**Form Status:** Data Complete, Verified

**Site Name:** (1217) Kocaeli University Faculty of Medicine

**Subject Initials:** ---

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

[Back to Form](#)

Item	Date	User	Comment
6	Nov-24-2020 14:43:38 (UTC+03:00) Istanbul	(b) (4), (b) (6)	This section will be enter Not Done

**Header Text:** C4591001

**Visit:** V2\_VAX2\_L

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

**Site No:** 1217

**Subject No:** 12171031

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

**Form:** VACCINATION - Comments

**Form Status:** Data Complete, Verified

**Site Name:** (1217) Kocaeli University Faculty of Medicine

**Subject Initials:** ---

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

[Back to Form](#)

Item	Date	User	Comment
11	Nov-24-2020 14:44:17 (UTC+03:00) Istanbul	(b) (4), (b) (6)	This section will be enter Not Done

**Header Text:** C4591001

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

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

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

**Form Status:** Data Complete, Verified

**Site No:** 1217

**Site Name:** (1217) Kocaeli University Faculty of Medicine

**Subject No:** 12171031

**Subject Initials:** ---

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

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

[Back to Form](#)

Item	Date	User	Comment
Form	Dec-17-2020 13:37:36 (UTC+03:00) Istanbul	(b) (4), (b) (6)	Not Applicable

090177e196ae2f27\Final\Final On: 01-Apr-2021 03:36 (GMT)

**Header Text:** C4591001

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

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

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

**Form Status:** Data Complete, Verified

**Site No:** 1217

**Site Name:** (1217) Kocaeli University Faculty of Medicine

**Subject No:** 12171031

**Subject Initials:** ---

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

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

[Back to Form](#)

Item	Date	User	Comment
1	Dec-17-2020 13:37:36 (UTC+03:00) Istanbul	(b) (4), (b) (6)	Not Applicable

**Header Text:** C4591001

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

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

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

**Form Status:** Data Complete, Verified

**Site No:** 1217

**Site Name:** (1217) Kocaeli University Faculty of Medicine

**Subject No:** 12171031

**Subject Initials:** ---

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

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

[Back to Form](#)

Item	Date	User	Comment
2.a	Dec-17-2020 13:37:36 (UTC+03:00) Istanbul	(b) (4), (b) (6)	Not Applicable

090177e196ae2f27\Final\Final On: 01-Apr-2021 03:36 (GMT)

**Header Text:** C4591001

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

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

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

**Form Status:** Data Complete, Verified

**Site No:** 1217

**Site Name:** (1217) Kocaeli University Faculty of Medicine

**Subject No:** 12171031

**Subject Initials:** ---

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

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

[Back to Form](#)

Item	Date	User	Comment
2.b	Dec-17-2020 13:37:36 (UTC+03:00) Istanbul	(b) (4), (b) (6)	Not Applicable

**Header Text:** C4591001

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

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

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

**Form Status:** Data Complete, Verified

**Site No:** 1217

**Site Name:** (1217) Kocaeli University Faculty of Medicine

**Subject No:** 12171031

**Subject Initials:** ---

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

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

[Back to Form](#)

Item	Date	User	Comment
2.c	Dec-17-2020 13:37:36 (UTC+03:00) Istanbul	(b) (4), (b) (6)	Not Applicable

090177e196ae2f27\Final\Final On: 01-Apr-2021 03:36 (GMT)

**Header Text:** C4591001

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

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

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

**Form Status:** Data Complete, Verified

**Site No:** 1217

**Site Name:** (1217) Kocaeli University Faculty of Medicine

**Subject No:** 12171031

**Subject Initials:** ---

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

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

[Back to Form](#)

Item	Date	User	Comment
2.d	Dec-17-2020 13:37:36 (UTC+03:00) Istanbul	(b) (4), (b) (6)	Not Applicable

**Header Text:** C4591001

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

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

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

**Form Status:** Data Complete, Verified

**Site No:** 1217

**Site Name:** (1217) Kocaeli University Faculty of Medicine

**Subject No:** 12171031

**Subject Initials:** ---

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

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

[Back to Form](#)

Item	Date	User	Comment
2.e	Dec-17-2020 13:37:36 (UTC+03:00) Istanbul	(b) (4), (b) (6)	Not Applicable

090177e196ae2f27\Final\Final On: 01-Apr-2021 03:36 (GMT)

**Header Text:** C4591001

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

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

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

**Form Status:** Data Complete, Verified

**Site No:** 1217

**Site Name:** (1217) Kocaeli University Faculty of Medicine

**Subject No:** 12171031

**Subject Initials:** ---

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

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

[Back to Form](#)

Item	Date	User	Comment
2 f	Dec-17-2020 13:37:36 (UTC+03:00) Istanbul	(b) (4), (b) (6)	Not Applicable

**Header Text:** C4591001

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

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

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

**Form Status:** Data Complete, Verified

**Site No:** 1217

**Site Name:** (1217) Kocaeli University Faculty of Medicine

**Subject No:** 12171031

**Subject Initials:** ---

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

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

[Back to Form](#)

Item	Date	User	Comment
2.g	Dec-17-2020 13:37:36 (UTC+03:00) Istanbul	(b) (4), (b) (6)	Not Applicable

090177e196ae2f27\Final\Final On: 01-Apr-2021 03:36 (GMT)

**Header Text:** C4591001

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

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

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

**Form Status:** Data Complete, Verified

**Site No:** 1217

**Site Name:** (1217) Kocaeli University Faculty of Medicine

**Subject No:** 12171031

**Subject Initials:** ---

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

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

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Item	Date	User	Comment
2 h	Dec-17-2020 13:37:36 (UTC+03:00) Istanbul	(b) (4), (b) (6)	Not Applicable

**Header Text:** C4591001

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

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

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

**Form Status:** Data Complete, Verified

**Site No:** 1217

**Site Name:** (1217) Kocaeli University Faculty of Medicine

**Subject No:** 12171031

**Subject Initials:** ---

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

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

[Back to Form](#)

Item	Date	User	Comment
3	Dec-17-2020 13:37:36 (UTC+03:00) Istanbul	(b) (4), (b) (6)	Not Applicable

**Header Text:** C4591001

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

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

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

**Form Status:** Data Complete, Verified

**Site No:** 1217

**Site Name:** (1217) Kocaeli University Faculty of Medicine

**Subject No:** 12171031

**Subject Initials:** ---

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

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

[Back to Form](#)

Item	Date	User	Comment
4	Dec-17-2020 13:37:36 (UTC+03:00) Istanbul	(b) (4), (b) (6)	Not Applicable

**Header Text:** C4591001

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

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

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

**Form Status:** Data Complete, Verified

**Site No:** 1217

**Site Name:** (1217) Kocaeli University Faculty of Medicine

**Subject No:** 12171031

**Subject Initials:** ---

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

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

[Back to Form](#)

Item	Date	User	Comment
5.a	Dec-17-2020 13:37:36 (UTC+03:00) Istanbul	(b) (4), (b) (6)	Not Applicable

**Header Text:** C4591001

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

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

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

**Form Status:** Data Complete, Verified

**Site No:** 1217

**Site Name:** (1217) Kocaeli University Faculty of Medicine

**Subject No:** 12171031

**Subject Initials:** ---

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

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

[Back to Form](#)

Item	Date	User	Comment
5.b	Dec-17-2020 13:37:36 (UTC+03:00) Istanbul	(b) (4), (b) (6)	Not Applicable

**Header Text:** C4591001

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

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

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

**Form Status:** Data Complete, Verified

**Site No:** 1217

**Site Name:** (1217) Kocaeli University Faculty of Medicine

**Subject No:** 12171031

**Subject Initials:** ---

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

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

[Back to Form](#)

Item	Date	User	Comment
5.c	Dec-17-2020 13:37:36 (UTC+03:00) Istanbul	(b) (4), (b) (6)	Not Applicable

090177e196ae2f27\Final\Final On: 01-Apr-2021 03:36 (GMT)

**Header Text:** C4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1217

**Subject No:** 12171031

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

**Form:** ADVERSE EVENT REPORT - Comments

**Form Status:** Data Complete, Verified

**Site Name:** (1217) Kocaeli University Faculty of Medicine

**Subject Initials:** ---

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

[Back to Form](#)

Item	Date	User	Comment
4	Dec-16-2020 16:47:43 (UTC+03:00) Istanbul	Binnur Yildirim (b) (4)	The AE date was updated according to DM request ;CCG page184 "In the absence of ultrasound, the data from the last menstrual period (LMP) should be used to estimate date of conception". So the AE date updated according to LMP.

**Header Text:** C4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1217

**Subject No:** 12171031

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

**Form:** ADVERSE EVENT REPORT - Comments

**Form Status:** Data Complete, Verified

**Site Name:** (1217) Kocaeli University Faculty of Medicine

**Subject Initials:** ---

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

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Item	Date	User	Comment
6	Dec-09-2020 19:58:56 (UTC+03:00) Istanbul	(b) (4), (b) (6)	Not Applicable

090177e196ae2f27\Final\Final On: 01-Apr-2021 03:36 (GMT)

**Header Text:** C4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1217

**Subject No:** 12171031

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

**Form:** ADVERSE EVENT REPORT - Comments

**Form Status:** Data Complete, Verified

**Site Name:** (1217) Kocaeli University Faculty of Medicine

**Subject Initials:** ---

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

[Back to Form](#)

Item	Date	User	Comment
7	Dec-14-2020 16:02:44 (UTC+03:00) Istanbul	(b) (4), (b) (6)	The AE "exposure during pregnancy" has already submitted as SAE to sponsor. This is a SAE per protocol due to Subject is pregnant. This is an important medical event, however subject does not meet other options.

**Header Text:** C4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1217

**Subject No:** 12171031

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

**Form:** ADVERSE EVENT REPORT - Comments

**Form Status:** Data Complete, Verified

**Site Name:** (1217) Kocaeli University Faculty of Medicine

**Subject Initials:** ---

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

[Back to Form](#)

Item	Date	User	Comment
13	Dec-18-2020 15:06:59 (UTC+03:00) Istanbul	Binnur Yildirim (b) (4)	data was changed according to the 'the latest EDP guidance, outcome should be recorded as UNKNOWN'.

090177e196ae2f27\Final\Final On: 01-Apr-2021 03:36 (GMT)

**Header Text:** C4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1217

**Subject No:** 12171031

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

**Form:** ADVERSE EVENT REPORT - Comments

**Form Status:** Data Complete, Verified

**Site Name:** (1217) Kocaeli University Faculty of Medicine

**Subject Initials:** ---

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

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Item	Date	User	Comment
15	Dec-08-2020 16:05:21 (UTC+03:00) Istanbul	Binnur Yildirim (b) (4)	2020484307

**Header Text:** C4591001

**Visit:** Disposition - Unscheduled

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

**Site No:** 1217

**Subject No:** 12171031

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

**Form:** TREATMENT UNBLINDED - Comments

**Form Status:** Data Complete, Verified

**Site Name:** (1217) Kocaeli University Faculty of Medicine

**Subject Initials:** ---

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

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Item	Date	User	Comment
Form	Jan-20-2021 18:51:04 (UTC+03:00) Istanbul	(b) (4), (b) (6)	this page is not applicale for this subject due to pragnency of subject.unblinding did not applicable for this subject. <hr/> Not Applicable
Form	Jan-20-2021 18:48:00 (UTC+03:00) Istanbul	(b) (4), (b) (6)	
Form	Jan-20-2021 18:38:46 (UTC+03:00) Istanbul	(b) (4), (b) (6)	this page is not applicale for this subject due to pragnency of subject.unblinding did not applicable for this subject. <hr/> Not Applicable

090177e196ae2f27\Final\Final On: 01-Apr-2021 03:36 (GMT)

**Header Text:** C4591001

**Visit:** Disposition

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

**Site No:** 1217

**Subject No:** 12171031

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

**Form:** TREATMENT UNBLINDED - Comments

**Form Status:** Data Complete, Verified

**Site Name:** (1217) Kocaeli University Faculty of Medicine

**Subject Initials:** ---

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

[Back to Form](#)

Item	Date	User	Comment
1	Jan-20-2021 18:51:04 (UTC+03:00) Istanbul	(b) (4), (b) (6)	this page is not applicale for this subject due to pragnency of subject.unblinding did not applicable for this subject. <hr/> Not Applicable
1	Jan-20-2021 18:48:00 (UTC+03:00) Istanbul	(b) (4), (b) (6)	
1	Jan-20-2021 18:38:46 (UTC+03:00) Istanbul	(b) (4), (b) (6)	this page is not applicale for this subject due to pragnency of subject.unblinding did not applicable for this subject. <hr/> Not Applicable

090177e196ae2f27\Final\Final On: 01-Apr-2021 03:36 (GMT)

**Header Text:** C4591001

**Visit:** Disposition

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

**Site No:** 1217

**Subject No:** 12171031

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

**Form:** TREATMENT UNBLINDED - Comments

**Form Status:** Data Complete, Verified

**Site Name:** (1217) Kocaeli University Faculty of Medicine

**Subject Initials:** ---

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

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Item	Date	User	Comment
2	Jan-20-2021 18:51:04 (UTC+03:00) Istanbul	(b) (4), (b) (6)	this page is not applicale for this subject due to pragnency of subject.unblinding did not applicable for this subject. <hr/> Not Applicable
2	Jan-20-2021 18:48:00 (UTC+03:00) Istanbul	(b) (4), (b) (6)	
2	Jan-20-2021 18:38:46 (UTC+03:00) Istanbul	(b) (4), (b) (6)	this page is not applicale for this subject due to pragnency of subject.unblinding did not applicable for this subject. <hr/> Not Applicable

090177e196ae2f27\Final\Final On: 01-Apr-2021 03:36 (GMT)

**Header Text:** C4591001

**Visit:** Disposition - Unscheduled

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

**Site No:** 1217

**Subject No:** 12171031

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

**Form:** WITHDRAWAL OF CONSENT - Comments

**Form Status:** Data Complete, Verified

**Site Name:** (1217) Kocaeli University Faculty of Medicine

**Subject Initials:** ---

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

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Item	Date	User	Comment
Form	Jan-20-2021 18:51:45 (UTC+03:00) Istanbul	(b) (4), (b) (6)	this page is not applicale for this subject due to pragnency of subject.unblinding did not applicable for this subject. <hr/> Not Applicable
Form	Jan-20-2021 18:49:05 (UTC+03:00) Istanbul	(b) (4), (b) (6)	
Form	Jan-20-2021 18:39:44 (UTC+03:00) Istanbul	(b) (4), (b) (6)	this page is not applicale for this subject due to pragnency of subject.unblinding did not applicable for this subject. <hr/> Not Applicable

**Header Text:** C4591001

**Visit:** Disposition

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

**Site No:** 1217

**Subject No:** 12171031

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

**Form:** WITHDRAWAL OF CONSENT - Comments

**Form Status:** Data Complete, Verified

**Site Name:** (1217) Kocaeli University Faculty of Medicine

**Subject Initials:** ---

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

[Back to Form](#)

Item	Date	User	Comment
1	Jan-20-2021 18:51:45 (UTC+03:00) Istanbul	(b) (4), (b) (6)	this page is not applicale for this subject due to pragnency of subject.unblinding did not applicable for this subject. <hr/> Not Applicable
1	Jan-20-2021 18:49:05 (UTC+03:00) Istanbul	(b) (4), (b) (6)	
1	Jan-20-2021 18:39:44 (UTC+03:00) Istanbul	(b) (4), (b) (6)	this page is not applicale for this subject due to pragnency of subject.unblinding did not applicable for this subject. <hr/> Not Applicable
1	Jan-15-2021 15:12:01 (UTC+03:00) Istanbul	(b) (4), (b) (6)	
1	Jan-15-2021 15:10:32 (UTC+03:00) Istanbul	(b) (4), (b) (6)	Not Applicable

090177e196ae2f27\Final\Final On: 01-Apr-2021 03:36 (GMT)

**Header Text:** C4591001

**Visit:** Disposition - Unscheduled

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

**Site No:** 1217

**Subject No:** 12171031

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

**Form:** DEATH DETAILS CODED - Comments

**Form Status:** Data Complete, Verified

**Site Name:** (1217) Kocaeli University Faculty of Medicine

**Subject Initials:** ---

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

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Item	Date	User	Comment
Form	Jan-20-2021 18:40:04 (UTC+03:00) Istanbul	(b) (4), (b) (6)	this page is not applicale for this subject due to pragnency of subject.unblinding did not applicable for this subject. <hr/> Not Applicable
Form	Jan-20-2021 17:20:03 (UTC+03:00) Istanbul	(b) (4), (b) (6)	
Form	Jan-15-2021 15:12:19 (UTC+03:00) Istanbul	(b) (4), (b) (6)	Not Applicable

**Header Text:** C4591001

**Visit:** Disposition

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

**Site No:** 1217

**Subject No:** 12171031

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

**Form:** DEATH DETAILS CODED - Comments

**Form Status:** Data Complete, Verified

**Site Name:** (1217) Kocaeli University Faculty of Medicine

**Subject Initials:** ---

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

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Item	Date	User	Comment
1	Jan-20-2021 18:40:04 (UTC+03:00) Istanbul	(b) (4), (b) (6)	this page is not applicale for this subject due to pragnency of subject.unblinding did not applicable for this subject. <hr/> Not Applicable
1	Jan-20-2021 17:20:03 (UTC+03:00) Istanbul	(b) (4), (b) (6)	
1	Jan-15-2021 15:12:19 (UTC+03:00) Istanbul	(b) (4), (b) (6)	Not Applicable

090177e196ae2f27\Final\Final On: 01-Apr-2021 03:36 (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:** 12171031

**Subject Initials:** ---

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

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

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

- CRF\_Sign

Name	Signature Meaning	Date	Type	Action
Sila Akhan	Approved	Jan-21-2021 13:29:41 (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	Jan-20-2021 17:19:19 (UTC+03:00) Istanbul		Edit - All signatures invalidated
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**Affidavit:**

N/A

Sila Akhan	Approved	Jan-20-2021 15:29:22 (UTC+03:00) Istanbul	BOOK	Signed
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**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	Jan-19-2021 15:55:09 (UTC+03:00) Istanbul		Edit - All signatures invalidated
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**Affidavit:**

N/A

Sila Akhan	Approved	Jan-18-2021 14:41:26 (UTC+03:00) Istanbul	BOOK	Signed
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090177e196ae2f27\Final\Final On: 01-Apr-2021 03:36 (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:** 12171031

**Subject Initials:** ---

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

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

**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	Jan-15-2021 15:10:21 (UTC+03:00) Istanbul		Edit - All signatures invalidated
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**Affidavit:**

N/A

Sila Akhan	Approved	Jan-04-2021 14:52:01 (UTC+03:00) Istanbul	BOOK	Signed
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**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.

Binnur Yildirim	N/A	Jan-03-2021 17:35:03 (UTC+03:00) Istanbul		Edit - All signatures invalidated
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**Affidavit:**

N/A

Sila Akhan	Approved	Dec-23-2020 12:20:45 (UTC+03:00) Istanbul	BOOK	Signed
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**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.

Binnur Yildirim	N/A	Dec-22-2020 16:49:49 (UTC+03:00) Istanbul		Edit - All signatures invalidated
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090177e196ae2f27\Final\Final On: 01-Apr-2021 03:36 (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:** 12171031

**Subject Initials:** ---

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

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

**Affidavit:**

N/A

Sila Akhan	Approved	Dec-18-2020 15:31:28 (UTC+03:00) Istanbul	BOOK	Signed
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**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.

Binnur Yildirim	N/A	Dec-18-2020 15:03:20 (UTC+03:00) Istanbul		Edit - All signatures invalidated
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**Affidavit:**

N/A

Sila Akhan	Approved	Dec-17-2020 13:43:58 (UTC+03:00) Istanbul	BOOK	Signed
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**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.

Binnur Yildirim	N/A	Dec-16-2020 16:47:43 (UTC+03:00) Istanbul		Edit - All signatures invalidated
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**Affidavit:**

N/A

Sila Akhan	Approved	Dec-15-2020 13:30:28 (UTC+03:00) Istanbul	BOOK	Signed
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090177e196ae2f27\Final\Final On: 01-Apr-2021 03:36 (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:** 12171031

**Subject Initials:** ---

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

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

**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.

Binnur Yildirim	N/A	Dec-15-2020 10:55:23 (UTC+03:00) Istanbul		Edit - All signatures invalidated
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**Affidavit:**

N/A

Sila Akhan	Approved	Dec-15-2020 08:33:18 (UTC+03:00) Istanbul	BOOK	Signed
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**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	Dec-09-2020 19:56:53 (UTC+03:00) Istanbul		Edit - All signatures invalidated
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**Affidavit:**

N/A

Sila Akhan	Approved	Dec-09-2020 16:20:57 (UTC+03:00) Istanbul	BOOK	Signed
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**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.

Binnur Yildirim	N/A	Dec-07-2020 16:42:16 (UTC+03:00) Istanbul		Edit - All signatures invalidated
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090177e196ae2f27\Final\Final On: 01-Apr-2021 03:36 (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:** 12171031

**Subject Initials:** ---

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

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

**Affidavit:**

N/A

Sila Akhan	Approved	Dec-02-2020 20:54:20 (UTC+03:00) Istanbul	BOOK	Signed
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**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	Nov-19-2020 15:23:11 (UTC+03:00) Istanbul		Edit - All signatures invalidated
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**Affidavit:**

N/A

Sila Akhan	Approved	Nov-04-2020 11:24:36 (UTC+03:00) Istanbul	BOOK	Signed
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**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.

090177e196ae2f27\Final\Final On: 01-Apr-2021 03:36 (GMT)

**Header Text:** C4591001

**Visit:** COHORT\_SELECTION

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

**Site No:** 1217

**Subject No:** 12171031

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

**Form:** COHORT SELECTION - eCRF Audit Trail History

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

**Site Name:** (1217) Kocaeli University Faculty of Medicine

**Subject Initials:** ---

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

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*1. Select appropriate response - Protocol version*

Date	Location	User	Value	Reason
Oct-30-2020 11:30:08 (UTC+03:00) Istanbul	ACV0PFEINFP6000	Binnur Yildirim (b) (4)	<b>Data Entry:</b> 08 SEP 2020	Initial Entry

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

Date	Location	User	Value	Reason
Oct-30-2020 11:30:08 (UTC+03:00) Istanbul	ACV0PFEINFP6000	Binnur Yildirim (b) (4)	<b>Data Entry:</b> STAGE 3 COHORTS	Initial Entry

**Header Text:** C4591001

**Visit:** COHORT\_SELECTION

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

**Site No:** 1217

**Subject No:** 12171031

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

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

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

**Site Name:** (1217) Kocaeli University Faculty of Medicine

**Subject Initials:** ---

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

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*I. Consent Was:*

Date	Location	User	Value	Reason
Oct-30-2020 11:30:17 (UTC+03:00) Istanbul	ACV0PFEINFP6000	Binnur Yildirim (b) (4)	<b>Data Entry:</b> OBTAINED Date Written Consent Obtained  Oct/30/2020	Initial Entry

Header Text: C4591001

Visit: COHORT\_SELECTION

Form Version: 15-Sep-2020 21:54

Site No: 1217

Subject No: 12171031

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): 29-Mar-2021 13:11

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**1. Subject ID**

Date	Location	User	Value	Reason
Oct-30-2020 11:29:58 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> 12171031	Item copied from previous form

**2. Birth Date:**

Date	Location	User	Value	Reason
Oct-30-2020 11:29:51 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> (b) (6) 1985	Enrollment Entry

**3. Sex:**

Date	Location	User	Value	Reason
Oct-30-2020 11:30:32 (UTC+03:00) Istanbul	ACV0PFEINFP6000	Binnur Yildirim (b) (4)	<u>Data Entry:</u> FEMALE	Initial Entry

**4. Ethnicity:**

Date	Location	User	Value	Reason
Oct-30-2020 11:30:32 (UTC+03:00) Istanbul	ACV0PFEINFP6000	Binnur Yildirim (b) (4)	<u>Data Entry:</u> NOT HISPANIC OR LATINO(A) OR OF SPANISH ORIGIN	Initial Entry

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

Date	Location	User	Value	Reason
Oct-30-2020 11:30:32 (UTC+03:00) Istanbul	ACV0PFEINFP6000	Binnur Yildirim (b) (4)	<u>Data Entry:</u> WHITE	Initial Entry

090177e196ae2f27\Final\Final On: 01-Apr-2021 03:36 (GMT)

**Header Text:** C4591001

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

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

**Site No:** 1217

**Subject No:** 12171031

**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):** 29-Mar-2021 13:11

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**1. Date of Visit**

Date	Location	User	Value	Reason
Nov-03-2020 19:47:47 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Nov-03-2020 19:47:30 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	Erroneous Visit is marked, but date of visit is entered. Please check whether other assessments are performed at this visit.
Oct-30-2020 15:03:46 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Oct/30/2020	Initial Entry

**2. Erroneous Visit**

Date	Location	User	Value	Reason
Nov-03-2020 19:47:47 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>	Transcription Error
Nov-03-2020 19:47:30 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> ERRONEOUS VISIT	Initial Entry

090177e196ae2f27\Final\Final On: 01-Apr-2021 03:36 (GMT)

**Header Text:** C4591001

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

**Form Version:** 15-Sep-2020 21:52

**Site No:** 1217

**Subject No:** 12171031

**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):** 29-Mar-2021 13:11

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

Date	Location	User	Value	Reason
Oct-30-2020 15:04:22 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Oct/30/2020	Initial Entry

**2. Phase of Disposition:**

Date	Location	User	Value	Reason
Oct-30-2020 15:04:22 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SCREENING	Initial Entry

**3. Status:**

Date	Location	User	Value	Reason
Oct-30-2020 15:04:22 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> COMPLETED	Initial Entry

090177e196ae2f27\Final\Final On: 01-Apr-2021 03:36 (GMT)

**Header Text:** C4591001

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

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

**Site No:** 1217

**Subject No:** 12171031

**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):** 29-Mar-2021 13:11

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

Date	Location	User	Value	Reason
Oct-30-2020 15:43:43 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> The subject is NOT known to be HIV POSITIVE	Initial Entry

Header Text: C4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 10-Oct-2020 16:04

Site No: 1217

Subject No: 12171031

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): 29-Mar-2021 13:11

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**1. Date:**

Date	Location	User	Value	Reason
Oct-30-2020 15:44:27 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Oct/30/2020	Initial Entry

**2. Weight:**

Date	Location	User	Value	Reason
Oct-30-2020 15:44:27 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 65.0	Initial Entry

**3. Unit:**

Date	Location	User	Value	Reason
Oct-30-2020 15:44:27 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> kg	Initial Entry

**4. Height:**

Date	Location	User	Value	Reason
Oct-30-2020 15:44:27 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 155.0	Initial Entry

**5. Unit:**

Date	Location	User	Value	Reason
Oct-30-2020 15:44:27 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> cm	Initial Entry

**6. Body Mass Index:**

Date	Location	User	Value	Reason
Oct-30-2020 15:44:27 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 27.1	Initial Entry

**7.a**

090177e196ae2f27\Final\Final On: 01-Apr-2021 03:36 (GMT)

Header Text: C4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 10-Oct-2020 16:04

Site No: 1217

Subject No: 12171031

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): 29-Mar-2021 13:11

Date	Location	User	Value	Reason
Oct-30-2020 15:44:27 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Record Identifier::</b> 1 <b>Temperature:</b> 36.3 <b>Temperature Unit:</b> C <b>Temperature Locatio</b> <b>n::</b> FOREHEA D	Initial Entry

7.a Record Identifier:

Date	Location	User	Value	Reason
Oct-30-2020 15:44:27 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 1	Initial Entry

7.a Temperature:

Date	Location	User	Value	Reason
Oct-30-2020 15:44:27 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 36.3	Initial Entry

7.a Unit:

Date	Location	User	Value	Reason
Oct-30-2020 15:44:27 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> C	Initial Entry

7.a Temperature Location:

Date	Location	User	Value	Reason
Oct-30-2020 15:44:27 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> FOREHEAD	Initial Entry

090177e196ae2f27\Final\Final On: 01-Apr-2021 03:36 (GMT)

Header Text: C4591001

Visit: V1\_DAY1\_VAX1\_L

Form: LAB URINALYSIS - PREGNANCY TEST - eCRF Audit Trail History

Form Version: 10-Oct-2020 15:58

Form Status: Data Complete, Frozen, Verified

Site No: 1217

Site Name: (1217) Kocaeli University Faculty of Medicine

Subject No: 12171031

Subject Initials: ---

Generated By: (b) (4)

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

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**1. Lab Panel:**

Date	Location	User	Value	Reason
Oct-30-2020 15:45:13 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> URINALYSIS	Initial Entry

**2. Lab Sub-Panel:**

Date	Location	User	Value	Reason
Oct-30-2020 15:45:13 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> PREGNANCY	Initial Entry

**3. Collection Date:**

Date	Location	User	Value	Reason
Oct-30-2020 15:45:13 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Oct/30/2020	Initial Entry

**4. Laboratory Name and Address (Derived)**

Date	Location	User	Value	Reason
Oct-30-2020 15:45:13 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> STUDY SITE	Initial Entry

**5. Specimen Type:**

Date	Location	User	Value	Reason
Oct-30-2020 15:45:13 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> URINE	Initial Entry

**6.a**

Date	Location	User	Value	Reason
Oct-30-2020 15:45:13 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> Sponsor-Define 113 d Identifier: Test:: Choriogonadotropin Beta_PX113 Result:: NEGATIVE	Initial Entry

090177e196ae2f27\Final\Final On: 01-Apr-2021 03:36 (GMT)

Header Text: C4591001

Visit: V1\_DAY1\_VAX1\_L

Form: LAB URINALYSIS - PREGNANCY TEST - eCRF Audit Trail History

Form Version: 10-Oct-2020 15:58

Form Status: Data Complete, Frozen, Verified

Site No: 1217

Site Name: (1217) Kocaeli University Faculty of Medicine

Subject No: 12171031

Subject Initials: ---

Generated By: (b) (4)

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

			Not Done::	
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6.a Sponsor ID:

Date	Location	User	Value	Reason
Oct-30-2020 15:45:13 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 113	Initial Entry

6.a Test:

Date	Location	User	Value	Reason
Oct-30-2020 15:45:13 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) [redacted] (4), (b) (6)	<b>Data Entry:</b> Choriogonadotropin Beta_PX113	Initial Entry

6.a Result:

Date	Location	User	Value	Reason
Oct-30-2020 15:45:13 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) [redacted] (4), (b) (6)	<b>Data Entry:</b> NEGATIVE	Initial Entry

090177e196ae2f27\Final\Final On: 01-Apr-2021 03:36 (GMT)

**Header Text:** C4591001

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

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

**Site No:** 1217

**Subject No:** 12171031

**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):** 29-Mar-2021 13:11

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**1. Randomization Date :**

Date	Location	User	Value	Reason
Oct-30-2020 15:45:34 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Oct/30/2020	Initial Entry

**2. Randomization Number:**

Date	Location	User	Value	Reason
Oct-30-2020 15:45:34 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 114923	Initial Entry

Header Text: C4591001

Visit: V1\_DAY1\_VAX1\_L

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1217

Site Name: (1217) Kocaeli University Faculty of Medicine

Subject No: 12171031

Subject Initials: ---

Generated By: (b) (4)

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

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**1. Data Origin**

Date	Location	User	Value	Reason
Oct-30-2020 15:04:53 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SITE	Initial Entry

**2. Sample Type**

Date	Location	User	Value	Reason
Oct-30-2020 15:04:53 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SERUM	Initial Entry

**3. Sample Collected?**

Date	Location	User	Value	Reason
Oct-30-2020 15:05:06 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Oct-30-2020 15:04:53 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Oct-30-2020 15:04:53 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES Date of Collection:  Oct/30/2020	Initial Entry

**5.a**

Date	Location	User	Value	Reason
Oct-30-2020 15:05:06 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sample ID: BPZ96W	Initial Entry

**5.a Sample ID**

Date	Location	User	Value	Reason
Oct-30-2020 15:05:06	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>	Initial Entry

090177e196ae2f27\Final\Final On: 01-Apr-2021 03:36 (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: 12171031

Subject Initials: ---

Generated By: (b) (4)

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

(UTC+03:00) Istanbul		(b) (4), (b) (6)	BPZ96W	
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5.b

Date	Location	User	Value	Reason
Oct-30-2020 15:05:25 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sample ID: BPZ96X	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Oct-30-2020 15:05:25 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BPZ96X	Initial Entry

5.c

Date	Location	User	Value	Reason
Nov-19-2020 15:23:11 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sample ID: BS2S3V	Initial Entry

5.c Sample ID

Date	Location	User	Value	Reason
Nov-19-2020 15:23:11 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BS2S3V	Initial Entry

5.d

Date	Location	User	Value	Reason
Nov-19-2020 15:23:25 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sample ID: BS2S3W	Initial Entry

5.d Sample ID

Date	Location	User	Value	Reason
Nov-19-2020 15:23:25 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BS2S3W	Initial Entry

090177e196ae2f27\Final\Final On: 01-Apr-2021 03:36 (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: 12171031

Subject Initials: ---

Generated By: (b) (4)

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

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**1. Data Origin**

Date	Location	User	Value	Reason
Oct-30-2020 15:07:14 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SITE	Initial Entry

**2. Sample Type**

Date	Location	User	Value	Reason
Oct-30-2020 15:07:14 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> NASAL_SWAB	Initial Entry

**3. Sample Collected?**

Date	Location	User	Value	Reason
Oct-30-2020 15:07:35 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Oct-30-2020 15:07:14 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Oct-30-2020 15:07:14 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES Date of Collection:  Oct/30/2020	Initial Entry

**5.a**

Date	Location	User	Value	Reason
Oct-30-2020 15:07:35 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sample ID: BPZ96H	Initial Entry

**5.a Sample ID**

Date	Location	User	Value	Reason
Oct-30-2020 15:07:35	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>	Initial Entry

090177e196ae2f27\Final\Final On: 01-Apr-2021 03:36 (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:** 12171031

**Subject Initials:** ---

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

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

(UTC+03:00) Istanbul

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

BPZ96H

Header Text: C4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 22-Apr-2020 21:04

Site No: 1217

Subject No: 12171031

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): 29-Mar-2021 13:11

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

Date	Location	User	Value	Reason
Oct-30-2020 15:46:17 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**2. Treatment Name**

Date	Location	User	Value	Reason
Oct-30-2020 15:46:17 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> BLINDED THERAPY	Initial Entry

**3. Formulation:**

Date	Location	User	Value	Reason
Oct-30-2020 15:46:17 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> INJECTION	Initial Entry

**4. Dose Date Time:**

Date	Location	User	Value	Reason
Oct-30-2020 15:46:17 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Oct/30/2020 11:55	Initial Entry

**5. Anatomical Location:**

Date	Location	User	Value	Reason
Oct-30-2020 15:46:17 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> DELTOID MUSCLE	Initial Entry

**6. Body Side:**

Date	Location	User	Value	Reason
Oct-30-2020 15:46:17 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> LEFT	Initial Entry

**7. Route:**

Date	Location	User	Value	Reason
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090177e196ae2f27\Final\Final On: 01-Apr-2021 03:36 (GMT)

**Header Text:** C4591001

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

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

**Site No:** 1217

**Subject No:** 12171031

**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):** 29-Mar-2021 13:11

Oct-30-2020 15:46:17 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> INTRAMUSCULAR	Initial Entry
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**10. Timeframe Subject Was Observed**

Date	Location	User	Value	Reason
Oct-30-2020 15:46:17 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> THE PROTOCOL SPECIFIED OBS ERVATION 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
Oct-30-2020 15:46:17 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

090177e196ae2f27\Final\Final On: 01-Apr-2021 03:36 (GMT)

**Header Text:** C4591001

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

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

**Site No:** 1217

**Subject No:** 12171031

**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):** 29-Mar-2021 13:11

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*1. Select appropriate response - Reactogenicity diary collection*

Date	Location	User	Value	Reason
Oct-30-2020 15:46:28 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES - REACTOGENICITY E-DIARY COLLECTED FOR THIS SUBJECT	Initial Entry

**Header Text:** C4591001

**Visit:** V2\_VAX2\_L

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

**Site No:** 1217

**Subject No:** 12171031

**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):** 29-Mar-2021 13:11

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**I. Date of Visit**

Date	Location	User	Value	Reason
Nov-24-2020 14:26:03 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Nov-23-2020 14:27:04 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	updated
Nov-23-2020 13:50:43 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	DM: Kindly consider to update missing SWAB PFE and VACIN TRT form or else clarify. Thank you.
Nov-19-2020 15:26:21 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Nov/19/2020	Initial Entry

090177e196ae2f27\Final\Final On: 01-Apr-2021 03:36 (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: 12171031

Subject Initials: ---

Generated By: (b) (4)

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

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

Date	Location	User	Value	Reason
Nov-19-2020 15:34:47 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

*2.a*

Date	Location	User	Value	Reason
Nov-19-2020 15:34:47 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptom::</b> FE VE R  Were fever or systemic symptoms present on the last day the Subject Diary was completed?:	Initial Entry

*2.a Symptom:*

Date	Location	User	Value	Reason
Nov-19-2020 15:34:47 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> FEVER	Initial Entry

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

Date	Location	User	Value	Reason
Nov-19-2020 15:34:47 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

*2.b*

Date	Location	User	Value	Reason
Nov-19-2020 15:34:47 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptom::</b> FAT IG UE	Initial Entry

090177e196ae2f27\Final\Final On: 01-Apr-2021 03:36 (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: 12171031

Subject Initials: ---

Generated By: (b) (4)

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

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

Date	Location	User	Value	Reason
Nov-19-2020 15:34:47 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> FATIGUE	Initial Entry

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

Date	Location	User	Value	Reason
Nov-19-2020 15:34:47 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NO	Initial Entry

2.c

Date	Location	User	Value	Reason
Nov-19-2020 15:34:47 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> <u>Symptom::</u> HEA DAC HE  Were fever or systemic symptoms present on the last day the Subject Diary was completed?:	Initial Entry

090177e196ae2f27\Final\Final On: 01-Apr-2021 03:36 (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: 12171031

Subject Initials: ---

Generated By: (b) (4)

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

2.c Symptom:

Date	Location	User	Value	Reason
Nov-19-2020 15:34:47 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> HEADACHE	Initial Entry

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

Date	Location	User	Value	Reason
Nov-19-2020 15:34:47 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

2.d

Date	Location	User	Value	Reason
Nov-19-2020 15:34:47 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptom::</b> CH ILL S  <b>Were fever or systemic symptoms present on the last day the Subject Diary was completed?:</b> NO	Initial Entry

2.d Symptom:

Date	Location	User	Value	Reason
Nov-19-2020 15:34:47 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 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-19-2020 15:34:47 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

2.e

Date	Location	User	Value	Reason
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090177e196ae2f27\Final\Final On: 01-Apr-2021 03:36 (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: 12171031

Subject Initials: ---

Generated By: (b) (4)

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

Nov-19-2020 15:34:47 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptom::</b> VO MIT ING  <b>Were fever or systemic symptoms present on the last day the Subject Diary was completed?:</b> NO	Initial Entry
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2.e Symptom:

Date	Location	User	Value	Reason
Nov-19-2020 15:34:47 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 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-19-2020 15:34:47 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

2.f

Date	Location	User	Value	Reason
Nov-19-2020 15:34:47 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptom::</b> DIA RR HE A  <b>Were fever or systemic symptoms present on the last day the Subject Diary was completed?:</b> NO	Initial Entry

090177e196ae2f27\Final\Final On: 01-Apr-2021 03:36 (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: 12171031

Subject Initials: ---

Generated By: (b) (4)

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

2.f Symptom:

Date	Location	User	Value	Reason
Nov-19-2020 15:34:47 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> DIARRHEA	Initial Entry

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

Date	Location	User	Value	Reason
Nov-19-2020 15:34:47 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

2.g

Date	Location	User	Value	Reason
Nov-19-2020 15:34:47 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptom::</b> NEW OR WORSE ED MUSC LE PAIN  <b>Were fever or systemic NO symptoms present on t he last day the Subject Diary was completed?:</b>	Initial Entry

2.g Symptom:

Date	Location	User	Value	Reason
Nov-19-2020 15:34:47 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NEW OR WORSE NED MUSCLE P AIN	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-19-2020 15:34:47 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

2.h

Date	Location	User	Value	Reason
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090177e196ae2f27\Final\Final On: 01-Apr-2021 03:36 (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: 12171031

Subject Initials: ---

Generated By: (b) (4)

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

Nov-19-2020 15:34:47 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptom::</b> NEW OR WORSE ED JOINT PAIN  <b>Were fever or systemic symptoms present on the last day the Subject Diary was completed?:</b> NO	Initial Entry
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**2.h Symptom:**

Date	Location	User	Value	Reason
Nov-19-2020 15:34:47 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NEW OR WORSE NED JOINT PAI N	Initial Entry

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

Date	Location	User	Value	Reason
Nov-19-2020 15:34:47 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**3. Injection Site Location:**

Date	Location	User	Value	Reason
Nov-19-2020 15:34:47 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> DELTOID MUSCLE	Initial Entry

**4. Injection Site Body Side:**

Date	Location	User	Value	Reason
Nov-19-2020 15:35:16 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> LEFT	Initial Entry

**5.a**

Date	Location	User	Value	Reason
Nov-19-2020 15:34:47 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Injection Site Reaction::</b> RE DN	Initial Entry

090177e196ae2f27\Final\Final On: 01-Apr-2021 03:36 (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: 12171031

Subject Initials: ---

Generated By: (b) (4)

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

			ESS Were injection site reactions present on the last day the Subject Diary was completed? :	
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5.a Injection Site Reaction:

Date	Location	User	Value	Reason
Nov-19-2020 15:34:47 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> REDNESS	Initial Entry

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

Date	Location	User	Value	Reason
Nov-19-2020 15:34:47 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NO	Initial Entry

5.b

Date	Location	User	Value	Reason
Nov-19-2020 15:34:47 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Injection Site Reaction:: SWE LLI NG Were injection site reactions present on the last day the Subject Diary was completed ?:	Initial Entry

090177e196ae2f27\Final\Final On: 01-Apr-2021 03:36 (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: 12171031

Subject Initials: ---

Generated By: (b) (4)

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

**5.b Injection Site Reaction:**

Date	Location	User	Value	Reason
Nov-19-2020 15:34:47 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> SWELLING	Initial Entry

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

Date	Location	User	Value	Reason
Nov-19-2020 15:34:47 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**5.c**

Date	Location	User	Value	Reason
Nov-19-2020 15:34:47 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Injection Site Reaction::</b> PAIN AT INJECTION SITE  <b>Were injection site reactions present on the last day the Subject Diary was completed?:</b> NO	Initial Entry

**5.c Injection Site Reaction:**

Date	Location	User	Value	Reason
Nov-19-2020 15:34:47 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> PAIN AT INJECTION SITE	Initial Entry

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

Date	Location	User	Value	Reason
Nov-19-2020 15:34:47 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

090177e196ae2f27\Final\Final On: 01-Apr-2021 03:36 (GMT)

Header Text: C4591001

Visit: V2\_VAX2\_L

Form Version: 10-Oct-2020 16:01

Site No: 1217

Subject No: 12171031

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): 29-Mar-2021 13:11

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**1. Date:**

Date	Location	User	Value	Reason
Nov-19-2020 15:31:54 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Nov/19/2020	Initial Entry

**2.a**

Date	Location	User	Value	Reason
Nov-19-2020 15:31:54 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Record Identifier::</b> 1 <b>Temperature:</b> 36.3 <b>Temperature Unit:</b> C <b>Temperature Location::</b> FOREHEAD	Initial Entry

**2.a Record Identifier:**

Date	Location	User	Value	Reason
Nov-19-2020 15:31:54 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 1	Initial Entry

**2.a Temperature:**

Date	Location	User	Value	Reason
Nov-19-2020 15:31:54 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 36.3	Initial Entry

**2.a Unit:**

Date	Location	User	Value	Reason
Nov-19-2020 15:31:54 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> C	Initial Entry

**2.a Temperature Location:**

Date	Location	User	Value	Reason
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090177e196ae2f27\Final\Final On: 01-Apr-2021 03:36 (GMT)

**Header Text:** C4591001

**Visit:** V2\_VAX2\_L

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

**Site No:** 1217

**Subject No:** 12171031

**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):** 29-Mar-2021 13:11

Nov-19-2020 15:31:54 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> FOREHEAD	Initial Entry
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090177e196ae2f27\Final\Final On: 01-Apr-2021 03:36 (GMT)

Header Text: C4591001

Visit: V2\_VAX2\_L

Form: LAB URINALYSIS - PREGNANCY TEST - eCRF Audit Trail History

Form Version: 10-Oct-2020 15:58

Form Status: Data Complete, Frozen, Verified

Site No: 1217

Site Name: (1217) Kocaeli University Faculty of Medicine

Subject No: 12171031

Subject Initials: ---

Generated By: (b) (4)

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

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**1. Lab Panel:**

Date	Location	User	Value	Reason
Nov-19-2020 15:26:38 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> URINALYSIS	Initial Entry

**2. Lab Sub-Panel:**

Date	Location	User	Value	Reason
Nov-19-2020 15:26:38 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> PREGNANCY	Initial Entry

**3. Collection Date:**

Date	Location	User	Value	Reason
Nov-19-2020 15:26:38 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Nov/19/2020	Initial Entry

**4. Laboratory Name and Address (Derived)**

Date	Location	User	Value	Reason
Nov-19-2020 15:26:38 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> STUDY SITE	Initial Entry

**5. Specimen Type:**

Date	Location	User	Value	Reason
Nov-19-2020 15:26:38 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> URINE	Initial Entry

**6.a**

Date	Location	User	Value	Reason
Nov-19-2020 15:26:38 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> Sponsor-Define 113 d Identifier: Test:: Choriogonadotropin Beta_PX113 Result:: NEGATIVE	Initial Entry

090177e196ae2f27\Final\Final On: 01-Apr-2021 03:36 (GMT)

Header Text: C4591001

Visit: V2\_VAX2\_L

Form: LAB URINALYSIS - PREGNANCY TEST - eCRF Audit Trail History

Form Version: 10-Oct-2020 15:58

Form Status: Data Complete, Frozen, Verified

Site No: 1217

Site Name: (1217) Kocaeli University Faculty of Medicine

Subject No: 12171031

Subject Initials: ---

Generated By: (b) (4)

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

			Not Done::	
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6.a Sponsor ID:

Date	Location	User	Value	Reason
Nov-19-2020 15:26:38 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 113	Initial Entry

6.a Test:

Date	Location	User	Value	Reason
Nov-19-2020 15:26:38 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Choriogonadotropin Beta_PX113	Initial Entry

6.a Result:

Date	Location	User	Value	Reason
Nov-19-2020 15:26:38 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NEGATIVE	Initial Entry

090177e196ae2f27\Final\Final On: 01-Apr-2021 03:36 (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: 12171031

Subject Initials: ---

Generated By: (b) (4)

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

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**1. Data Origin**

Date	Location	User	Value	Reason
Nov-23-2020 14:24:23 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SITE	Initial Entry

**2. Sample Type**

Date	Location	User	Value	Reason
Nov-23-2020 14:24:23 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> NASAL_SWAB	Initial Entry

**3. Sample Collected?**

Date	Location	User	Value	Reason
Nov-23-2020 14:24:39 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Nov-23-2020 14:24:23 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Nov-23-2020 14:24:23 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES Date of Collection:  Nov/19/2020	Initial Entry

**5.a**

Date	Location	User	Value	Reason
Nov-23-2020 14:24:39 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sample ID: BPZ9GX	Initial Entry

**5.a Sample ID**

Date	Location	User	Value	Reason
Nov-23-2020 14:24:39	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>	Initial Entry

090177e196ae2f27\Final\Final On: 01-Apr-2021 03:36 (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:** 12171031

**Subject Initials:** ---

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

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

(UTC+03:00) Istanbul	(b) (4), (b) (6)	BPZ9GX
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090177e196ae2f27\Final\Final On: 01-Apr-2021 03:36 (GMT)

Header Text: C4591001

Visit: V2\_VAX2\_L

Form Version: 22-Apr-2020 21:04

Site No: 1217

Subject No: 12171031

Generated By: (b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Verified

Site Name: (1217) Kocaeli University Faculty of Medicine

Subject Initials: ---

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

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

Date	Location	User	Value	Reason
Nov-23-2020 14:25:44 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES Date of First Delay:  Nov/19/2020  Reason(s) for Temporary Delay of Vaccination  RECENT NON-STUDY VACCINATION	Initial Entry

*4. Dose Date Time:*

Date	Location	User	Value	Reason
Dec-18-2020 11:03:11 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Dec-18-2020 11:02:09 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	DM: Please let us know planned vaccination 2 date or else clarify on recent subject status. Thank you.
Nov-25-2020 14:41:05 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Candidate	to follow up delay
Nov-24-2020 14:44:01 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry
Nov-24-2020 14:40:56 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

*6. Body Side:*

Date	Location	User	Value	Reason
Nov-24-2020 14:43:38 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

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

090177e196ae2f27\Final\Final On: 01-Apr-2021 03:36 (GMT)

**Header Text:** C4591001

**Visit:** V2\_VAX2\_L

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

**Site No:** 1217

**Subject No:** 12171031

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

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

**Form Status:** Data Complete, Verified

**Site Name:** (1217) Kocaeli University Faculty of Medicine

**Subject Initials:** ---

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

*administration?*

Date	Location	User	Value	Reason
Nov-24-2020 14:44:17 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

**Header Text:** C4591001

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

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

**Site No:** 1217

**Subject No:** 12171031

**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):** 29-Mar-2021 13:11

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*I. Date of Visit*

Date	Location	User	Value	Reason
Dec-17-2020 13:37:22 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Dec/17/2020	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, Verified

Site No: 1217

Site Name: (1217) Kocaeli University Faculty of Medicine

Subject No: 12171031

Subject Initials: ---

Generated By: (b) (4)

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

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

Date	Location	User	Value	Reason
Dec-21-2020 09:37:33 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	As per site confirmation - updated PD tracker
Dec-18-2020 14:58:21 (UTC+03:00) Istanbul	ACV0PFEINFP6000	Binnur Yildirim (b) (4)	Query 1: Answered	the visit 2 was done, but vaccination 2 did not give. so second 'Vaccination Symptoms Diary-Symptom Resolved Dates' is not applicable for subject.
Dec-18-2020 11:56:08 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	PDQ: Vaccination is given, however FORM level comment added as NOT Applicable added on 'Vaccination Symptoms Diary-Symptom Resolved Dates' CRF. Please review and update else clarify.
Dec-17-2020 13:37:36 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**2.a**

Date	Location	User	Value	Reason
Dec-17-2020 13:37:36 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptom::</b> Not Applicable  <b>Were fever or systemic symptoms present on the last day the Subject Diary was completed?:</b> Not Applicable	Initial Entry

090177e196ae2f27\Final\Final On: 01-Apr-2021 03:36 (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, Verified

Site No: 1217

Site Name: (1217) Kocaeli University Faculty of Medicine

Subject No: 12171031

Subject Initials: ---

Generated By: (b) (4)

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

2.a Symptom:

Date	Location	User	Value	Reason
Dec-17-2020 13:37:36 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

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

Date	Location	User	Value	Reason
Dec-21-2020 09:24:03 (UTC+03:00) Istanbul	ACV0PFEINFP6000	Bhumika Prabhu (b) (4)	Query 1: Closed	Response satisfies query
Dec-19-2020 19:36:34 (UTC+03:00) Istanbul	ACV0PFEINFP6000	Binnur Yildirim (b) (4)	Query 1: Answered	The second vaccination did not administrated to the subject. so there is no second vaccination questionnaire.
Dec-18-2020 20:18:03 (UTC+03:00) Istanbul	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (b) (4)	Query 1: Opened	DMW6491346;Symptoms Occur? is not expected to be Unknown or Not Applicable. Please review and update appropriately or clarify
Dec-17-2020 13:37:36 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

2.b

Date	Location	User	Value	Reason
Dec-17-2020 13:37:36 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptom::</b>  <b>Were fever or systemic symptoms present on the last day the Subject Diary was completed?:</b>	Initial Entry

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Header Text: C4591001

Visit: V3\_MONTH1\_POSTVAX2\_L

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Form Version: 10-Oct-2020 16:03

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Site No: 1217

Site Name: (1217) Kocaeli University Faculty of Medicine

Subject No: 12171031

Subject Initials: ---

Generated By: (b) (4)

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

2.b Symptom:

Date	Location	User	Value	Reason
Dec-17-2020 13:37:36 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

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

Date	Location	User	Value	Reason
Dec-21-2020 07:33:29 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Dec-19-2020 19:36:03 (UTC+03:00) Istanbul	ACV0PFEINFP6000	Binnur Yildirim (b) (4)	Query 1: Answered	The second vaccination did not administrated to the subject. so there is no second vaccination questionnaire.
Dec-18-2020 20:18:03 (UTC+03:00) Istanbul	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (b) (4)	Query 1: Opened	DMW6491347;Symptoms Occur? is not expected to be Unknown or Not Applicable. Please review and update appropriately or clarify
Dec-17-2020 13:37:36 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

2.c

Date	Location	User	Value	Reason
Dec-17-2020 13:37:36 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptom::</b>  <b>Were fever or systemic symptoms present on the last day the Subject Diary was completed?:</b>	Initial Entry

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Header Text: C4591001

Visit: V3\_MONTH1\_POSTVAX2\_L

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Subject Initials: ---

Generated By: (b) (4)

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2.c Symptom:

Date	Location	User	Value	Reason
Dec-17-2020 13:37:36 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

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

Date	Location	User	Value	Reason
Dec-21-2020 12:08:27 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Dec-19-2020 19:36:50 (UTC+03:00) Istanbul	ACV0PFEINFP6000	Binnur Yildirim (b) (4)	Query 1: Answered	The second vaccination did not administrated to the subject. so there is no second vaccination questionnaire.
Dec-18-2020 20:18:03 (UTC+03:00) Istanbul	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (b) (4)	Query 1: Opened	DMW6491348;Symptoms Occur? is not expected to be Unknown or Not Applicable. Please review and update appropriately or clarify
Dec-17-2020 13:37:36 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

2.d

Date	Location	User	Value	Reason
Dec-17-2020 13:37:36 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptom::</b>  <b>Were fever or systemic symptoms present on the last day the Subject Diary was completed?:</b>	Initial Entry

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Header Text: C4591001

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Subject Initials: ---

Generated By: (b) (4)

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2.d Symptom:

Date	Location	User	Value	Reason
Dec-17-2020 13:37:36 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

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

Date	Location	User	Value	Reason
Dec-21-2020 12:08:27 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Dec-19-2020 19:37:43 (UTC+03:00) Istanbul	ACV0PFEINFP6000	Binnur Yildirim (b) (4)	Query 1: Answered	The second vaccination did not administrated to the subject. so there is no second vaccination questionnaire.
Dec-18-2020 20:18:03 (UTC+03:00) Istanbul	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (b) (4)	Query 1: Opened	DMW6491349;Symptoms Occur? is not expected to be Unknown or Not Applicable. Please review and update appropriately or clarify
Dec-17-2020 13:37:36 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

2.e

Date	Location	User	Value	Reason
Dec-17-2020 13:37:36 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptom::</b>  <b>Were fever or systemic symptoms present on the last day the Subject Diary was completed?:</b>	Initial Entry

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Header Text: C4591001

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Site Name: (1217) Kocaeli University Faculty of Medicine

Subject No: 12171031

Subject Initials: ---

Generated By: (b) (4)

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2.e Symptom:

Date	Location	User	Value	Reason
Dec-17-2020 13:37:36 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

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

Date	Location	User	Value	Reason
Dec-21-2020 12:08:27 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Dec-19-2020 19:37:25 (UTC+03:00) Istanbul	ACV0PFEINFP6000	Binnur Yildirim (b) (4)	Query 1: Answered	The second vaccination did not administrated to the subject. so there is no second vaccination questionnaire.
Dec-18-2020 20:18:03 (UTC+03:00) Istanbul	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (b) (4)	Query 1: Opened	DMW6491350;Symptoms Occur? is not expected to be Unknown or Not Applicable. Please review and update appropriately or clarify
Dec-17-2020 13:37:36 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

2.f

Date	Location	User	Value	Reason
Dec-17-2020 13:37:36 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptom::</b>  <b>Were fever or systemic symptoms present on the last day the Subject Diary was completed?:</b>	Initial Entry

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Generated By: (b) (4)

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2.f Symptom:

Date	Location	User	Value	Reason
Dec-17-2020 13:37:36 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

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

Date	Location	User	Value	Reason
Dec-21-2020 12:08:27 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Dec-19-2020 19:37:09 (UTC+03:00) Istanbul	ACV0PFEINFP6000	Binnur Yildirim (b) (4)	Query 1: Answered	The second vaccination did not administrated to the subject. so there is no second vaccination questionnaire.
Dec-18-2020 20:18:03 (UTC+03:00) Istanbul	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (b) (4)	Query 1: Opened	DMW6491351;Symptoms Occur? is not expected to be Unknown or Not Applicable. Please review and update appropriately or clarify
Dec-17-2020 13:37:36 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

2.g

Date	Location	User	Value	Reason
Dec-17-2020 13:37:36 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptom::</b>  <b>Were fever or systemic symptoms present on the last day the Subject Diary was completed?:</b>	Initial Entry

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Subject Initials: ---

Generated By: (b) (4)

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2.g Symptom:

Date	Location	User	Value	Reason
Dec-17-2020 13:37:36 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

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

Date	Location	User	Value	Reason
Dec-21-2020 09:23:27 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Dec-19-2020 19:36:19 (UTC+03:00) Istanbul	ACV0PFEINFP6000	Binnur Yildirim (b) (4)	Query 1: Answered	The second vaccination did not administrated to the subject. so there is no second vaccination questionnaire.
Dec-18-2020 20:18:03 (UTC+03:00) Istanbul	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (b) (4)	Query 1: Opened	DMW6491352;Symptoms Occur? is not expected to be Unknown or Not Applicable. Please review and update appropriately or clarify
Dec-17-2020 13:37:36 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

2.h

Date	Location	User	Value	Reason
Dec-17-2020 13:37:36 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptom::</b>  <b>Were fever or systemic symptoms present on the last day the Subject Diary was completed?:</b>	Initial Entry

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Header Text: C4591001

Visit: V3\_MONTH1\_POSTVAX2\_L

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Subject Initials: ---

Generated By: (b) (4)

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2.h Symptom:

Date	Location	User	Value	Reason
Dec-17-2020 13:37:36 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

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

Date	Location	User	Value	Reason
Dec-21-2020 12:08:27 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Dec-19-2020 19:38:00 (UTC+03:00) Istanbul	ACV0PFEINFP6000	Binnur Yildirim (b) (4)	Query 1: Answered	The second vaccination did not administrated to the subject. so there is no second vaccination questionnaire.
Dec-18-2020 20:18:03 (UTC+03:00) Istanbul	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (b) (4)	Query 1: Opened	DMW6491353;Symptoms Occur? is not expected to be Unknown or Not Applicable. Please review and update appropriately or clarify
Dec-17-2020 13:37:36 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

3. Injection Site Location:

Date	Location	User	Value	Reason
Dec-17-2020 13:37:36 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

4. Injection Site Body Side:

Date	Location	User	Value	Reason
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Visit: V3\_MONTH1\_POSTVAX2\_L

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Dec-17-2020 13:37:36 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry
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5.a

Date	Location	User	Value	Reason
Dec-17-2020 13:37:36 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Injection Site Reaction::</b> Not Applicable  <b>Were injection site reaction s present on the last day the Subject Diary was complete d?:</b> Not Applicable	Initial Entry

5.a Injection Site Reaction:

Date	Location	User	Value	Reason
Dec-17-2020 13:37:36 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

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

Date	Location	User	Value	Reason
Dec-21-2020 11:05:33 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Dec-19-2020 19:35:25 (UTC+03:00) Istanbul	ACV0PFEINFP6000	Binnur Yildirim (b) (4)	Query 1: Answered	The second vaccination did not administrated to the subject. so there is no second vaccination questionnaire.
Dec-18-2020 20:22:47 (UTC+03:00) Istanbul	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (b) (4)	Query 1: Opened	DMW6491355;Reactions Occur? is not expected to be Unknown or Not Applicable. Please review and update appropriately or clarify
Dec-17-2020 13:37:36	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>	Initial Entry

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**Header Text:** C4591001

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

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

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**Subject No:** 12171031

**Subject Initials:** ---

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

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

(UTC+03:00) Istanbul			Not Applicable	
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**5.b**

Date	Location	User	Value	Reason
Dec-17-2020 13:37:36 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Injection Site Reaction::</b> Not Applicable  <b>Were injection site reactions present on the last day the Subject Diary was completed?:</b> Not Applicable	Initial Entry

090177e196ae2f27\Final\Final On: 01-Apr-2021 03:36 (GMT)

Header Text: C4591001

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Site Name: (1217) Kocaeli University Faculty of Medicine

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5.b Injection Site Reaction:

Date	Location	User	Value	Reason
Dec-17-2020 13:37:36 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

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

Date	Location	User	Value	Reason
Dec-21-2020 12:08:27 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Dec-19-2020 19:35:47 (UTC+03:00) Istanbul	ACV0PFEINFP6000	Binnur Yildirim (b) (4)	Query 1: Answered	The second vaccination did not administrated to the subject. so there is no second vaccination questionnaire.
Dec-18-2020 20:22:47 (UTC+03:00) Istanbul	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (b) (4)	Query 1: Opened	DMW6491356;Reactions Occur? is not expected to be Unknown or Not Applicable. Please review and update appropriately or clarify
Dec-17-2020 13:37:36 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

5.c

Date	Location	User	Value	Reason
Dec-17-2020 13:37:36 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Injection Site Reaction::</b> Not Applicable <b>Were injection site reactions present on the last day the Subject Diary was completed?:</b> Not Applicable	Initial Entry

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Header Text: C4591001

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Subject No: 12171031

Subject Initials: ---

Generated By: (b) (4)

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5.c Injection Site Reaction:

Date	Location	User	Value	Reason
Dec-17-2020 13:37:36 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

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

Date	Location	User	Value	Reason
Dec-21-2020 12:08:27 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Dec-19-2020 19:35:02 (UTC+03:00) Istanbul	ACV0PFEINFP6000	Binnur Yildirim (b) (4)	Query 1: Answered	The second vaccination did not administrated to the subject. so there is no second vaccination questionnaire.
Dec-18-2020 20:22:47 (UTC+03:00) Istanbul	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (b) (4)	Query 1: Opened	DMW6491357;Reactions Occur? is not expected to be Unknown or Not Applicable. Please review and update appropriately or clarify
Dec-17-2020 13:37:36 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

090177e196ae2f27\Final\Final On: 01-Apr-2021 03:36 (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: 12171031

Subject Initials: ---

Generated By: (b) (4)

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

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**1. Data Origin**

Date	Location	User	Value	Reason
Dec-17-2020 13:37:58 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SITE	Initial Entry

**2. Sample Type**

Date	Location	User	Value	Reason
Dec-17-2020 13:37:58 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SERUM	Initial Entry

**3. Sample Collected?**

Date	Location	User	Value	Reason
Dec-17-2020 13:38:19 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Dec-17-2020 13:37:58 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Dec-17-2020 13:37:58 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES Date of Collection:  Dec/17/2020	Initial Entry

**5.a**

Date	Location	User	Value	Reason
Dec-17-2020 13:38:19 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sample ID: BPZ9CV	Initial Entry

**5.a Sample ID**

Date	Location	User	Value	Reason
Dec-17-2020 13:38:19	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>	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

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Subject Initials: ---

Generated By: (b) (4)

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(UTC+03:00) Istanbul		(b) (4), (b) (6)	BPZ9CV	
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5.b

Date	Location	User	Value	Reason
Dec-17-2020 13:38:31 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sample ID: BPZ9CW	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Dec-17-2020 13:38:31 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BPZ9CW	Initial Entry

5.c

Date	Location	User	Value	Reason
Dec-17-2020 13:38:45 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sample ID: BNLZT7	Initial Entry

5.c Sample ID

Date	Location	User	Value	Reason
Dec-17-2020 13:38:45 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BNLZT7	Initial Entry

5.d

Date	Location	User	Value	Reason
Dec-17-2020 13:38:56 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sample ID: BNLZT8	Initial Entry

5.d Sample ID

Date	Location	User	Value	Reason
Dec-17-2020 13:38:56 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BNLZT8	Initial Entry

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**Header Text:** C4591001

**Visit:** Logs - Unscheduled

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**Site No:** 1217

**Subject No:** 12171031

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

**Form:** ADVERSE EVENT REPORT - Audit Trail

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Date	Location	User	Value	Reason
Dec-07-2020 16:42:16 (UTC+03:00) Istanbul	ACV0PFEINFP6000	Binnur Yildirim (b) (4)	Form Created	

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Subject No: 12171031

Generated By: (b) (4)

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**1. Category:**

Date	Location	User	Value	Reason
Dec-07-2020 16:42:16 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> ADVERSE EVENT	Initial Entry

**2. AE ID:**

Date	Location	User	Value	Reason
Dec-07-2020 16:42:16 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 1	Initial Entry

**3. Adverse Event:**

*(If possible specify diagnosis, not individual symptoms)*

Date	Location	User	Value	Reason
Dec-17-2020 13:19:39 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Closed	Response satisfies query
Dec-11-2020 15:55:01 (UTC+03:00) Istanbul	ACV0PFEINFP6000	Binnur Yildirim (b) (4)	Query 2: Answered	The termination name will be updated and sent today with new SAE follow up report
Dec-11-2020 14:42:56 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Opened	SAE RECON:AER#2020484307,ter, updated to Exposure during pregnancy in AE CRF. Please confirm if a follow up AEM form was submitted to update term in Safety database.
Dec-11-2020 11:48:18 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Dec-09-2020 20:50:56 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	New Information
Dec-09-2020 20:50:56 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> exposure during pregnancy	New Information
Dec-09-2020 16:07:14 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	clinical query: as per CRF guideline section 8.50.2.5 a healthy Pregnancy is not an AE term that is required to be on the CRF please change into

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				exposure during pregnancy. Thanks
Dec-07-2020 16:42:16 (UTC+03:00) Istanbul	ACV0PFEINFP6000	Binnur Yildirim (b) (4)	<b>Data Entry:</b> pregnancy	Initial Entry

4. Start Date Time:

Date	Location	User	Value	Reason
Jan-04-2021 12:50:57 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 4: Closed	Onset date matched in both DB
Jan-03-2021 17:35:03 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto query (autoquery)	Query 4: Answered	The date of start date was updated according to the SAE follow up-6.
Jan-03-2021 17:35:03 (UTC+03:00) Istanbul	ACV0PFEINFP6000	Binnur Yildirim (b) (4)	<b>Data Entry:</b> Oct/30/2020 11:55	The date of start date was updated according to the SAE follow up-6.
Dec-31-2020 12:00:51 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 4: Reissued:Opened	SAE RECON: Per narrative,the date of Last menstrual period is 26Oct2020. Based on CRG specific guidelines for pregnancy this is the correct onset date.LMP could be used as date of conception if ultrasound results are not available.Please update accordinly
Dec-22-2020 16:09:03 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 4: Reissued:Candidate	Pending SDB update
Dec-19-2020 20:12:59 (UTC+03:00) Istanbul	ACV0PFEINFP6000	Binnur Yildirim (b) (4)	Query 4: Answered	SAE follow up form will be update as soon as possible
Dec-18-2020 15:54:29 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 4: Opened	SAE RECON: AER#2020484307, onset date was

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				recorded as 02Nov2020 in Safety database while 26OCT2020 in AE CRF. Please submit a follow up AEM form to update onset date in Safety database.
Dec-17-2020 07:32:39 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Closed	Response satisfies query
Dec-16-2020 16:47:26 (UTC+03:00) Istanbul	ACV0PFEINFP6000	Binnur Yildirim (b) (4)	Query 3: Answered	AE date was updated according to DM request;CCG page184 "In the absence of ultrasound, the data from the last menstrual period (LMP) should be used to estimate date of conception".So the AE date updated according to LMP.
Dec-16-2020 12:31:41 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Reissued:Opened	DM: Thank you for response. Kindly refer CCG section '8.50.2.5. Specific Guidance for Pregnancy' for 'Date of Onset' part and update AE start date if needed per CCG. Else clarify.
Dec-15-2020 07:50:32 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Closed	Response satisfies query
Dec-14-2020 19:59:23 (UTC+03:00) Istanbul	ACV0PFEINFP6000	Giselle Castillo (b) (4)	Query 1: Closed	Response satisfies query
Dec-14-2020 14:05:48 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Answered	This date is last menstrual period(LMP) all fast pregnancy test , test result were negative before consent date

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				(VID1VX1L).
Dec-14-2020 14:05:39 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Answered	This date is last menstrual period(LMP) all fast pregnancy test , test result were negative before consent date (VID1VX1L).
Dec-14-2020 13:59:44 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto query (autoquery)	Query 3: Opened	For exposure during pregnancy: Start date 26/Oct/2020 is before VID1VX1L visit date 30/Oct/2020. Please review and update as appropriate.
Dec-14-2020 13:59:44 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Opened	Start date is before Consent Date 30/Oct /2020.
Dec-14-2020 13:59:44 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Changed Information
Dec-14-2020 13:59:44 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Oct/26/2020 UNK:UNK	Changed Information
Dec-14-2020 05:05:38 (UTC+03:00) Istanbul	ACV0PFEINFP6000	Giselle Castillo (b) (4)	Query 1: Reissued:Opened	Thank you for your response. Per CRF CG 8.50.2.5, the date of Last menstrual period (LMP) could be used as the onset date for the AE of Exposure during pregnancy in the absence of ultrasound report. Kindly revise form. Thank you.
Dec-12-2020 23:22:55 (UTC+03:00) Istanbul	ACV0PFEINFP6000	Binnur Yildirim (b) (4)	Query 1: Answered	sstart date will be updated when ultrasound report is available
Dec-11-2020 16:56:52 (UTC+03:00) Istanbul	ACV0PFEINFP6000	Giselle Castillo (b) (4)	Query 1: Opened	Per SAE report, the LMP was 26Oct2020. Based on CRF CG (section 8.50.2.5), when the pregnancy

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				occurred after Vax1, the onset date should be determined by ultrasound or LMP. Please revise and update accordingly. Thank you.
Dec-07-2020 16:42:16 (UTC+03:00) Istanbul	ACV0PFEINFP6000	Binnur Yildirim (b) (4)	<b>Data Entry:</b> Nov/UNK/2020 UNK:UNK	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Dec-07-2020 16:42:16 (UTC+03:00) Istanbul	ACV0PFEINFP6000	Binnur Yildirim (b) (4)	<b>Data Entry:</b> YES	Initial Entry

6. Toxicity Grade:

Date	Location	User	Value	Reason
Dec-11-2020 11:47:36 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Dec-09-2020 19:58:56 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry
Dec-09-2020 19:56:53 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Transcription Error
Dec-09-2020 19:56:53 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>	Transcription Error
Dec-09-2020 16:09:16 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	clinical query: as per eCRF guideline toxicity grade is not applicable
Dec-07-2020 22:23:04 (UTC+03:00) Istanbul	ACV0PFEINFP6000	Binnur Yildirim (b) (4)	<b>Data Entry:</b> 4	Initial Entry

7. Is the adverse event serious?

If Yes, NOTIFY PFIZER IMMEDIATELY.

Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant

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*disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).*

Date	Location	User	Value	Reason
Dec-31-2020 12:01:15 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 6: Closed	Response satisfies query
Dec-22-2020 16:49:49 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto query (autoquery)	Query 6: Answered	Changed Information
Dec-22-2020 16:49:49 (UTC+03:00) Istanbul	ACV0PFEINFP6000	Binnur Yildirim (b) (4)	<b>Data Entry:</b> NO	Changed Information
Dec-22-2020 16:11:48 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 6: Reissued:Opened	SAE RECON 1: seriousness criteria is met there is an abnormal pregnancy outcome/protocol section 8.3.5.1.. Please downgrade seriousness to No
Dec-18-2020 18:15:16 (UTC+03:00) Istanbul	ACV0PFEINFP6000	Binnur Yildirim (b) (4)	Query 6: Answered	these "EXPOSURE DURING PREGNANCY" has already submitted as SAE to Pfizer according to the protocol and the SAE number is "2020484307".could you please help how should these section will be update?
Dec-17-2020 16:29:33 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 6: Opened	SAE RECON: AER#2020484307,'EXPOSURE DURING PREGNANCY' event was appropriately reported to safety; however, seriousness criteria is met there is an abnormal pregnancy outcome/protocol section 8.3.5.1. Please update seriousness criteria accordingly.
Dec-17-2020 16:28:45 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 5: Deleted	Query can be addressed internally
Dec-14-2020 22:27:06 (UTC+03:00) Istanbul	ACV0PFEINFP6000	Binnur Yildirim (b) (4)	<b>Data Entry:</b> YES Is this serious event associated with congenital an	Transcription Error

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			<p>omaly or birth defect?</p> <p>NO</p> <p>Did this serious event result in death?</p> <p>NO</p> <p>Did this serious event require or prolong hospitalization?</p> <p>NO</p> <p>Did this serious event result in persistent or significant disability/incapacity?</p> <p>NO</p> <p>Is this serious event life threatening?</p> <p>NO</p> <p>Other medically important serious event</p> <p>YES</p>	
Dec-14-2020 16:02:14 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto query (autoquery)	Query 5: Candidate	For AE exposure during pregnancy: Response to "Is the adverse event serious?" is 'Yes' but "Serious Adverse Event Number" is blank.
Dec-14-2020 16:02:14 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<p><b>Data Entry:</b></p> <p>YES</p> <p>Is this serious event associated with congenital anomaly or birth defect?</p> <p>YES</p> <p>Did this serious event result in death?</p>	The AE "exposure during pregnancy" has already submitted as SAE to sponsor. This is a SAE per protocol due to Subject is pregnant. This is an important medical event, however subject does not meet other options.

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			NO Did this serious event require or prolong hospitalization? NO Did this serious event result in persistent or significant disability/incapacity? NO Is this serious event life threatening? NO Other medically important serious event YES	
Dec-11-2020 14:36:58 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Closed	Response satisfies query

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7. Is the adverse event serious?

If Yes, NOTIFY PFIZER IMMEDIATELY.

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

Date	Location	User	Value	Reason
Dec-09-2020 20:53:19 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto query (autoquery)	Query 4: Deleted	Close Auto Query
Dec-09-2020 20:53:19 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto query (autoquery)	Query 3: Answered	Transcription Error
Dec-09-2020 20:53:19 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Transcription Error
Dec-09-2020 20:50:56 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto query (autoquery)	Query 4: Candidate	For AE exposure during pregnancy: Response to "Is the adverse event serious?" is 'Yes' but "Serious Adverse Event Number" is blank.
Dec-09-2020 16:39:24 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Opened	SAE RECON: AER#2020484307, pregnancy event was appropriately reported to safety; however, seriousness criteria is met there is an abnormal pregnancy outcome/protocol section 8.3.5.1. Please update seriousness criteria accordingly.
Dec-09-2020 16:34:28 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Dec-09-2020 11:19:29 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Closed	Response satisfies query
Dec-08-2020 16:46:40 (UTC+03:00) Istanbul	ACV0PFEINFP6000	Binnur Yildirim (b) (4)	Query 1: Answered	serious adverse number :2020484307. 1 can not enter this number on the page.
Dec-08-2020 12:56:10 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	For AE pregnancy: Response to "Is the adverse event

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				serious?" is 'Yes' but "Serious Adverse Event Number" is blank.
Dec-08-2020 09:37:40 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Answered	Answer Auto Query
Dec-08-2020 09:37:40 (UTC+03:00) Istanbul	ACV0PFEINFP6000	Binnur Yildirim (b) (4)	<p><b>Data Entry:</b></p> <p>YES</p> <p>Is this serious event associated with congenital anomaly or birth defect?</p> <p>NO</p> <p>Did this serious event result in death?</p> <p>NO</p> <p>Did this serious event require or prolong hospitalization?</p> <p>NO</p> <p>Did this serious event result in persistent or significant disability/incapacity?</p> <p>NO</p> <p>Is this serious event life threatening?</p> <p>NO</p> <p>Other medically important serious event</p> <p>YES</p>	the subject is pregnant. so this event is serious.
Dec-08-2020 07:36:43 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Reissued:Opened	Response does not satisfy query. Response to several Seriousness criteria' are still missing. If Serious is YES, then response to all Seriousness Criteria' should be selected NO or YES as

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				appropriate. Please update.
Dec-07-2020 22:23:32 (UTC+03:00) Istanbul	ACV0PFEINFP6000	Binnur Yildirim (b) (4)	Query 2: Answered	updated
Dec-07-2020 16:42:46 (UTC+03:00) Istanbul	ACV0PFEINFP6000	Binnur Yildirim (b) (4)	<b>Data Entry:</b> YES Other medically important serious event  YES	Transcription Error
Dec-07-2020 16:42:16 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Opened	Is this adverse event serious? is reported 'Yes', but at least one seriousness criteria is missing. Please review and update as appropriate.
Dec-07-2020 16:42:16 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	For AE pregnancy: Response to "Is the adverse event serious?" is 'Yes' but "Serious Adverse Event Number" is blank.
Dec-07-2020 16:42:16 (UTC+03:00) Istanbul	ACV0PFEINFP6000	Binnur Yildirim (b) (4)	<b>Data Entry:</b> YES	Initial Entry

**8. Is this adverse event the result of a study Medication Error?**  
If Yes, record the type of medication error on the Medication Error Log.

Date	Location	User	Value	Reason
Dec-07-2020 22:23:04 (UTC+03:00) Istanbul	ACV0PFEINFP6000	Binnur Yildirim (b) (4)	<b>Data Entry:</b> NO	Initial Entry

**9. Is this event related to study treatment:**

Date	Location	User	Value	Reason
Dec-07-2020 22:23:04 (UTC+03:00) Istanbul	ACV0PFEINFP6000	Binnur Yildirim (b) (4)	<b>Data Entry:</b> NOT RELATED If Not Related to study treatment (s), this event is due to:  OTHER  If Other, specify:	Initial Entry

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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, Verified

Site No: 1217

Site Name: (1217) Kocaeli University Faculty of Medicine

Subject No: 12171031

Subject Initials: ---

Generated By: (b) (4)

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

subject pregnant

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Jan-19-2021 10:13:28 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Jan-15-2021 13:39:51 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Volunteer will not be able to take study drug because she is pregnant
Jan-15-2021 07:47:36 (UTC+03:00) Istanbul	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (b) (4)	Query 1: Opened	DMW6842220;The Latest Action to Study Treatment is DRUG WITHDRAWN, but the Disposition-Treatment Form Status is not DEATH OR ADVERSE EVENT. Please review and update as appropriate.
Dec-14-2020 22:31:00 (UTC+03:00) Istanbul	ACV0PFEINFP6000	Binnur Yildirim (b) (4)	<b>Data Entry:</b> DRUG WITHDRAWN	Transcription Error
Dec-07-2020 22:23:04 (UTC+03:00) Istanbul	ACV0PFEINFP6000	Binnur Yildirim (b) (4)	<b>Data Entry:</b> NOT APPLICABLE	Initial Entry

11. Was a Concomitant Medication given?

Date	Location	User	Value	Reason
Dec-07-2020 22:23:04 (UTC+03:00) Istanbul	ACV0PFEINFP6000	Binnur Yildirim (b) (4)	<b>Data Entry:</b> NO	Initial Entry

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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, 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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12. Was a Non-Drug Treatment given?				
Date	Location	User	Value	Reason
Dec-07-2020 22:23:04 (UTC+03:00) Istanbul	ACV0PFEINFP6000	Binnur Yildirim (b) (4)	<b>Data Entry:</b> NO	Initial Entry

13. What was the outcome of this adverse event?:				
Date	Location	User	Value	Reason
Dec-22-2020 12:27:57 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 4: Closed	Response satisfies query
Dec-18-2020 15:50:58 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Closed	Response satisfies query
Dec-18-2020 15:04:22 (UTC+03:00) Istanbul	ACV0PFEINFP6000	Binnur Yildirim (b) (4)	Query 4: Answered	data was change according to the 'the latest EDP guidance, outcome should be recorded as UNKNOWN'.
Dec-18-2020 15:03:20 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto query (autoquery)	Query 4: Opened	For AE exposure during pregnancy: Response to "What was the outcome of this adverse event?" is 'Unknown' but End Date/Time is provided or "Is the adverse event still ongoing?" is marked "Yes".
Dec-18-2020 15:03:20 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto query (autoquery)	Query 3: Answered	data updated according to the 'the latest EDP guidance, outcome should be recorded as UNKNOWN'.
Dec-18-2020 15:03:20 (UTC+03:00) Istanbul	ACV0PFEINFP6000	Binnur Yildirim (b) (4)	<b>Data Entry:</b> UNKNOWN	data updated according to the 'the latest EDP guidance, outcome should be recorded as

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Header Text: C4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

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Form Status: Data Complete, Verified

Site No: 1217

Site Name: (1217) Kocaeli University Faculty of Medicine

Subject No: 12171031

Subject Initials: ---

Generated By: (b) (4)

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				UNKNOWN'
Dec-17-2020 16:32:05 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Opened	SAE RECON: AER#2020484307, the outcome in AE CRF was reported as NOT RECOVERED/NOT RESOLVED.Based on the latest EDP guidance, outcome should be recorded as UNKNOWN. Please confirm and update accordingly.
Dec-11-2020 16:08:15 (UTC+03:00) Istanbul	ACV0PFEINFP6000	Binnur Yildirim (b) (4)	<b>Data Entry:</b> NOT RECOVERED/NOT RES OLVED	Changed Information
Dec-11-2020 11:47:02 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Dec-11-2020 07:44:00 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Closed	Response satisfies query
Dec-09-2020 20:56:39 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Answered	the adverse event still ongoing
Dec-09-2020 20:54:25 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Opened	For AE exposure during pregnancy: Response to "What was the outcome of this adverse event?" is 'Unknown' but End Date/Time is provided or "Is the adverse event still ongoing?" is marked "Yes".
Dec-09-2020 20:54:25 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Changed Information
Dec-09-2020 20:54:25 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> UNKNOWN	Changed Information
Dec-09-2020 16:11:27 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	clinical query: as per eCRF guideline AE outcome for ongoing

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Generated By: (b) (4)

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				pregnancy should be unknown. Please check and update the eCRF if needed.
Dec-07-2020 22:23:04 (UTC+03:00) Istanbul	ACV0PFEINFP6000	Binnur Yildirim (b) (4)	<b>Data Entry:</b> NOT RECOVERED/NOT RESOLVED	Initial Entry

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

Date	Location	User	Value	Reason
Dec-15-2020 14:44:43 (UTC+03:00) Istanbul	ACV0PFEINFP6000	Hayley Wyper (b) (4)	Query 1: Closed	Response satisfies query
Dec-15-2020 11:00:04 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	subject's treatment is stopped, but she will come to the follow up visits
Dec-15-2020 11:00:04 (UTC+03:00) Istanbul	ACV0PFEINFP6000	Binnur Yildirim (b) (4)	<b>Data Entry:</b> NO	subject's treatment is stopped, but she will come to the follow up visits
Dec-15-2020 00:26:03 (UTC+03:00) Istanbul	ACV0PFEINFP6000	Hayley Wyper (b) (4)	Query 1: Reissued:Opened	CLINQUERY: Thank you for confirming treatment was discontinued. Will the subject continue to participate in follow up visits? If so, please review response to this field
Dec-14-2020 22:33:01 (UTC+03:00) Istanbul	ACV0PFEINFP6000	Binnur Yildirim (b) (4)	Query 1: Answered	Line #9 was updated.Subject was discontinued on the Impala due to pregnancy.
Dec-14-2020 21:03:53 (UTC+03:00) Istanbul	ACV0PFEINFP6000	Hayley Wyper (b) (4)	Query 1: Opened	CLINQUERY: Field indicates subject will no longer participate in study follow up. Meanwhile question 10 'Last Action Taken with Study Drug' reports no

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**Visit:** Logs - Unscheduled

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**Site No:** 1217

**Subject No:** 12171031

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

**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History

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				change (Not applicable). Please review if questions have been answered correctly
Dec-07-2020 22:23:04 (UTC+03:00) Istanbul	ACV0PFEINFP6000	Binnur Yildirim (b) (4)	<b>Data Entry:</b> YES	Initial Entry

**Header Text:** C4591001

**Visit:** Logs - Unscheduled

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

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

**Form Status:**

**Site No:** 1217

**Site Name:** (1217) Kocaeli University Faculty of Medicine

**Subject No:** 12171031

**Subject Initials:** ---

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

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

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Date	Location	User	Value	Reason
Nov-24-2020 18:06:48 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Created	

**Header Text:** C4591001

**Visit:** Logs - Unscheduled

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

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

**Form Status:**

**Site No:** 1217

**Site Name:** (1217) Kocaeli University Faculty of Medicine

**Subject No:** 12171031

**Subject Initials:** ---

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

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

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Date	Location	User	Value	Reason
Nov-24-2020 18:07:15 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Created	

Header Text: C4591001

Visit: Logs - Unscheduled

Form: CONCOMITANT MEDICATIONS - NON STUDY  
VACCINATIONS - eCRF Audit Trail History

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Form Status: Data Complete, Frozen, Verified

Site No: 1217

Site Name: (1217) Kocaeli University Faculty of Medicine

Subject No: 12171031

Subject Initials: ---

Generated By: (b) (4)

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**1. What is the medication identifier?**

Date	Location	User	Value	Reason
Nov-24-2020 18:06:48 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 1	Initial Entry

**2. Category:**

Date	Location	User	Value	Reason
Nov-24-2020 18:06:48 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> VACCINATIONS	Initial Entry

**3. Concomitant Medications Pre-specified:**

Date	Location	User	Value	Reason
Nov-24-2020 18:06:48 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> NO	Initial Entry

**4. Medication:**

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

Date	Location	User	Value	Reason
Nov-24-2020 18:06:48 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Hepatitis A Vaccination	Initial Entry

**5. Date:**

Date	Location	User	Value	Reason
Nov-24-2020 18:06:48 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Nov/9/2020	Initial Entry

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Header Text: C4591001

Visit: Logs - Unscheduled

Form: CONCOMITANT MEDICATIONS - NON STUDY VACCINATIONS - 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: 12171031

Subject Initials: ---

Generated By: (b) (4)

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

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**1. What is the medication identifier?**

Date	Location	User	Value	Reason
Nov-24-2020 18:07:15 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 2	Initial Entry

**2. Category:**

Date	Location	User	Value	Reason
Nov-24-2020 18:07:15 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> VACCINATIONS	Initial Entry

**3. Concomitant Medications Pre-specified:**

Date	Location	User	Value	Reason
Nov-24-2020 18:07:15 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> NO	Initial Entry

**4. Medication:**

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

Date	Location	User	Value	Reason
Nov-24-2020 18:07:15 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Hepatitis B Vaccination	Initial Entry

**5. Date:**

Date	Location	User	Value	Reason
Nov-24-2020 18:07:15 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Nov/9/2020	Initial Entry

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**Header Text:** C4591001

**Visit:** Unplanned 1 - Unscheduled Visit on  
Nov/03/2020

**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:** 12171031

**Subject Initials:** ---

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

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

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*1. Date of Visit*

Date	Location	User	Value	Reason
Nov-03-2020 12:19:09 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Nov/3/2020	Initial Entry

**Header Text:** C4591001

**Visit:** Unplanned 1 - Unscheduled Visit on Nov/03/2020

**Form:** UNPLANNED VISIT - 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:** 12171031

**Subject Initials:** ---

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

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

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*I. Assessments*

Date	Location	User	Value	Reason
Nov-03-2020 12:19:38 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Nov-03-2020 12:19:17 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Contact Outcome is ticked however 'CONTACT OUTCOME' form is not entered. Please review and update as appropriate.
Nov-03-2020 12:19:17 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> CONTACT OUTCOME	Initial Entry

090177e196ae2f27\Final\Final On: 01-Apr-2021 03:36 (GMT)

**Header Text:** C4591001

**Visit:** Unplanned 1 - Unscheduled Visit on  
Nov/03/2020

**Form:** CONTACT OUTCOME - UNPLANNED - 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:** 12171031

**Subject Initials:** ---

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

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**1. Contact Type:**

Date	Location	User	Value	Reason
Nov-03-2020 12:19:38 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> TELEPHONE VISIT	Initial Entry

**2. Was contact made?**

Date	Location	User	Value	Reason
Nov-03-2020 12:19:38 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES Date of Contact: Nov/3/2020 Contact Outcome: VISIT NOT REQUIRED, INVESTIGATOR DECISION	Initial Entry

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**Header Text:** C4591001

**Visit:** End of Treatment - Unscheduled

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**Site No:** 1217

**Subject No:** 12171031

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

**Form:** DISPOSITION - TREATMENT - eCRF Audit Trail History

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

**Site Name:** (1217) Kocaeli University Faculty of Medicine

**Subject Initials:** ---

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

Date	Location	User	Value	Reason
Dec-07-2020 22:24:19 (UTC+03:00) Istanbul	ACV0PFEINFP6000	Binnur Yildirim (b) (4)	<b>Data Entry:</b> Dec/7/2020	Initial Entry

**2. Phase of Disposition:**

Date	Location	User	Value	Reason
Dec-07-2020 22:24:19 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> VACCINATION	Initial Entry

**3. Status:**

Date	Location	User	Value	Reason
Dec-15-2020 14:39:19 (UTC+03:00) Istanbul	ACV0PFEINFP6000	Hayley Wyper (b) (4)	Query 3: Closed	Response satisfies query
Dec-15-2020 10:56:07 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto query (autoquery)	Query 4: Closed	Close Auto Query
Dec-15-2020 10:55:23 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto query (autoquery)	Query 4: Opened	Response to "Status" is PREGNANCY but "Specify Status" is Provided.
Dec-15-2020 10:55:23 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto query (autoquery)	Query 3: Answered	Changed Information
Dec-15-2020 10:55:23 (UTC+03:00) Istanbul	ACV0PFEINFP6000	Binnur Yildirim (b) (4)	<b>Data Entry:</b> PREGNANCY	Changed Information
Dec-14-2020 22:34:30 (UTC+03:00)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Opened	CLINQUERY: per AE log and Specify status field, study treatment

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Header Text: C4591001

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Subject Initials: ---

Generated By: (b) (4)

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Istanbul				was ceased due to pregnancy. Please capture PREGNANCY as status selection for EOT
Dec-14-2020 20:58:10 (UTC+03:00) Istanbul	ACV0PFEINFP6000	Hayley Wyper (b) (4)	Query 3: Can didate	CLINQUERY: per AE log and Specify status field, study treatment was ceased due to pregnancy. Please capture PREGNANCY as status selection for EOT
Dec-12-2020 23:29:58 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Clos ed	Close Auto Query
Dec-12-2020 23:29:06 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Ope ned	Response to "Status" is NO LONGER MEETS ELIGIBILITY CRITERIA but "Specify Status" is missing.
Dec-12-2020 23:29:06 (UTC+03:00) Istanbul	ACV0PFEINFP6000	Binnur Yildirim (b) (4)	Query 1: Dele ted	Changed Information
Dec-12-2020 23:29:06 (UTC+03:00) Istanbul	ACV0PFEINFP6000	Binnur Yildirim (b) (4)	<b>Data Entry:</b> NO L ONGE R ME ETS E LIGIB ILITY CRITE RIA	Changed Information
Dec-11-2020 11:54:15 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reis sued:C andidat e	Issue added in DM Meeting and Q & A sheet.
Dec-09-2020 11:16:38	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Ans	This is not schedule visit.However unplan

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Header Text: C4591001

Visit: End of Treatment - Unscheduled

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Site No: 1217

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Generated By: (b) (4)

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(UTC+03:00) Istanbul			wered	page should be completed for only REACTOGENICITY contacts per protocol.eCRF manuel:"Unscheduled Visit for a Grade 3 or Suspected Grade 4 Reaction for Stage 3 Cohorts section".So these local lab result can not ent
Dec-09-2020 09:46:51 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reissued:Opened	Please confirm if 'positive beta HCG test on 07dec2020 in local laboratory' occurred as a scheduled visit? or an unplanned visit? and update applicable visit and CRFs accordingly.
Dec-08-2020 16:47:57 (UTC+03:00) Istanbul	ACV0PFEINFP6000	Binnur Yildirim (b) (4)	Query 1: Answered	subject has a positive beta HCG test on 07dec2020 in local laboratory. could you please inform me where can I enter this result in the eCRF
Dec-08-2020 09:57:08 (UTC+03:00) Istanbul	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (b) (4)	Query 1: Opened	DMW6380622;Response to 'Status' is PREGNANCY, but there is no pregnancy tests with a positive result with a 'Collection Date' on or before the disposition date. Please review and update as appropriate.
Dec-07-2020 22:24:19 (UTC+03:00) Istanbul	ACV0PFEINFP6000	Binnur Yildirim (b) (4)	<b>Data Entry:</b> PREGNANCY	Initial Entry

4. Specify Status:

Date	Location	User	Value	Reason
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**Header Text:** C4591001

**Visit:** End of Treatment - Unscheduled

**Form:** DISPOSITION - TREATMENT - eCRF Audit Trail History

**Form Version:** 15-Sep-2020 21:55

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

**Site No:** 1217

**Site Name:** (1217) Kocaeli University Faculty of Medicine

**Subject No:** 12171031

**Subject Initials:** ---

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

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

Dec-15-2020 10:56:07 (UTC+03:00) Istanbul	ACV0PFEINFP6000	Binnur Yildirim (b) (4)	<b>Data Entry:</b>	Transcription Error
Dec-15-2020 10:56:00 (UTC+03:00) Istanbul	ACV0PFEINFP6000	Binnur Yildirim (b) (4)	<b>Data Entry:</b> t	Transcription Error
Dec-12-2020 23:29:58 (UTC+03:00) Istanbul	ACV0PFEINFP6000	Binnur Yildirim (b) (4)	<b>Data Entry:</b> Meet Excl 11. Subject is pregnant	Initial Entry

090177e196ae2f27\Final\Final On: 01-Apr-2021 03:36 (GMT)

Header Text: C4591001

Visit: Disposition - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1217

Subject No: 12171031

Generated By: (b) (4)

Form: TREATMENT UNBLINDED - eCRF Audit Trail History

Form Status: Data Complete, Verified

Site Name: (1217) Kocaeli University Faculty of Medicine

Subject Initials: ---

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

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**1. Date Treatment Unblinded :**

Date	Location	User	Value	Reason
Jan-20-2021 18:51:04 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry
Jan-20-2021 18:48:00 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>	Initial Entry
Jan-20-2021 18:38:46 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry
Jan-20-2021 17:19:19 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>	Transcription Error
Jan-19-2021 16:31:26 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Jan-19-2021 15:55:09 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Transcription Error
Jan-19-2021 15:55:09 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Dec/30/2020	Transcription Error
Jan-19-2021 09:01:13 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	DM: The response for "Date Treatment Unblinded" is missing. Kindly review and update.

**2. Primary Reason for Unblinding:**

Date	Location	User	Value	Reason
Jan-20-2021 18:51:04 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry
Jan-20-2021 18:48:00 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>	Initial Entry
Jan-20-2021 18:38:46 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry
Jan-20-2021 17:19:19	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>	Transcription Error

090177e196ae2f27\Final\Final On: 01-Apr-2021 03:36 (GMT)

**Header Text:** C4591001

**Visit:** Disposition - Unscheduled

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

**Site No:** 1217

**Subject No:** 12171031

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

**Form:** TREATMENT UNBLINDED - eCRF Audit Trail History

**Form Status:** Data Complete, Verified

**Site Name:** (1217) Kocaeli University Faculty of Medicine

**Subject Initials:** ---

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

(UTC+03:00) Istanbul		(b) (4), (b) (6)		
Jan-15-2021 15:10:21 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> ASSESS ELIGIBILITY FOR ADDITIONAL VACCINATION	Initial Entry

090177e196ae2f27\Final\Final On: 01-Apr-2021 03:36 (GMT)

**Header Text:** C4591001

**Visit:** Disposition - Unscheduled

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

**Site No:** 1217

**Subject No:** 12171031

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

**Form:** WITHDRAWAL OF CONSENT - eCRF Audit Trail History

**Form Status:** Data Complete, Verified

**Site Name:** (1217) Kocaeli University Faculty of Medicine

**Subject Initials:** ---

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

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**I. Withdrawal of Consent Date :**

Date	Location	User	Value	Reason
Jan-20-2021 18:51:45 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry
Jan-20-2021 18:49:05 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>	Initial Entry
Jan-20-2021 18:39:44 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry
Jan-20-2021 18:39:14 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>	Transcription Error
Jan-15-2021 15:14:05 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Dec/7/2020	Initial Entry
Jan-15-2021 15:12:01 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>	Initial Entry
Jan-15-2021 15:10:32 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

090177e196ae2f27\Final\Final On: 01-Apr-2021 03:36 (GMT)

**Header Text:** C4591001

**Visit:** Disposition - Unscheduled

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

**Site No:** 1217

**Subject No:** 12171031

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

**Form:** DEATH DETAILS CODED - eCRF Audit Trail History

**Form Status:** Data Complete, Verified

**Site Name:** (1217) Kocaeli University Faculty of Medicine

**Subject Initials:** ---

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

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*1. Date of Collection / Notification of Death:*

Date	Location	User	Value	Reason
Jan-20-2021 18:40:04 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry
Jan-20-2021 17:20:03 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>	Initial Entry
Jan-15-2021 15:12:19 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

090177e196ae2f27\Final\Final On: 01-Apr-2021 03:36 (GMT)

**Header Text:** C4591001

**Visit:** Subject Status - Unscheduled

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

**Site No:** 1217

**Subject No:** 12171031

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

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

**Form Status:** Data Complete, Verified

**Site Name:** (1217) Kocaeli University Faculty of Medicine

**Subject Initials:** ---

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

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**1. Subject Status**

Date	Location	User	Value	Reason
Dec-15-2020 10:55:23 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> DISCONTINUED	Changed Information
Dec-12-2020 23:29:06 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> DISCONTINUED	Changed Information
Dec-07-2020 22:24:19 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> DISCONTINUED	Initial Entry
Oct-30-2020 15:45:34 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> ENROLLED/RANDOMIZED	Initial Entry
Oct-30-2020 15:04:22 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SCREENED	Initial Entry

**2. Subject Status Date**

Date	Location	User	Value	Reason
Dec-15-2020 10:55:23 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> Dec/7/2020	Changed Information
Dec-12-2020 23:29:06 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> Dec/7/2020	Changed Information
Dec-07-2020 22:24:19 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> Dec/7/2020	Initial Entry
Oct-30-2020 15:45:34 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> Oct/30/2020	Initial Entry
Oct-30-2020 15:04:22 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> Oct/30/2020	Initial Entry

090177e196ae2f27\Final\Final On: 01-Apr-2021 03:36 (GMT)

**Header Text:** C4591001

**Visit:** Investigator Signature - Unscheduled

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

**Site No:** 1217

**Subject No:** 12171031

**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):** 29-Mar-2021 13:11

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*I. Casebook Signature*

Date	Location	User	Value	Reason
Nov-03-2020 19:48:00 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Click Here to Enable	Initial Entry